The Medicare Specialty Care Bundles (SCB) Program:

Playbook and Technical Specifications

Acknowledgements

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Executive Summary

One hundred percent of all Medicare FFS beneficiaries in an accountable care relationship. That's the goal expressed in The CMS Innovation Center's (Innovation Center) strategy refresh, and it's a bold one given that less than half are in such a relationship today. Attracting providers into accountable care relationships -- and therefore bringing more beneficiaries into those relationships -- will require a number of changes to current advanced alternative payment models, and the introduction of versions of existing models that will be attractive to all stakeholders, not just in the short term, but the long term. Current data[1] underline the need to carefully and skillfully redesign these models. Specifically, differences have been observed between existing standalone bundle payment programs versus bundled payment + ACO models. This only strengthens the case we believe to i) reconfigure the current models to advanced models that more intentionally address the attribution of functions among specialty care and ACO players, and ii) enable some 'give' or sliding scale in the way in which beneficiaries are attributed between specialty and ACO entity.

The model described in this document is designed to accomplish several important policy goals and program objectives clearly articulated by the Innovation Center, thanks to some key features:

1. **The focus on clinical condition categories (CCCs)** – CCCs are analogous to the current clinical service line categories used in BPCI-A, but more expansive because they include all of the conditions, procedures and acute events related to a clinical category – a bundle of bundles. Implementing a model around CCCs has several benefits:
    a. Reduction of adverse selection observed in current bundle programs – providers would not be allowed to pick and choose episodes within a CCC because it's expressed as a condition category population-based payment;
    b. Close collaboration of PCPs with Specialty Care Practices (SCPs) – in order to optimize the use of clinicians at various levels of clinical expertise and to ensure the coordination of patient care across CCCs, this model purposefully binds SCPs with PCPs, while maintaining organizational autonomy and agility;
    c. Broadscale availability of an advanced APM for specialty care providers – SCP options to participate in any AAPM is almost impossible as an autonomous or quasi-autonomous manner. And yet SCPs are directly responsible for a very significant percentage of beneficiary costs of care. This proposed model can be leveraged across any number of CCCs, including cancer[2].
2. **Savings and sources of savings with a tight lens on quality and equity** – The analyses in this document clearly show the significant savings that can accrue to participating providers and Medicare – especially the Medicare Trust Fund – because CCCs should encourage participating providers to reduce avoidable hospitalizations and other acute events. A per beneficiary per month payment for a CCC will also encourage

[1] See literature review in appendix
[2] Note that in this document we focused on cardiology, orthopedics and gastroenterology, but those are by no means exclusive

specialty care providers to reduce unnecessary tests and procedures, and seek the most effective and efficient drug treatment regimen for all drugs covered under Part B. This has heretofore been a challenging zone of savings for CMS to capture because the hospitals and health systems running most ACOs are loathe to decrease these sources of revenue[3]. As such, focusing on these savings within CCCs should also help pull more providers into greater risk models for an important reason:

   a. Shifting the delivery system's locus of power – Specialty care providers are critical sources of revenue for hospitals and health systems, and when these specialists are not at risk for the care they deliver (e.g. a cardiology CCC for a cardiology practice) they can produce a lot of facility revenue. Putting the SCPs at risk for clinical and financial outcomes puts them in the driver's seat and should be a cause of concern for hospitals and health systems that are not yet in high-risk models (as explained further below in the model overlap section);
   b. Creating a greater pull to move to full population risk – the overlap policy in this model proposes to split the locus of control over beneficiary costs, until there is a total cost of care model with significant risk such as the ACO Enhanced model or the Direct Contracting model.

3. **A new method of determining benchmarks** – Current pricing/benchmarking policy includes yearly adjustments, usually negative, due to rebasing. This has caused some potential model participants to not participate because their starting benchmark was low, making incremental savings harder and harder every year; and for others to participate if they have a favorable benchmark, until the point at which they feel incremental savings will be harder to achieve. Fixing the benchmark policies for new models, as proposed in this model, should be appealing to all providers, irrespective of their historical performance, and should keep them in the model, further reducing the potential for adverse selection against Medicare.

The recommendations, suggestions and other advice contained in this playbook reflect the experience of organizations that have been managing billions of dollars in advanced alternative payment models, across public and private sector payers, and that are animated by a common passion that, as a country, we can and must do better for all of our citizens and residents, especially the elderly and most vulnerable. This model[4] is an essential component for how we can do better, and is respectfully submitted to the Innovation Center for its consideration.

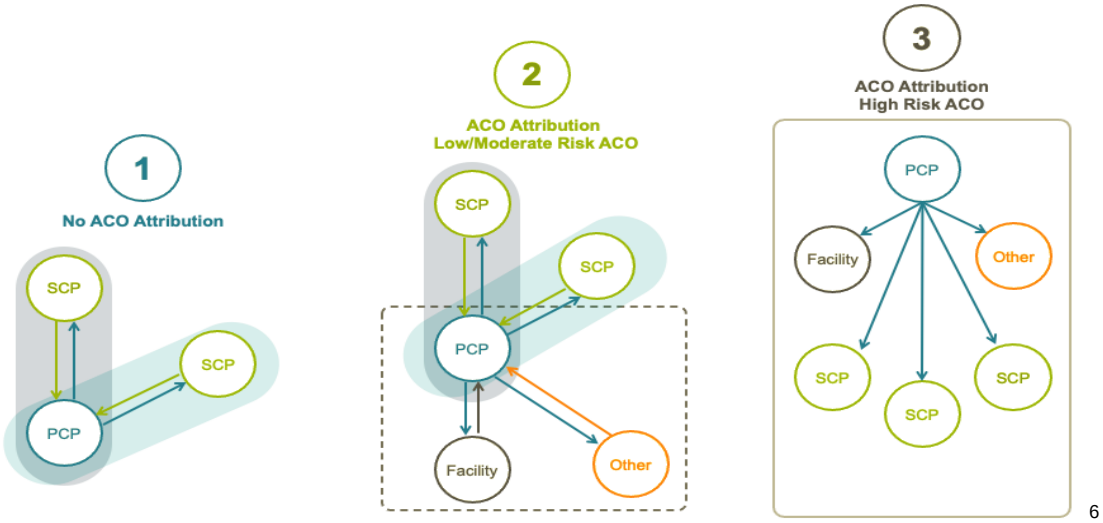
[3] While the current BPCI-A program has shown savings, these have been limited to post-acute care and, because the bundles were mostly triggered by inpatient stays, they don't directly address the need to reduce avoidable hospitalizations.

[4] This document contains important technical appendices. However, these appendices are not exhaustive and we recognize the need for additional supplements which are flagged for delivery Q1 2022

Foreword On Model Fit With Other Models

The attractiveness of a given model, or even all models, is not sufficient to transform the delivery system and give it the attributes expressed in the strategy refresh. The models have to fit with one another and complement each other, pulling the entire system into the desired end state -- one in which primary and specialty care providers closely collaborate with each other and other providers to deliver safe, timely, equitable, efficient, effective and patient-centered care. That fit and complementarity can be illustrated by the following figure that shows (1) how primary and specialty care providers whose patients are not attributed to an ACO can start on the path to full accountability, focusing on the care they can manage and on which they're willing to go at risk. The figure also illustrates how (2) the relationships can evolve to include other providers and the formation of low-to-moderate risk ACOs, and (3) how ACOs can control all relationships when they finally move into full risk arrangements[5].

At the heart of the model described in this document is the collaboration between primary and specialty care providers -- a collaboration that is open and voluntary and supports organizational independence and agility; but also essential to ensure the beneficiaries' outcomes are the overarching concern of the providers taking risk. That core is then enveloped by nuances that are designed to draw organizations deeper into full risk arrangements because doing so is in their best interest across all payers, not just Medicare.



[6]

The function of these providers is driven by the model's incentives, which are to improve the health of a population of patients, reducing waste and improving outcomes -- evidenced by net reductions in preventable hospitalizations and other avoidable complications as well as unnecessary procedures -- while significantly reducing current disparities in outcomes caused by inequities in the way patients have been traditionally cared for and managed.

[5] See page 21 for a complete description of the model's fit with total costs of care (TCC) models
[6] The relationships in the figure are illustrative and not meant to comprehensively depict a complex delivery system. SCP refers to specialty care providers and we expect many SCPs to be a part of an ACO, whether taking nominal/low risk or high risk.

Defined Terms

- **Adverse Actionable Events (AAE):** Potentially avoidable complications.
- **Clinical Condition Category (CCC):** A collection of services organized into a series of bundled episodes in a specific service line.
- **Condition-Based Bundles:** Condition-based bundles are designed to include all the care associated with the management of a condition, whether a procedure or an acute event. For example, a condition-based bundle for Coronary Artery Disease would include associated procedures such as stent and other percutaneous coronary interventions, as well as acute events such as myocardial infarction. The bundles would also include all drugs costs covered under Part B.
- **Convener:** A risk bearing entity that acts as the Specialist Contracting Entity by directly contracting with CMS and coordinating participating specialty practices.
- **Gross Savings:** Savings before accounting for shared savings disbursements.
- **Health Equity:** Populations that experience disproportionately high burdens of disease, worse quality of care, and barriers to accessing care – specifically, racial and ethnic minorities, sexual and gender minorities, people with disabilities, individuals living in rural areas, and other individuals in lower social and economic strata.
- **Historical Baseline Period**: The fixed three year period used to determine to establish the SCE's historical baseline expenditure used to calculate the Performance Year Benchmark.
- **Lookback Period:** The six month period before the start of a performance period that is used to attribute beneficiaries to a SCE.
- **Participants:** Specialist Contracting Entities (SCE's) who take risk in the Medicare Specialty Care Bundles (SCB) program recommended in this playbook.
- **Participant Providers:** Upstream or downstream providers that sub-contract with a Specialist Contracting Entity/participant in the program as part of a preferred provider network.
- **Patient Reported Outcomes Measures (PROMs):**
- **Performance Period:** This program has two six month Performance Periods, a fixed period of time to measure the SCE's performance and attribute beneficiaries, in a given Performance Year.
- **Performance Year (PY)**: The calendar year, 12 month period, for measuring the SCE's performance for shared savings/shared losses.
- **Performance Year Benchmark**: The benchmark is a Per Beneficiary per Month (PBPM) dollar amount against which an SCE is held accountable for Performance Period (PP)

Medicare FFS expenditures within the elected Clinical Condition Category(ies) for its aligned beneficiaries.

- **Risk Bearing Entity (RBE):** The organization taking on and managing risk.
- **Specialty Care Prospective Payment:** Monthly PBPM prospective payment from CMS to the SCE to cover the expected FFS claims for the selected Clinical Condition Categories managed by contracted Participant Providers. Calculated as: Monthly Specialty Care payment = (performance period Benchmark) minus (withhold for remaining FFS claims).
- **Specialist Contracting Entity (SCE):** Specialists or Conveners of specialists who enroll in the Medicare Specialty Care Bundles program and elect to take responsibility for the cost and care of all the conditions, procedures, and acute episodes in the clinical condition categories they enroll in.
- **The Medicare Specialty Care Bundles (SCB) Program:** The bundled payment program aims to address Medicare's goals, building upon the Medicare Direct Contracting Model as well as BPCI-A and other ACO programs. Designed to encourage care innovation at the condition level, rather than at the procedural level, this proposed program focuses on generating savings and improving quality through the longitudinal management of condition episodes by specialists and primary care physicians.
- **Total Cost of Care (TCC)**: Programs where participants elect to take and manage risk for the total cost of care of the attributed population.

Model Overview

Part 1 – Clinical Condition Categories

In its recently published white paper[7], the Center for Medicare and Medicaid Innovation (the Innovation Center) sets out appropriately bold objectives to increase the number of Medicare beneficiaries that are in an accountable care relationship with providers. In the same document, the Innovation Center soberly indicates that close to 60% of Medicare FFS beneficiaries are not attributed to an accountable care organization (ACO) and that there were many shortcomings in past and existing alternative models that have to be addressed in order to meet the stated objectives.

The Innovation Center white paper and other announcements[8] from the Biden Administration emphasize the importance of engaging specialty care physicians and using bundled payments as a means to increase accountability for care, which would include a focused reduction in low value care services and an optimization of patient outcomes.

A year ago, several of us contributed to drafting a report outlining a roadmap for the Innovation Center to implement bundled payment programs, with a specific lens towards specialty care. For several years, the Duke Margolis Center at Duke University, in collaboration with the Dell Medical School, has been working on a specialty care alternative payment model focused on orthopedics[9]. According to a RAND study, medical care services not associated with primary care represent over 90% of all Medicare costs[10].

> *The overarching theme is that creating accountable care payment models for specialty care is a necessity to get the majority of Medicare FFS beneficiaries engaged with an accountable care organization.*

Early on in the Innovation Center's development of alternative payment models, the premise adopted by the agency's leadership was that ACOs should be health systems that included a variety of specialty care physicians that could coordinate and optimize patient care. And yet studies suggest that the most effective ACOs are not health systems but physician-led organizations, many of them PCP-led. The emergence of the new Direct Contracting model solidified the Innovation Center's focus on putting the primary care physician at the center of care and leaving it to that group to engage with specialty care providers. However, specialists

[7] See https://innovation.cms.gov/strategic-direction-whitepaper
[8] See https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf
[9] See https://www.healthaffairs.org/do/10.1377/hblog20180416.346268/full/
[10] See https://www.rand.org/news/press/2019/04/15/index1.html#:~:text=Depending%20on%20whether%20narrow%20or,D%20of%20the%20Medicare%20program.

are still not engaged with the PCP-led ACOs but are instead selectively referred to in an attempt by primary care physicians to direct patients to what they believe to be high performing specialists. However, there is no evidence that these specialists, operating entirely in fee-for-service with no delegation of risk, are modifying their practice patterns to optimize value delivered to patients.

Engaging specialists in advanced APMs represents an enormous opportunity to better coordinate care across primary and specialty care physicians and create greater accountability for costs and outcomes across the continuum of care.

The Innovation Center's strategy refresh recognizes these shortcomings and makes explicit the importance of full engagement of primary and specialty care physicians in accountable care relationships. To that end, the use of specialty care bundles can significantly advance that policy objective.

Analyses show that total Part A and B medical costs attributed to three clinical condition categories (CCCs) -- cardiac care, orthopedic care, and gastroenterological care -- consume over a third of Medicare Part A and B costs.[11] This concept of a clinical condition category is essential to the model because it creates a population health payment for cohorts of patients in a CCC. And that payment covers a combination of conditions and related procedures and acute events into a payment that therefore encourages a reduction in procedures that are not medically necessary as well as preventable hospitalizations. And while this document focuses on three specific CCS to illustrate the impact to Medicare, the model can be applied to any clinical condition category, including cancer.

Figure 1. Example of conditions, procedures and acute events including in the cardiology CCC

Conditions	Procedures	Acute Events
• atrial fibrillation/flutter • heart failure • hypertension essential, • cardiac aneurysm • cardiomyopathy • endocarditis • heart block • ischemic heart disease	• aorta - aneurysm/dissect repair • cath - coronary • coronary art proc - cabg • coronary art proc - pci • heart rhythm - pacemaker/AICD	• acute myocardial infarction • acute pulmonary embolism • prinzmetal angina • thoracic ruptured aortic aneurysm • pacer/aicd comp/malfnct

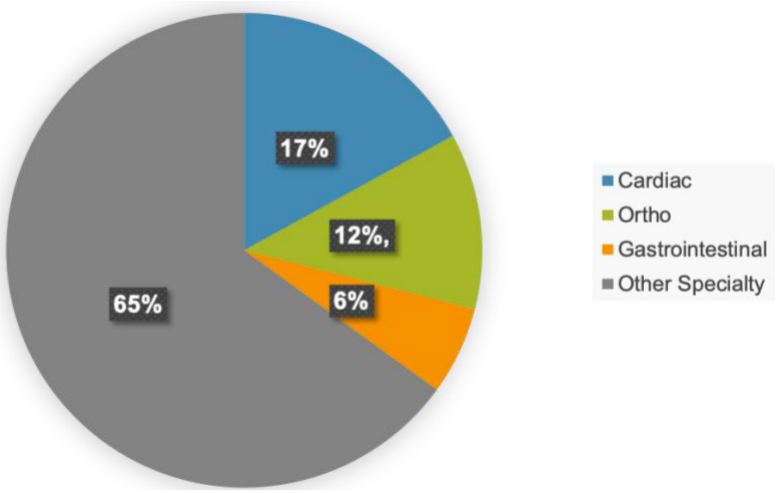
One of the main cost drivers in each CCC is the volume of hospitalizations incurred by beneficiaries with included underlying conditions. For example, 39% of beneficiaries with heart failure are hospitalized at least once a year, and the overall rate of hospitalization is 58 per 100 beneficiaries with that condition, indicating that many have multiple inpatient stays per year. In addition, as the Lown Institute has shown,[12] a significant source of waste in medical spending

[11] Estimates were derived from the PACES grouper logic and episode definitions. See pacescenter.org

[12] See https://lowninstitute.org/lown-issues/low-value-care/

associated with low-value care is the provision of unnecessary procedures, especially in cardiology and orthopedics. Without a change in payment and greater accountability of specialty care physicians for the costs associated with the management of their patients, these facts -- the significant percent of beneficiary costs associated with low value care -- will not change.

Figure 2. Estimated clinical condition category spend



Examples From The Field

As mentioned above, for several years practitioners at the Dell Medical School at the University of Texas at Austin and at Duke University have been working on a value-based care and payment model[13] for a range of musculoskeletal conditions that incorporates a multi-disciplinary approach to the management of chronic conditions such as arthritis and back pain, and encourages appropriate utilization of surgical care. Results show that outcomes reported by patients are consistently better on the back end of management even though the frequency of surgical procedures has been reduced. Under the auspices of the Margolis Center for Health Policy at Duke University, several workgroups have been convened to inform the Innovation Center about ways in which a specialty model for musculoskeletal conditions could be implemented by the Agency.

A similar model has been implemented in gastroenterology (GI) care[14], in particular for inflammatory bowel diseases that are increasingly being treated with specialty drugs. The model was proposed to, and recommended for testing[15] by, the Physician-focused Payment Model Technical Advisory Committee (PTAC). Unfortunately, like most specialty care models that only include costs related to the management of the targeted conditions and procedures instead of total costs of care, it was not tested by the Innovation Center.

[13] See https://www.healthaffairs.org/do/10.1377/hblog20200714.732842/full/
[14] See https://www.gastrojournal.org/article/S0016-5085(17)36337-0/fulltext
[15] See https://aspe.hhs.gov/sites/default/files/private/pdf/255906/SonarReportSecretary.pdf

Contrary to the GI model, the American College of Cardiology was given a grant from the Innovation Center to pilot its specialty payment model, SMARTCare[16]. That model, like the two others, was tightly focused on ensuring appropriateness of care for patients with a specific cardiac condition, reducing the overuse of low-value care. Because SMARTCare was being implemented by the ACC, the grant allowed the Innovation Center to monitor the implementation without having to formally implement the program. At the end of the grant period, the program was not adopted by the Innovation Center.

Overall, these examples and others (such as global maternity bundles) show the interest of specialists in participating in advanced APMs and becoming fully accountable for the financial and clinical outcomes of a population of managed patients.

However, the lack of advanced APMs for specialty care points to barriers, real or perceived, that will need to be addressed in order to implement and scale such models.

Some of these barriers may be technical, such as defining the inclusions and exclusions of services for which specialty care providers would be held accountable. Another may be the breadth and scope of the APM for the specialty care provider, which most providers prefer being centered around the type of care that they can manage and impact.

Some of these barriers can be tied to policy, in particular the strong desire from many in successive administrations to focus almost exclusively on total costs of care and the management of those costs by accountable care organizations, preferably those with a variety of providers that are clinically and, often organizationally, integrated.

The rationale for that preference is that focusing on specialty care could lead to siloing the care of a patient, especially those with various concurrent conditions in different clinical condition categories. There are several important counterpoints to that position:

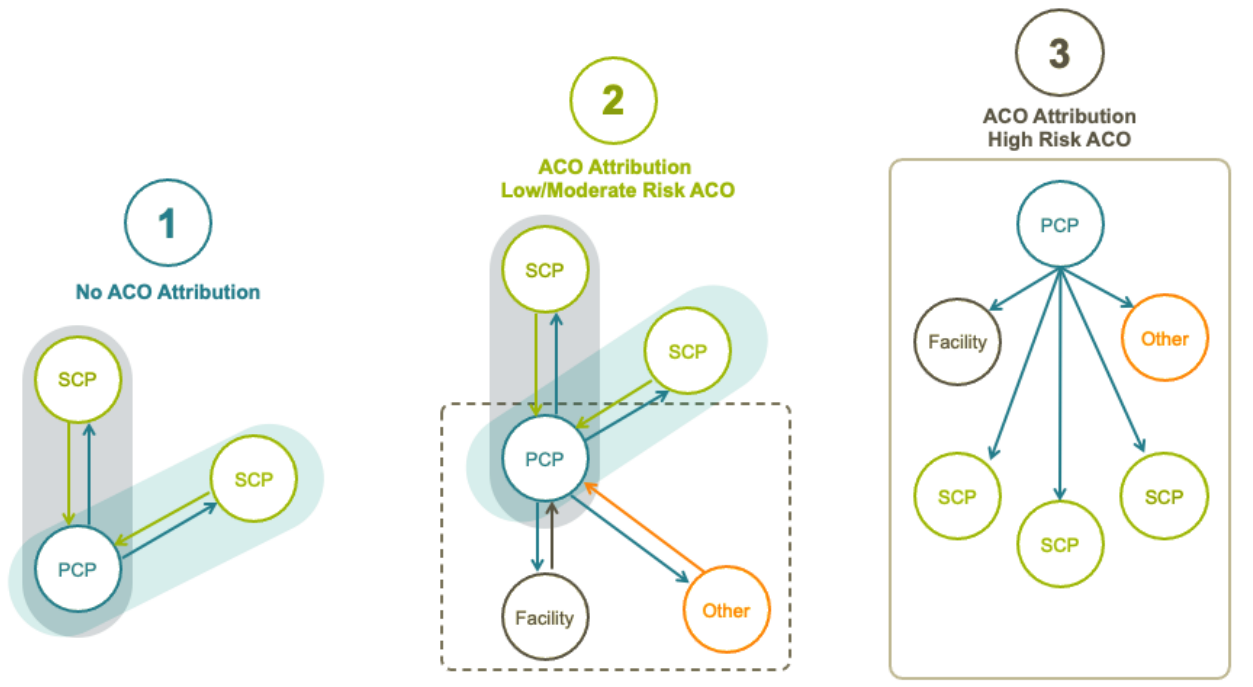
1. **The care of beneficiaries is highly fragmented in FFS and specialty bundles will reduce that fragmentation** – as the examples from the field illustrate, the physicians engaged in specialty-focused advanced APMs (AAPMs) have significantly improved patient care, reducing inappropriate procedures and acute care events. Furthermore, specialty-focused AAPMs create incentives to form multi-disciplinary teams with the expertise in providing comprehensive management of common, quality of life-impacting conditions, focused on improving health outcomes that matter to patients. Engaging Medicare beneficiaries who are not otherwise attributed to or supported by an ACO managed by physicians in a specialty bundle can only be of benefit.
2. **No health care organization is good at everything** – hospital and health system-led ACOs that are accountable for a patient's total costs of care should actively seek out high-performing specialty care practices in their community. Having groups engaged in

[16] See https://www.acc.org/about-acc/leadership/features/bog/2016/04/0415

advanced APMs and fully accountable for patient outcomes should be a welcome policy for all ACOs who can delegate the responsibility of specialty care to those groups while continuing to coordinate overall care and focus on achieving optimal outcomes relative to cost.

3. **Provider consolidation hurts the private sector** – policies that systematically encourage the consolidation of providers into dominant organizations have been proven to result in higher prices with neutral to negative effects on health outcomes in the private sector. Consequently, Medicare payment policy and programs should encourage market competition that prevents further provider consolidation. Encouraging specialty care providers to manage patients independent of hospitals and health systems would accomplish that policy goal.

The policy rationale for adding specialty care bundles to the Innovation Center's portfolio of advanced APMs is very strong, and must be implemented as an integral part of that portfolio, reinforcing the overarching objective to drive more providers into greater levels of accountability. The proposed model accomplishes this by creating clear and strong ties between specialty and primary care providers. These ties and the progression to greater system accountability, which are further detailed in the model overlap section of this document, are summarized in the figure below.



In all three instances depicted in the figure, there are explicit risk contracts between primary and specialty care physicians, which will also allow for eventual attribution of the patient to a primary care physician when that primary care physician decides to enter into contracts with a greater degree of responsibility for the total cost of care. This allows for scaling of the program, not just with additional specialties, but also across models -- all the way to enhanced ACOs. Consider a

PCP practice that has contracted with one or more specialty care practices enrolled in this model to provide care for lower acuity patients in a specific clinical condition category. The contract is likely to be upside only, but includes commitments on patient management and associated processes[17]. This dyad -- specialist and PCP -- forms the nucleus of an ACO, and will also cause local hospitals or health systems to pay attention. That's because hospitals rely on specialty care physicians for patient volume and these hospitals will not want to be left behind by the PCP-SCP combination. As such, providers in phase (1) above will pull facilities and other providers currently sitting on the sidelines into configurations depicted in phase (2). New ACO entrants will start with low to moderate risk and in those instances, the specialty care provider enrolled in this model will continue to bear the majority of the risk for the management of the clinical condition category, while the ACO will maintain risk on the balance of the beneficiary's costs and work with the specialty care practices. As the ACO gains more experience, it will want to assert control over the entirety of the beneficiary's costs of care, which will happen when they move to phase (3). As such, the policies in, and design elements proposed for, this model can help to pull the entire delivery system into greater accountability.

The importance of this model is also underscored by the substantial savings that can accrue to the Medicare program at a point in its history when it is going to have the greatest number of beneficiaries.

Part 2 – Savings Estimates

Given that a substantial portion of the total yearly costs of heart failure are consumed by acute inpatient stays, and that studies have consistently shown the variation in the use of treatments and procedures in the management of conditions, the amplitude of savings that can be derived from the better management of Medicare FFS beneficiaries shouldn't be surprising.

In the analyses below we relied on three sources of data -- the CMS Limited Data Set (LDS) with full Part A and B claims for a subset of 48K beneficiaries in a single geography; an analysis of the full Medicare file from the VRDC by Motive Medical Intelligence; and the analysis of ACO and other files from the VRDC by Care Journey.

The analyses divide the sources of savings into two components: (1) savings that can be achieved by "episode initiators" in optimizing care for patients, and (2) savings that could be achieved by encouraging the referral of patients to the higher-value providers that are directly or indirectly contracted for specialty bundles.

The first source of savings was divided into two parts: the first comprised reductions in potentially avoidable complications, which are referred to in the analysis as adverse actionable events (AAEs); and the second stemming from the reduction of procedures that could be considered medically unnecessary or of low therapeutic value.

[17] Specific ways in which PCPs and Specialty Care Practices can share in the benefits/savings of co-managing patients will be the subject of a forthcoming additional appendix

Savings from reduction in Actionable Adverse Events (AAEs) within clinical condition categories

Approach: Savings estimates were calculated based on claims data from the CMS Limited Data Set (LDS) for 2018 for a subset of members with Part A and Part B claims that had continuous eligibility from 2017-2018. Members were assigned to a Cardiology or Musculoskeletal CCC based on clinically approved EGM-PACES based episodes. In order to be included in a CCC, members must either have two conditional PACES based episodes, or one PACES based procedure in a given year. Once assigned to the CCC, relevant CCC diagnoses and service codes are applied to encompass a wider scope of CCC care. Actionable Adverse Events are flagged based on a clinically approved list of diagnosis codes, as well as inpatient stays (identified by DRG) that are associated with relevant CCC codes. When looking at the entire scope of membership claims, Cardiology CCC-related claims were preferentially assigned to that CCC which may understate the total MSK costs.

Figure 3: The estimated annual spend for clinical condition category services for Medicare in a sample Medicare population, and the potential AAE savings

	Member Count	Average Cost	Total Cost	Total AAE Costs for CCCs	50% AAE Reduction (% of Total Cost)
Total Population	48,020	$13,833	$664 M	$82 M	$41 M (6%)
Cardiology	33,885	$3,311	$112 M	$52 M	$26 M (23%)
Musculoskeletal (MSK)	25,662	$3,012	$77 M	$21 M	$11 M (14%)
Gastrointestinal	11,665	$3,395	$40 M	$9 M	$4.5 M (12%)

A 50% reduction in AAEs for these three CCCs could result in a 6% reduction in total Medicare expenditures for the sample of Medicare beneficiaries. Importantly, there are significantly more potential savings from AAEs in the cardiology CCC (23%) than the MSK CCC (14%) in part because of the volume of acute inpatient stays that are associated with cardiovascular conditions. For example, 40% of the yearly average costs of heart failure for a Medicare FFS beneficiary are consumed by inpatient stays.

Savings from reduction in avoidable and unnecessary procedures within clinical condition categories

A recent report from the Lown Institute[18] showed the significant variation in the appropriateness of procedural care for cardiac and musculoskeletal conditions, underscoring the importance of

[18] See https://lowninstitute.org/lown-issues/low-value-care/

reforming payment for these conditions. Motive Medical Intelligence (Motive) assisted in calculating savings estimates for appropriateness of care within the Medicare population using a set of algorithms that rates providers based on their adherence to guidelines and volume of procedures done for specific conditions.

Motive used the Medicare FFS data set from the VRDC, government research reports, and their own appropriateness of care measures and cost savings models to calculate cost savings as a percentage of Medicare spend and then scaled to represent a sample population's cost and member makeup.

Figure 4: Motive Medical Intelligence's appropriateness analysis results showing savings estimates for the Medicare program based on scaled Medicare specialty spend on a sample population

	Medicare Savings Estimate	Sample Population Total Cost	Estimate Savings Scaled to Sample (% of Sample Population Total Cost)
Cardiology	$1,130 M	$112 M	$1.7 M (1.5%)
Ortho	$637 M	$77 M	$1.1 M (1.4%)

Savings from taking advantage of model overlap/shifting care to higher value providers

Incentivizing total cost of care risk-bearing entities (TCC RBEs) to subcontract with those specialists that can most efficiently manage an array of clinical conditions for their patients yields per episode savings that, cumulatively, would lead to reductions in total costs of care for Medicare. The recommendations contained in the Model Overlap section detail the mechanisms that could be used by the Innovation Center to create the incentives for appropriate referrals to higher-value providers.

The figure below summarizes the findings of a model to estimate potential savings opportunities from optimal referrals among TCC RBEs for ischemic heart disease and osteoarthritis. The analysis was limited to TCC RBEs located in the 10 Core Based Statistical Areas (CBSAs) with the highest number of attributed beneficiaries in the Medicare Shared Savings Program who had at least 5,000 beneficiaries with the condition. Referral savings for each condition were estimated as the difference between the TCC RBE's risk-adjusted per beneficiary per month (PBPM) spending and: 1) The practice affiliated with the RBE in the CBSA having the lowest risk-adjusted PBPM; and 2) The practice at the 20th percentile of risk-adjusted PBPM in the CBSA regardless of affiliation. Shown in the figure are the average RBE savings and 10th and 90th percentile savings. All costs were estimated by CareJourney and Signify leveraging the PACES episode definitions.

The analysis shows several critical points: 1) Virtually all RBEs across all markets have numerous opportunities for savings by seeking out and contracting with the most efficient practices; 2) Greater savings can be attained, on average, by referrals to the most efficient practices in the market, not just those with which an RBE is affiliated; 3) These conditions-based savings would, in turn, translate into important reductions in RBEs' total cost of care.

Figure 5: Estimated RBE savings through optimal referral strategies for condition

	Ischemic Heart Disease			Osteoarthritis	
Most Efficient Practice…	**Average Savings**	**10th-90th Percentile Range**		**Average Savings**	**10th-90th Percentile Range**
Affiliated with RBE	16%	1% - 30%		64%	46% - 77%
20th Percentile in Market	22%	7% - 43%		68%	54% - 77%

Avoiding double counting of savings and losses

In order to maintain the integrity of APMs, it's important to ensure that savings and losses are not duplicated when programs overlap. There are two methods to avoid the risk of double-counting savings or losses when Medicare beneficiaries are accounted for in more than one APM:

- Specialty care bundle-attributed patients that are also attributed to an ACO for the balance of the care have the specialty care costs imputed to the ACO based on the specialist's target price. For example, if a beneficiary is attributed to an ACO and the benchmark total cost is $11,000 and the cardiac specialty bundle's benchmark is $2,300, the ACO will have the $2,300 imputed in its reconciliation for every beneficiary whose cardiac care is attributed to a specialist in the specialty care bundle program. Any savings or losses associated with the specialty bundle will be reconciled at the bundle level and either paid to, or collected from, the specialist.

- Costs associated with the specialty bundle are removed from the ACO's benchmark at baseline, using the same methodology as is used to calculate the specialty care bundle. Leveraging the example above, and assuming that the ACO's benchmark costs for the cardiac bundle are also $2,300, the ACO's benchmark would be reduced from $11,000 to $8,700. This method could create a more powerful incentive for ACOs in nominal risk arrangements to move towards a greater level of risk as further described in this document.

Part 3 – Performance Period Benchmark

Based on the experience of past programs, the Innovation Center's Innovation Strategy Refresh[19] identified the need to refine benchmark methodologies based on lessons learned and stakeholder input in order to: maximize provider participation, generate savings and limit spending growth, and motivate continuous improvement. Complementing these requirements, established benchmarks for SCEs must be stable and predictable over time and, most critically, fairly balance the interests of different program stakeholders, such as between different types of SCEs or between SCEs and CMS.

In order to meet these objectives, the methodology for establishing the Performance Period Benchmark for the SCB program would be similar to the standard claims-based alignment benchmarking methodology used in the Global and Professional Direct Contracting (GPDC) program[20] with several key differences across: the historical expenditure calculation, baseline trend, adjustment for risk and case-mix, and global discount, some of which have been articulated in a recent paper[21]:

Calculation of Historical Expenditures:

- *Clinical Condition Category Baseline*: Like the GPDC program, baselines are calculated as a per beneficiary per month (PBPM) amount based on a weighted average of the SCE's 3-year historical and regional expenditures, with the most recent year weighted more heavily. However, instead of total beneficiary costs, baseline and expenditures would reflect the costs of the specific clinical category as defined in Episode Definition section;
- *Fixed historical benchmarks throughout an SCE's participation:* Re-basing the historical baseline between contract periods creates a ratchet effect in which today's program successes (i.e., lower costs) begets tomorrow's failures. This invariably leads to program attrition, particularly among higher, more efficient performers. In the SCB program, all historical benchmarks would remain fixed and based on the same three years of historical data throughout an SCE's participation in the program. Fixing benchmarks in this way would no doubt accrue greater savings to providers relative to CMS in later years, however CMS would still continue to maintain program-level savings as compared to the absence of any program at all.

Trending Baseline

- *Prospective trends with explicit adjustments in outyears to re-balance program costs*: Developing methodologies that accurately predict trends at the condition- or episode-level is notoriously difficult. This is especially true as time progresses because factors such as changes to standards of practices, the introduction of new health care technologies, or external shocks can lead to wide differences between predicted and observed trends. In existing programs like BPCI Advanced, CMS has attempted to

[19]https://innovation.cms.gov/strategic-direction-whitepaper#:~:text=As%20part%20of%20its%20strategy,role%20in%20achieving%20these%20goals
[20] https://innovation.cms.gov/files/slides/dc-model-options-paymenttwo-slides.pdf
[21] The Merits of Administrative Benchmarks for Population-Based Payment Programs, AJMC: https://www.ajmc.com/view/the-merits-of-administrative-benchmarks-for-population-based-payment-programs

reconcile these differences by applying a retrospective adjustment at the end of each performance period. These adjustments allow CMS to maintain cost neutrality for the program year-to-year but pose significant challenges for participants because they produce highly unstable and unpredictable swings in benchmarks at the point of reconciliation.

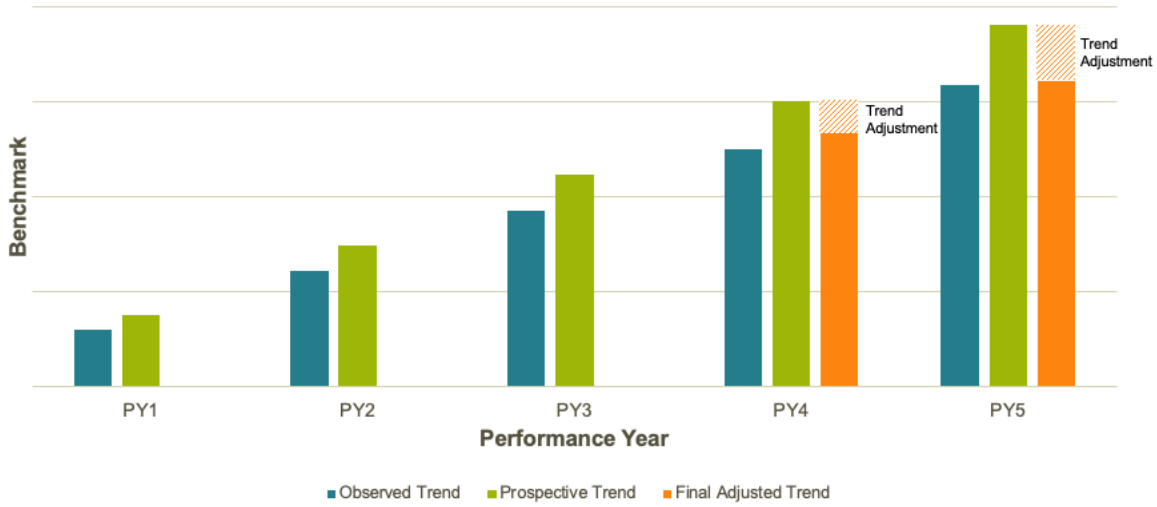
CMS must appropriately close gaps between predicted and observed trends over time to more closely balance the program's overall costs and savings. But this must be weighed against participants' interests in maintaining stable and predictable pricing from one Performance Period to the next. The SCB program would do this by building any necessary trend adjustments into benchmark discounts in later years of the contract period. Specifically, prospective trends would be determined on an annual basis by clinical condition category in Performance years 1-3 based on a consistent methodology. However, an adjustment would be applied to prospective trends in Performance Years 4 and 5 based on the observed gaps between the predicted and actual trends in the previous years.[22]

A simplified illustration showing this adjustment is shown in the figure below. In the example, prospective trends are consistently higher than actual trends during PY1-3. This results in a downward adjustment to the actual prospective trends in the final two years of the contract period to bring them more in line with "true" growth rate. Note that the adjustment is based on the direction of the observed gaps between predicted and actual trends. If, unlike in the figure, there was a scenario in which actual trends exceeded prospective trends in PY1-3, trends in PY4 and 5 would be upwardly adjusted instead.

With this methodology it is also important that guardrails be in place to prevent the adjustment from drastically increasing/decreasing benchmarks when prospective trends are found to be significantly higher or lower from observed. In the SCB program the magnitude of any trend adjustments would be capped at +/-2 percentage points from what the prospective trend would have been. In other words, if the initial prospective trend is +4% and adjustments would reduce it to +0.5%, the final prospective trend for the performance period trend would be limited to +2% due to the cap.

[22] Page 63: As a safeguard for CMS, Conveners and Specialists Contracting Entity participants should incur a penalty for dropping out of the program early.

Figure 6: Proposed trend adjustment illustration



Adjusting for Risk

- *Risk and case-mix adjustments should be calibrated to the individual clinical condition category:* Risk adjustment models and the risk scores derived from them for purposes of SCE case-mix adjustment should be tailored to each individual clinical condition category as opposed to models that combine multiple conditions or are based on total beneficiary cost of care. This ensures the contribution of any clinically important co-morbidity or risk factor to expected resource use represents its 'true' condition-specific effect and produces a more accurate measure of patient risk for the condition overall.

Discount Application

- *Discount Adjustments:*
    - *Lower global discounts over the 5-year contract period*: While the global discount would be phased in over the 5-year contract period like in the current DC program, it would be capped at -3% (See figure below). Although high discount rates maximize savings to CMS, the experience of past programs shows that high discount rates hinder providers' ability to be financially viable and qualify for shared savings, especially when start-up and administrative costs are factored in. High discount rates also discourage provider participation from the historically better performers. The lower global discount helps to appropriately balance between program savings for CMS and potential savings for individual SCEs;

    - *Preferential discounts for early entrants*: The program must aim to encourage early participation and discourage providers from entering in later years only after they've had time to "wait and see" how the program takes shape. To avoid this behavior and incentivize participation at the outset of the program, SCEs entering in the first two years of the program would be given a lower global discount in Performance Years 3-5 relative to those entering later by 0.5 percentage points (See figure below)

- *Discount adjustments for high / low performing participants:* Fixed global discounts disproportionately reduce high performing efficient providers' likelihood of achieving program savings given their marginal opportunities to reduce costs, even at minimal discount rates. The SCB Program would give a +0.5% adjustment to the global discount for all providers with risk-adjusted costs that are in the top two deciles of performance. This would be applied beginning in PY2 and be assessed annually based on the prior year's performance (See Figure 7 below). In order to offset these lower discounts at the program-level, an equal downward adjustment of -0.5% would be applied to the discount for SCEs in the bottom two deciles of the prior year's performance. The high performance adjustment would replace the High Performers Pool in the existing DC program.

- *Reduced discounts for providers that primarily care for underserved populations:* In keeping with its goal to advance health equity, in order to incentivize participation of providers that disproportionately care for underserved populations and are often under-resourced, such as Federally Qualified Health Centers and rural health clinics, the SCB program would reduce the size of the discount for these providers by 0.5%.

Figure 7: Discount schedule during 5-year contract period

	Year 1	Year 2	Year 3	Year 4	Year 5
Global Discount Rate	-2%	-2%	-3%	-3%	-3%
*Discount Adjustments**					
Early Participant (PY1/2)			+0.5%	+0.5%	+0.5%
High Performer^		+0.5%	+0.5%	+0.5%	+0.5%
Low Performer^		-0.5%	-0.5%	-0.5%	-0.5%
Underserved Population	+0.5%	+0.5%	+0.5%	+0.5%	+0.5%

**Added to global discount rate; ^Determined annually based on performance in prior performance year*

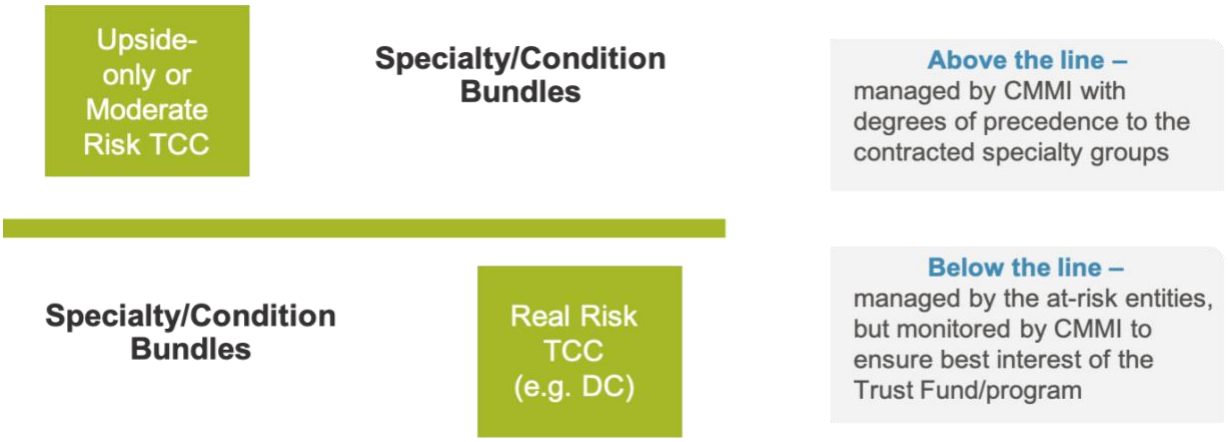
Managing Model Overlap

The way in which the Innovation Center manages model overlap and the policies that it sets to do so can have a significant impact on the larger transformation of the delivery system. Some of the overarching intended consequences of the overlap policies and associated rules should be:

1. Greater risk is what's preferred:
    - ACOs can maintain control of delegating patients and risk when they enter into greater risk arrangements -- the proposed overlap rules are designed to encourage ACOs that are in nominal risk arrangements to move to greater risk arrangements or see their role diminished.

2. PCPs and Specialists should closely collaborate:
    - In instances in which a beneficiary is not attributed to an ACO/PCP, the specialty care provider is encouraged to subcontract with a PCP to delegate lower acuity patients;
    - And when a beneficiary is attributed to an ACO/PCP, the ACO/PCP can increase savings by subcontracting to specialty care providers -- this is especially important since a peer-reviewed study slated for publication in 2022 shows that PCPs have little to no impact on the total costs of care of patients that have anything greater than moderate acuity in their on-going conditions, such as heart failure.

The policy expressed in (1) above can be summarized by the graphic below:



The concept of contracts with specialty care providers that are "above the line" and "under the line" are designed to articulate with whom the specialty care provider contracts and under what conditions. When a beneficiary is either not attributed to an ACO or attributed to an ACO that is taking nominal risk (e.g. MSSP tracks A-E), the specialty care bundle takes precedence, and the specialty care provider would contract with the Innovation Center directly or through a convener. When the beneficiary is attributed to an ACO that is taking substantial risk (such as MSSP Enhanced or Direct Contracting), it is the ACO's responsibility to contract with specialty care providers for specialty bundles.

In order to scale this model, the method of attribution of a beneficiary to a specialty care provider for a specific clinical condition category does not change. What changes is the entity that is taking risk for that clinical condition category -- "above the line" it's the specialty care provider, and "below the line" it's the ACO/TCC RBE.

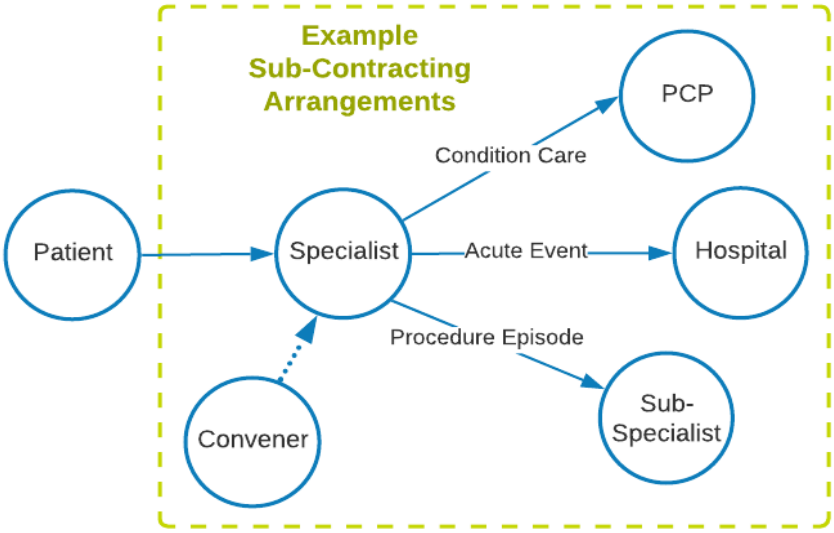
This policy should encourage ACOs that are only taking nominal risk to move to the MSSP Enhanced track or into Direct Contracting or see ever greater portions of the costs of care that are attributed to them go to another provider. Further, the ACOs would lose degrees of influence over specialty care providers, which is something that they want to avoid.

In addition, this policy should encourage providers that are not in an ACO/TCC contract to enter into such a model or, similarly, see their existing influence over specialty care providers diminished as the providers, now at risk, look at all other FFS providers as simply costs of producing care that they will try and reduce as much as possible. Importantly, the model creates a defined bind between primary and specialty care providers.

Whether "above the line" or "below the line" there is an important role for the Innovation Center to play to ensure a fair and level playing field for all providers in risk models. These are summarized below:

TCC risk level	Example models	CMS Role	ACO / Risk-bearing Entity (RBE) Role
High Risk Models "Below the Line"	• DCE • MSSP Enhanced ACO	Monitor and evaluate specialty spend. Maintain right of oversight and enforce "cost neutrality".	RBE can choose to delegate specialty care to any specialists and contract with specialists based on regular program rules.
Low to Moderate Risk Models "Above the Line"	• MSSP Levels A-E	Enrolls specialists into the Innovation Center specialty bundle model directly or through convener.	Specialist bears the risk and subcontracts with others to manage that risk.

Figure 8. The specialty care provider as the risk bearer



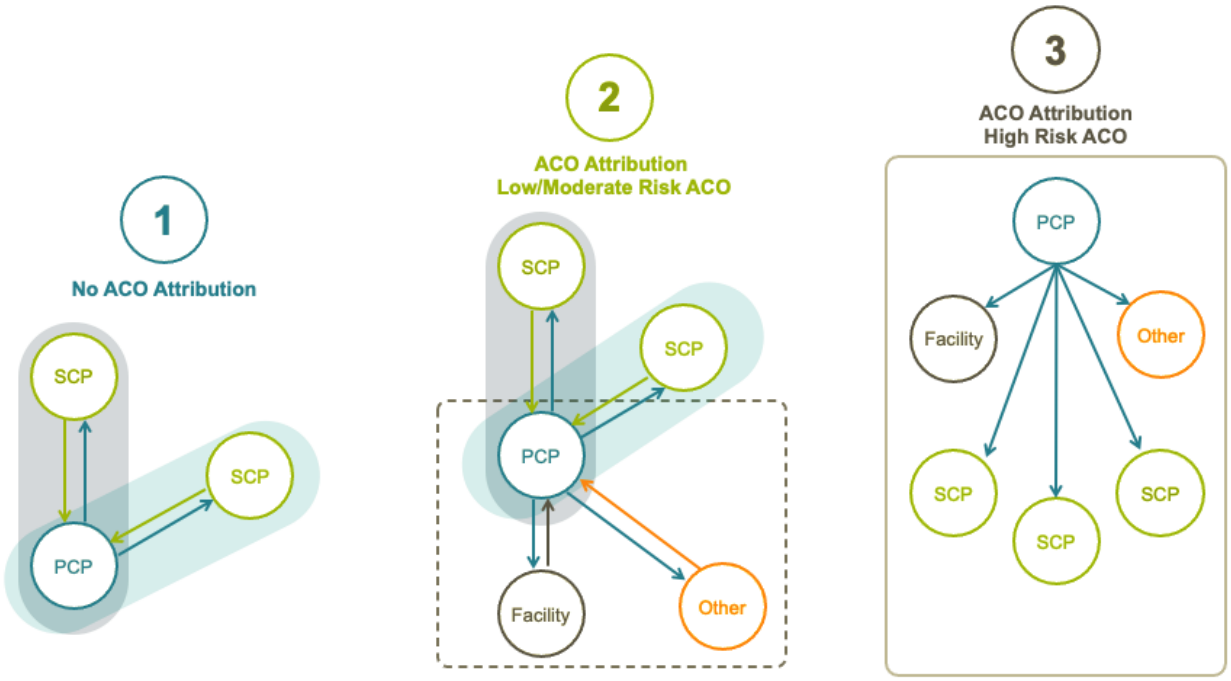
The current participants in the Innovation Center's ACO/TCC risk models are either PCP-led or led by an organization that has a variety of specialty care physicians and, in many instances, a variety of facilities. Given the different nature of these organizations and that the latter have the ability to manage specialty care while the former are highly limited in that ability, it's important for the overlap policy to be further nuanced as expressed in the table below:

Managing overlap to the benefit of Medicare beneficiaries

Type of ACO	No ACO Attribution	ACO Attribution	
		Nominal Risk – Specialty Practices Contracted by the Innovation Center	High Risk – Specialty Practices Contracted by ACO
Hospital/Health System/ Multi-Specialty Group Led	• Beneficiary attributed based on preponderance of evaluation and management claims. • Can be multi-attributed depending on combination of conditions.	• The ACO can retain attribution if they meet the specialty attribution rule. • Else the specialty practice attribution would be asserted.	• The ACO can retain attribution or delegate risk and subcontract with a special care provider.

PCP Led	• Specialists are encouraged to subcontract with PCPs for lower acuity patients.	• The ACO cannot retain attribution because it doesn't have specialty care providers. • Specialists should contract with PCPs to ensure holistic patient care.	• The ACO has an obligation to subcontract with a participating specialty practice; alternatively the ACO could be assessed a financial penalty at reconciliation.

The bottom row of the table is designed to express the second stated intended consequence of the overlap policies, namely to actively encourage the collaboration of specialty care providers with PCPs. Even when there is no attribution of a Medicare beneficiary to an ACO, it is in the specialty care provider's best interest to delegate the management of lower acuity patients to a PCP, in much the same way as in high risk TCC models it is in the best interest of ACOs to delegate the management and risk of high-acuity patients to specialty care providers. The figure below illustrates the way in which the models can work to reinforce the stated policies.

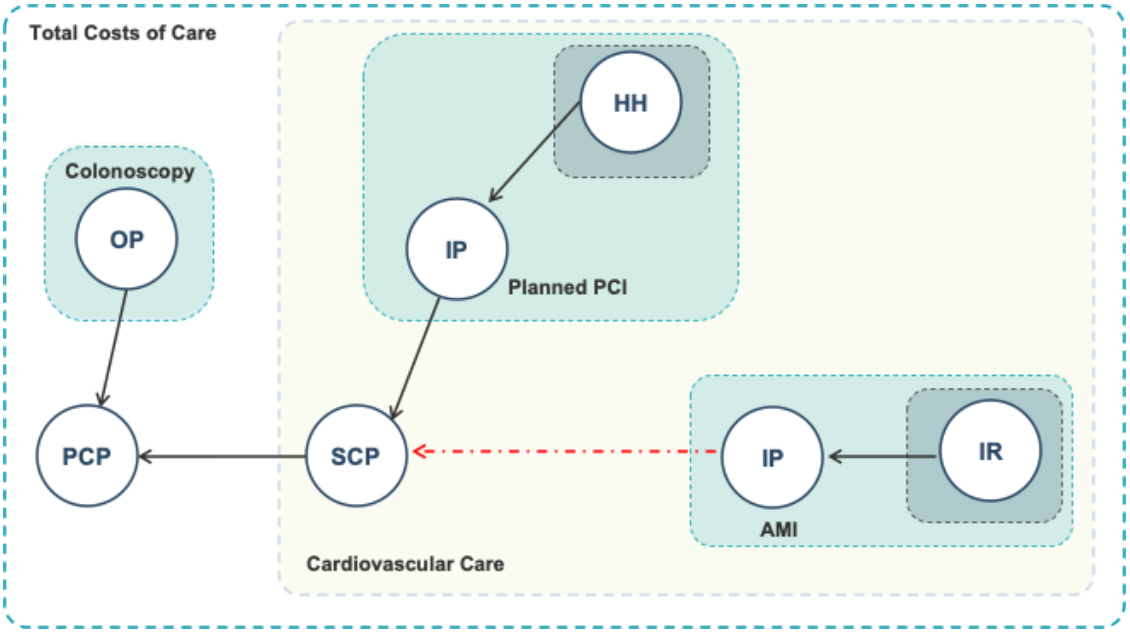


1. **No ACO Attribution** -- Specialty care providers are the primary risk-bearers and delegate a portion of that risk, for lower acuity patients, to primary care physicians. To that end, specialty care providers must have a formal contractual relationship with at least one primary care practice to participate in the model. PCPs could have more than one such contract and would not be compelled to take downside risk. Contracts between the specialty care providers and the PCPs would stipulate the portion of shared savings that would accrue to the PCPs for actively managing patients with lower acuity and performing an annual wellness visit to ensure that any emerging condition or change in

health status is actively managed by the PCP in collaboration with the specialty care provider taking risk[23].

2. **ACO Attribution to Low/Moderate Risk ACO** -- Specialty care providers are the primary risk-bearers and delegate a portion of that risk, for lower acuity patients, to the ACO. The ACO retains the risk for the balance of the patient's cost of care.

3. **ACO Attribution to High Risk ACOs** -- The ACO bears the risk for all beneficiary costs and delegates a portion of the risk to specialty care providers. Of note, it should be in the very best interest of a PCP-led ACO to always subcontract a portion of the risk to an engaged specialty care provider. That's because, as depicted below, any acute event that occurs during the course of a performance period and that is included in the specialty bundle would count against the specialty bundle or the total costs of the beneficiary. Working closely with specialty care physicians and delegating to them the risk of these acute events will encourage them to improve the management of their patients in order to reduce the incidence of acute events (as well as unnecessary procedures/low value care).



The Innovation Center should monitor this sub-contracting activity and potentially mandate that contracting when there are specialty care providers participating in the specialty model in the PCP-led ACO's market. That's because there is a potential for the PCP-led ACO to simply free-ride on the specialty care provider's care transformation efforts and reap the benefits of that management on the ACO's attributed beneficiaries without sharing any of that benefit with the specialty care provider. Alternatively, the Innovation Center could consider a financial penalty at reconciliation when a high-risk ACO's performance on a clinical condition category is worse than it would have been if the ACO had delegated the management of those patients to a specialty care provider enrolled in the model.

[23] Specific ways in which PCPs and Specialty Care Practices can share in the benefits/savings of co-managing patients will be the subject of a forthcoming additional appendix

The table below summarizes the impact on beneficiaries and providers based on the different overlap configurations and from the providers' perspective.

Patient Attribution	Impact on Specialist	Impact on ACO
Patients with **no ACO attribution**	• The specialist is accountable for the specialty care bundle and has a subcontract with at least one PCP practice to support the management of lower acuity patients.	• There is no ACO to which beneficiary costs are attributed. • The specialist's costs are reduced when subcontracting lower acuity patients to PCPs. • The sub-contracted PCP would receive some credit under MACRA for participation in an AAPM. • The PCP would also be engaged on a path to assuming risk.
Patients attributed to an **ACO (PCP-led or otherwise) at nominal risk**	• The specialist is accountable for the specialty care bundle. • The specialist also subcontracts with the ACO's PCPs, other specialists and facilities to ensure more holistic management of the patient's care.	• The ACO is still accountable for all costs of care of the beneficiary other than that which is included in the specialty bundle. • The ACO can share in savings/losses for the subcontracted portion of patients or care that the specialty care provider subcontracts. • Costs of the bundle contracted to the specialists by the Innovation Center would be reduced from the ACO's benchmark or the cost of the bundle would be imputed to the ACO.
Patients attributed to a multi-specialty/health system **ACO at high risk**	• The specialist is a subcontractor to the ACO and would have delegated risk on the care included in the specialty bundle.	• The ACO can choose to subcontract the care included in the specialty bundle to better engage the specialist in the management of the beneficiary. • The Innovation Center could financially penalize the ACO at reconciliation if the ACO's specialty care bundle costs are higher than what they would have been if the ACO had formally delegated the risk to a specialty care provider enrolled in the

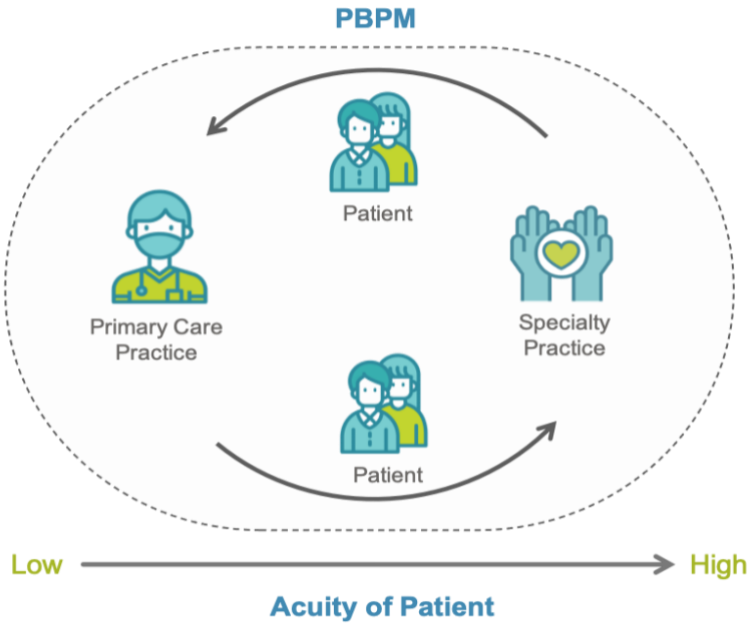
		model.
Patients attributed to a **PCP-led ACO at high risk**	• The specialist is a subcontractor to the ACO and would have delegated risk on the care included in the specialty bundle.	• The ACO should subcontract with the specialty care provider, and CMS should consider mandating such subcontracts or creating a potential financial penalty at reconciliation to minimize the potential for the ACO to free ride on the care transformation of the specialist.

Of particular note is that under current attribution policies, a beneficiary cannot be attributed to two models. While this makes sense when each model includes total costs of care, it loses its importance when one model includes total costs of care and the other is limited to a specific set of conditions/procedures/acute events, as is the case in the proposed specialty care model. That's why the proposed method for managing overlap when there is a specialty care bundle and a total costs of care model with nominal risk is to maintain the attribution to the ACO for all costs that are not included in the specialty care bundle while also attributing that beneficiary's specialty care bundle costs to the contracted specialist.

Figure 9: This table shows estimates of how the PBPM payment for each CCC and for the TCOC would be distributed amongst providers. When specialty bundles overlap with ACOs, High Risk ACOs are responsible for the total cost of care and can decide to delegate risk to specialists, whereas Lower Risk ACOs are not

			Who is Responsible for Risk?	
Care Provided	**Est PBPM**	**Provider**	**Low/Moderate Risk ACO**	**High Risk ACO**
Cardiology	$195	Specialist	Specialist	ACO
Orthopedics	$134	Specialist	Specialist	ACO
Gastroenterology	$69	Specialist	Specialist	ACO
Other	$755	Other	ACO	ACO
ACO Total	**$1,153**	**-**	**$755**	**$1,153**

Irrespective of the attribution of a beneficiary to an ACO, this model calls for the continuous collaboration of primary and specialty care providers to maximize the use of the most efficient providers based on patient acuity. As depicted in the figure below, the ACO or the specialty care providers (depending on who is the primary risk bearer) will be attributed a PBPM for a clinical condition category. That PBPM can be split between primary and specialty care providers based on the decision of the level of acuity at which the patient management shifts.


PBPM
Patient
Primary Care Practice
Specialty Practice
Patient
Low
High
Acuity of Patient

Linking Model Recommendations to the CMS Strategy Refresh

In its recently published Innovation Strategy Refresh, the Innovation Center articulated five strategic objectives to create lasting health system transformation. Analyses of a representative sample of approximately 50,000 Medicare beneficiaries suggest that this proposed model of specialty care bundles would help accelerate the vision expressed in the Strategy Refresh.

In the table below we articulate the ways in which the model will help the Innovation Center meet specific strategic objectives for beneficiaries and providers.

Accountable Care	
Beneficiary Goals	**How The Model Addresses Them**
Medicare FFS beneficiaries will be in an accountable care relationship with providers and will have the opportunity to select who will be responsible for assessing and coordinating their care needs and the cost and quality of their care. Medicare FFS beneficiaries will continue to have the choice to seek care from any FFS provider.	Many FFS beneficiaries receive the majority of their care from specialty care providers, especially when the acuity of their condition is significant. Having specialty care providers fully engaged in an advanced alternative payment model will allow Medicare FFS beneficiaries to select their specialty care provider as the one who is responsible for assessing and coordinating their care needs. This proposed model also specifically encourages the coordination between specialty and primary care physicians, which will enhance the overall accountability for Medicare beneficiary care needs.
Medicaid beneficiaries in FFS and managed care organizations (MCOs) will be in accountable care relationships that drive improved quality and outcomes for beneficiaries. Dual eligible beneficiaries will be in accountable care relationships that help manage the quality and cost of their care and improve their care across the Medicare and Medicaid programs.	A significant percentage of Medicaid beneficiaries have combinations of medical, mental and behavioral health conditions that require the deep involvement of specialty care providers. As specialty care physicians engage in specialty bundles and accept full accountability for the longitudinal care of their patients, they will also be encouraged to coordinate the care of the beneficiary with the PCP and share accountability.

Provider Goals	How The Model Addresses Them
Transformation supports, such as data-sharing, learning opportunities, and regulatory flexibilities, as well as varying levels of options to assume risk will be available for primary care practices to transition to population-based payments and to sustain accountable care relationships.	Having more engaged specialists who are assuming meaningful risk for their roles in managing patients with complex care, care that requires the knowledge and skills of the specialists, helps improve the ability of the PCP to also manage risk. In fact, for a PCP to accept nominal risk while the specialty care provider accepts more significant risk can help ease PCPs into accountable care relationships and advanced alternative payment models because they won't feel the pressure and burden of being accountable for all of the aspects of their patients' care, especially for those who have higher acuity and are being managed by the specialty care provider.
Increase the capability of primary care providers, as well as specialists and other providers, to engage in accountable care relationships with beneficiaries through incentives and flexibilities to manage quality and total cost of care.	The proposed model gives specialty care providers the ability to actively participate in advanced payment models -- something that has been denied to them unless they participate in an ACO's network. There are many specialty care providers that are independent and specialty-focused payment models should help them maintain that independence to avoid further, and unnecessary market consolidation. This model achieves the triple objective of giving the specialty care providers (1) an advanced alternative payment model; (2) an obligation to coordinate with PCPs; and (3) the ability to maintain their independence.

Health Equity	
Beneficiary Goals	**How The Model Addresses Them**
Underserved beneficiaries will have increased access to accountable, value-based care as the CMS Innovation Center focuses on increasing participation among safety net providers in its models. Underserved beneficiaries will experience improved quality and outcomes due to CMS Innovation Center efforts to design models that are simpler, responsive and more supportive of the needs of these beneficiaries and communities.	Specialty care models can benefit underserved beneficiaries in a number of ways. To reinforce the objective, the proposed model includes a very specific method for measuring and reducing inequities over time. This requires arming providers with specific tools and an approach to being successful. The proposed model also suggests having one or two mandatory geographies, beginning in performance year 2, in part to help with the evaluation. These geographies could also be focused on underserved areas in which there are safety net providers. Further, in the way in which the model sets benchmarks, trend rates and discounts, there are options to favorably impact providers who manage underserved beneficiaries.
Provider Goals	**How The Model Addresses Them**
The CMS Innovation Center will address barriers to participation for providers that serve a high proportion of underserved and rural beneficiaries, such as those in Health Professional Shortage Areas (HPSAs) and Medically Underserved Areas (MUAs), and designated provider types such as Federally Qualified Health Centers (FQHCs), rural health clinics (RHCs), and other safety net providers and create more opportunities for them to join models with supports needed to be successful.	A specialist participating in a specialty bundle model may be the only provider a beneficiary in an underserved area is connected to. In underserved areas, all providers often have to extend their reach to help manage a patient. By giving specialty care providers a population-based payment, they should have the financial resources and capabilities to use telehealth and other methods of caring for beneficiaries without having to depend on filing fee-for-service claims. This is all the more important when providers seek the collaboration of the community-based organizations that are so essential to helping improve patient outcomes. Note that while the expansion of telehealth has been helpful, there remain challenges particularly for underserved communities – lack of access to broadband, devices, etc. that limit their ability to meaningfully access telehealth services

	Further, the model proposes methods of benchmarking, trend rate setting and discounts that can create on-going financial support for providers who serve a high proportion of underserved beneficiaries and encourage them to participate and stay in the specialty bundle model.
The CMS Innovation Center will offer targeted learning opportunities for model participants to advance health equity, including collaborating with community partners to address social needs. The CMS Innovation Center will require and consider incentives and supports for model participants to collect data on race, ethnicity, geography, disability, and other demographics and results will be reported to the Innovation Center to help providers address health disparities (in a manner that protected health information (PHI) complies with HIPAA-and other applicable laws).	To encourage model participants to provide a more nuanced understanding of gaps in care for vulnerable populations, the model recommends providing a “quality bonus” to participants that report race/ethnicity and socioeconomic data for the Medicare population. In addition, the quality measurement and scorecarding includes a specific method to measure outcomes, including (and perhaps especially) patient-reported outcomes, and then reduce inequities and disparities.

Care Innovations	
Beneficiary Goals	**How The Model Addresses Them**
Drawing on more diverse beneficiary, caregiver, and patient perspectives will systematically inform development of models that test care delivery changes and innovations that are meaningful and understandable to them. Beneficiaries in accountable care relationships will receive more person centered, integrated care, which could include support with social determinants of health (SDoH) and greater access to care in the home and community.	As it builds upon ACOs and Direct contracting, the specialty care bundles model increases the opportunity to draw on a larger pool of providers and beneficiaries to make and test care delivery changes. That's because this model will help to address the most important needs of complex patients, which is to involve a patient's own specialists in a holistic manner. As mentioned above, the specialty bundles model can be expressed as a population health payment model, even prospectively paid. That means providers have the resources to engage and pay for the support of community-based organizations that are so essential in addressing social determinants of health.
Beneficiaries in accountable care relationships and their caregivers may have access to benefit enhancements and beneficiary engagement incentives that support engagement and care management.	As it is with other advanced APMs, this model includes certain waivers that will help specialty care providers engage with their patients and for their patients to engage with them.
Provider Goals	**How The Model Addresses Them**
Providers will receive support to leverage actionable, practice-specific data, detailed case studies, and other data to implement practice changes that deliver integrated, person-centered, and community-based care. Providers participating in models, particularly total cost of care models, will have access to more payment flexibilities that support accountable care, such as telehealth, remote patient monitoring, and home-based care.	The specialty care bundles model is a population health-based model that can include prospective payment in a manner similar to the Direct Contracting model. These per beneficiary payments can provide critical resources and payment flexibility that are needed for enhanced patient outreach. In particular, with the appropriate waivers, specialty care providers should have the flexibility to leverage telehealth, remote patient monitoring and home-based care.
Address Affordability	

Beneficiary Goals	How The Model Addresses Them
Beneficiaries in CMS Innovation Center models may have lower out-of-pocket costs through changes in cost-sharing or through reductions in avoidable utilization of duplicative or wasteful services. Beneficiaries may experience reduced out-of-pocket costs on drugs by lowering program spending, and by increasing biosimilar and generic drug utilization. Beneficiaries may experience reduced barriers to accessing high-value care using tools such as value-based insurance design that can help improve outcomes and lower overall costs.	Rewarding specialists for employing evidence-based practice, including reducing duplicative tests, tests and procedures when not indicated based on literature, and for coordinating care and supporting and providing strong communication with patients and other members of the care team leads to high-value, cost-saving care for the health system and for patients. The specialty care bundles model includes, for each clinical condition category, the conditions, procedures and acute events that are associated with the management of the patient. This model very specifically encourages appropriateness of care by reducing low-value care, including unnecessary tests and procedures, and any preventable hospitalization or acute event. In addition, the model should encourage specialty care physicians to use the most appropriate drug therapy for their patients, in particular all specialty drugs.
Provider Goals	**How The Model Addresses Them**
Better align provider and beneficiary incentives to increase use of high-value services that efficiently deliver and coordinate care, achieve the best outcomes for patients, and reduce utilization of duplicative or wasteful services – especially in total cost of care models. Create payment and performance incentives in models, especially in total cost of care models, for specialty and primary care providers to coordinate delivery of high-value care and to reduce duplicative or wasteful care.	Specialty care bundles, in which all of the costs for a group of conditions, procedures and acute events that are clinically related are included, create a significant incentive for the specialty care providers to manage patients appropriately, increasing the utilization of high value care services while at the same time reducing low-value services. In fact, helping specialty care providers focus on complete accountability over the type and frequency of the services they deliver will accelerate the move to greater system accountability in a way that total costs of care (TCC) models may not. That's because TCC models diffuse the focus on all costs and don't necessarily engage the front-line clinicians, especially the specialists, that deliver the care.

	The proposed model also includes strong incentives for the specialty care physicians to work closely with primary care physicians, but while maintaining organizational independence and agility. As such, the model encourages clinical integration and alignment, enabling providers to maintain their organizational independence.

Partner to Achieve Health System Transformation	
Beneficiary Goals	**How The Model Addresses Them**
Beneficiaries in accountable care relationships will experience more person centered, seamless care that supports their health and independence. The perspectives of all Medicare and Medicaid beneficiaries, including underserved populations, caregivers, and patient groups will help shape models from conceptualization and design to evaluation and potential expansion.	For many beneficiaries, their specialty care provider is their primary care provider. This holds as true for expectant women in Medicaid as it is for Medicare beneficiaries with complex chronic conditions. For these beneficiaries, having their specialty care provider (or providers) at the center of their health care experience is essential and given a choice they would name their specialty care provider as their “primary care provider” -- the proposed model would give them that opportunity, at least for the condition that is at the center of their health concerns.

Provider Goals	How The Model Addresses Them
Providers will be able to deliver more integrated care across settings and engage in more comprehensive and longitudinal care as a result of accountable care relationships and participation in total cost of care models. Providers will benefit from burden reduction as a result of alignment across payers on value-based care initiatives. Aligning and partnering with other payers on key design features such as clinical tools and outcome measures will enable improved evaluation and scaling of transformation.	The specialty care bundle model is designed to encourage specialists to own the accountability of their patients for specific sets of conditions, procedures and acute events. The focus on longitudinal care management of chronic conditions, such as heart failure or osteoarthritis, creates the accountable care relationship between the provider and the beneficiary. The model also closely encourages collaboration between specialty care providers and primary care physicians to ensure the holistic management of beneficiaries in a manner that creates close clinical integration without the need for organizational integration. This model is already being implemented in populations that are commercially insured and Medicaid, and its implementation in Medicare will help create consistency in APM models and the ability to more rapidly scale them across populations.

While the table above summarizes many of the features of the proposed model and its impact on providers and beneficiaries, this document is designed to be a comprehensive playbook to help support the Innovation Center's adoption of such a model or a model comparable to this one.

Model Design and Technical Specifications

Model Participation

Model Participation	
Model Participants	Organizations eligible to participate as a Specialist Contracting Entity (SCE): ● Physician Group Practices (PGPs) for Clinical Condition Bundles - independent practices or employed by health systems or other organizations. ● Conveners, who directly contract with CMS (as in BPCI-A today) Core Requirements: ● Organizations with historical experience serving Medicare FFS beneficiaries. ● Legal entity identified by tax identification number (TIN) that contracts with CMS for the Medicare Specialty Care Bundles program. ● Minimum of 1,000 attributed Medicare FFS beneficiaries is required prior to the start of each performance period. ● Responsible for receiving shared savings and paying shared losses to CMS. ● Must be capable of administering payments to Participant Providers. ● Must have at least one primary care practice as a Participant Provider at the start of the program.
Role of the Convener as a SCE	A convener acts as the Specialist Contracting Entity by directly contracting with CMS and coordinating participating specialty practices. This is beneficial to participants as the Convener shares financial risk and reduces overall investment costs for participants, while providing analytic and administrative support. Conveners are beneficial to CMS as they have the clearinghouse and means to help spread best practices and encourage broader participation - particularly from participants without the means to enter the program on their own.

Risk Option	Global: ● 100% shared savings / shared losses risk arrangement with the potential for a cap based on certain considerations such as the geographical service area of the SCE and/or the nature of the beneficiaries served. In directly contracting with CMS to participate in the program, the SCE elects which clinical condition categories in which to participate and take risk: ● Select an entire clinical condition category and all the conditions, procedures, and acute events that are included in that clinical condition category. ● Not obligated to select all/multiple clinical condition categories (Cardiology bundle, Orthopaedics bundle, GI bundle). ● Participant may sub-contract with upstream and downstream providers to create Participant Provider risk arrangements for managing services included within the clinical condition category. ● At a minimum a Participant must subcontract with at least one PCP. Note that several considerations can be given to providers who serve a high proportion of underserved beneficiaries: ● Risk can be capped at +/- 25% of total costs. ● Benchmarks can be favorably adjusted to provide more funding to reduce disparities and inequities.
Risk Mitigation	Risk Corridors: ● Automatically applied for all SCEs. ● Mitigates extreme shared savings or losses for SCEs if their actual Performance Period expenditures are far lower or higher than the benchmark. ● Calculated as an aggregate expenditure amount, relative to the Performance Period benchmark. ● See Figure 10A/B below. Risk can be capped at +/- 25% of total costs for SCEs serving in underserved areas.
Participant Providers	Participant Providers must be Medicare-enrolled providers and identified on the SCE's Participant Provider list. ● Used to align beneficiaries to the SCE. ● Accepts up to a 100% claims reduction from CMS. Accepts payment from the SCE through their negotiated payment arrangement.

	● Continue to submit FFS claims to Medicare. ● Report quality. ● Eligible to receive shared savings. ● Have the option to participate in benefit enhancement or patient engagement incentives. ● Are providing care as a licensed specialist included in the list of eligible specialists for a clinical condition category (Figure 11 Below). Participant Providers may include, but are not limited to: ● Physicians or other Practitioners in group practice arrangements. ● Network of individual practices of physicians or other practitioners. ● Federally Qualified Health Centers (FQHCs). ● Rural Health Clinics (RHCs). ● Critical Access Hospitals (CAHs).
Mandatory / voluntary model	Primarily voluntary, with a recommendation for a limited mandatory model in select geographies, one of which being populated with mostly underserved beneficiaries. MedPAC has recognized that one way to account for measuring model success across geographies may be to randomly assign providers to treatment and control groups. This will reduce the regional differences in health care spending and may enable target prices to be set regionally with only the differences in the production costs of workforce and labor (e.g. salary and wages) to account for cost variation. More specifically, to support Health Equity efforts, it would be beneficial to focus on geographies where the majority of beneficiaries are of lower socio-economic status and/or those with a majority minority population. Note that if the program is mandated in certain geographic areas that have a higher proportion of underserved beneficiaries and/or where there is evidence of disparities and inequities in controllable outcomes, benchmarks should be adjusted favorably to provide more funding to address these disparities and reduce them.

Figure 10A: Risk corridors for SCE serving non-underserved areas

Risk Band	Gross Savings / Losses as Percent of Final Performance Period Benchmark	SCE Shared Savings / Shared Losses Cap	CMS Shared Savings / Shared Losses Cap
1	Less than 25%	100% of Savings/Losses	0% of Savings/Losses
2	Between 25% and 35%	50% of Savings/Losses	50% of Savings/Losses
3	Between 35% and 50%	25% of Savings/Losses	75% of Savings/Losses
4	Greater than 50%	10% of Savings/Losses	90% of Savings/Losses

Figure 10B: Risk corridors for SCE serving underserved areas

Risk Band	Gross Savings / Losses as Percent of Final Performance Period Benchmark	SCE Shared Savings / Shared Losses Cap	CMS Shared Savings / Shared Losses Cap
1	Less than 25%	100% of Savings/Losses	0% of Savings/Losses
2	Greater than 25%	10% of Savings/Losses	90% of Savings/Losses

Figure 11: Eligible specialists for clinical condition categories

Clinical Condition	
Orthopedics	• Orthopedic • Spine Surgery • General Surgery • Physical Medicine and Rehabilitation • Rheumatologist • Hand Surgery • Foot/Ankle Surgery • Plastic Surgery • Neurology
Cardiology	• General Cardiology • ElectroPhysiology Cardiology • Interventional Cardiology • Cardiovascular and Thoracic Surgery
Gastrointestinal	• Gastroenterology • General Surgery • Colo-rectal Surgery • Bariatric Surgery

Beneficiary Attribution and Engagement

Beneficiaries are attributed for a clinical condition category to a specialty care provider and can also be attributed to an ACO in a low/moderate risk model for the balance of their costs of care.

Beneficiary alignment when the beneficiary is not attributed to an ACO in a high-risk model such as MSSP Enhanced or Direct Contracting	
Beneficiary Attribution	Beneficiaries are attributed to the Specialist Contracting Entity's roster through claims-based attribution as stated below. Semi-annual attribution process completed prior to each Performance Period (PP).
Claims-Based Attribution	CMS will attribute a beneficiary to a SCE if the beneficiary has historically received the plurality of their services for the given Clinical Condition Category from the SCE (for non-conveners) or the SCE's Participant Providers, as evidenced by claims utilization data. Claims-Based Attribution: ● Claims-based Attribution will occur prior to the start of each Performance Period. ● Beneficiaries will be attributed based on historical claims for certain Clinical Condition Category services furnished by Participant Providers, identified by TIN/NPI combination. ● A six month look back period, the "Attribution Period", will be used to identify claims submitted by a Participant Provider (either a primary care practitioner or a specialty care practitioner). ○ A new beneficiary visiting the SCE or Participant Provider, and diagnosed with a condition within the purview of the given specialists, will be attributed to the SCE in the following Performance Period. ● SCEs retain the attribution of beneficiaries throughout the program years, so long as the beneficiaries continue to seek the plurality of their care from the SCE or one of its Participant Providers (e.g., PCP), and meet the beneficiary eligibility criteria below.

Beneficiary Eligibility	Beneficiaries will be attributed to an SCE if they meet the following criteria:
	● Are enrolled in Medicare Parts A and Part B.
	● Have Medicare as its primary payer.
	● Are a resident of the United States.
	● Reside in a county included in the SCE's service area.
	● Are not enrolled in a Medicare Advantage plan, Medicare Cost Plan under section 1876, PACE organization, or other Medicare health plan, or fall into a category listed below:
	  ● ESRD.
	  ● Transplant.
	  ● Active cancer management or inclusion in OCM/OCF.
	  ● Advanced dementia.
	  ● Advanced neurological diseases.
	  ● Trauma.
	  ● Covered under Mine Workers or managed care plans.

Single SCE Attribution per Clinical Condition Category	Beneficiaries can be attributed to multiple SCE's for different CCC. As an example, a beneficiary with a cardiac condition and an orthopedic condition can be attributed to a Cardiology SCE and to an Orthopedic SCE for the respective clinical conditions.
Beneficiary Engagement	Include benefit enhancements and beneficiary engagement incentives currently permitted in NGACO and Direct Contracting (see list below). Consider to include new incentives that will help specialty care providers engage with their patients and for their patients to engage with them, such as: ● Chronic disease management reward (NGACO). ● Cost sharing support for SNF services. ● Home as the originating site. ● Health disparity management reward (e.g., food - nutrition-cardiac/GI access, DME, transportation to doctor's visit). Beneficiary Incentives from Direct Contracting: ● 3-Day Skilled Nursing Facility (SNF) Rule Waiver Benefit Enhancement. ● Telehealth Benefit Enhancement. ● Post-Discharge Home Visits Benefit Enhancement.

	● Care Management Home Visits Benefit Enhancement. ● Home Health Homebound Waiver Benefit Enhancement. ● Concurrent Care for Beneficiaries that Elect Medicare Hospice Benefit Enhancement. ● Alternative Sites of Care. ● Long-Term Care Hospital 25-day average Length of Stay requirement and Other Site of Care Restrictions. ● Nurse Practitioner Services Bundle3.

Episode Definition

The CCC episodes are designed to be longitudinal in nature and inclusive of all services a person could be expected to potentially receive over the course of the condition, including services necessary for routine management (labs, office visits, imaging), major procedures, and other related sequelae and complications. This represents a comprehensive approach to chronic condition management such that a focus on providing regular and medically appropriate care over time improves health and reduces the likelihood of major surgery or serious complications requiring hospitalization in the future.

Clinical Condition Category	Est PBPM for TCOC	% of Total Bene Costs
Cardiology	$195	17%
Ortho	$134	12%
Gastrointestinal	$69	6%

Episode Definition	
Condition Episodes Included	Covers Orthopedic, Cardiology, and Gastrointestinal Episodes and includes services within each CCC. All clinically associated procedures and acute events are also included in the condition episode and not separated out as separate bundles. See attached Episode Technical Appendix for list of Clinical Condition Categories and the respective nested acute and procedural episodes.
Episode Definitions	See attached Episode Technical Appendix for episode definitions.
Episode Duration	Individual episodes within the clinical condition category can have varying lengths, but the beneficiary is still considered to be in the clinical condition category if s/he has on-going evidence of that condition. The management of the patient can shift from a primary care physician to whom the specialty care provider has delegated a portion of the risk, to the specialty care provider.

Episode Trigger	At least one of the following conditions must be met: ● A Part B professional evaluation and management service carrying a diagnosis code for the condition followed by an additional Part B professional or outpatient facility evaluation and management service with a diagnosis code at least 30 days after. ● A single Part B outpatient facility claim for an evaluation and management carrying a diagnosis code for the condition. ● A single Part A facility claim with a diagnosis for the condition in the principal position.
Service Inclusion and Exclusion	1. All Part A facility claims with a diagnosis code for the condition in the principal position. 2. All Part B claims with a relevant diagnosis code (any position) for the condition.

As shown in the figure below, beneficiaries are continuously covered and considered in the "episode" as long as they have evidence of a condition included in the CCC.

The specialty care physician and the primary care physician can share the management of the patient as the acuity of the condition shifts or the need for an intervention requiring specialty care arises. In all "above the line" contracts the SCE is paid the PBPM for all attributed beneficiaries and delegates a portion of that PBPM to the PCP for the patients managed by that PCP.

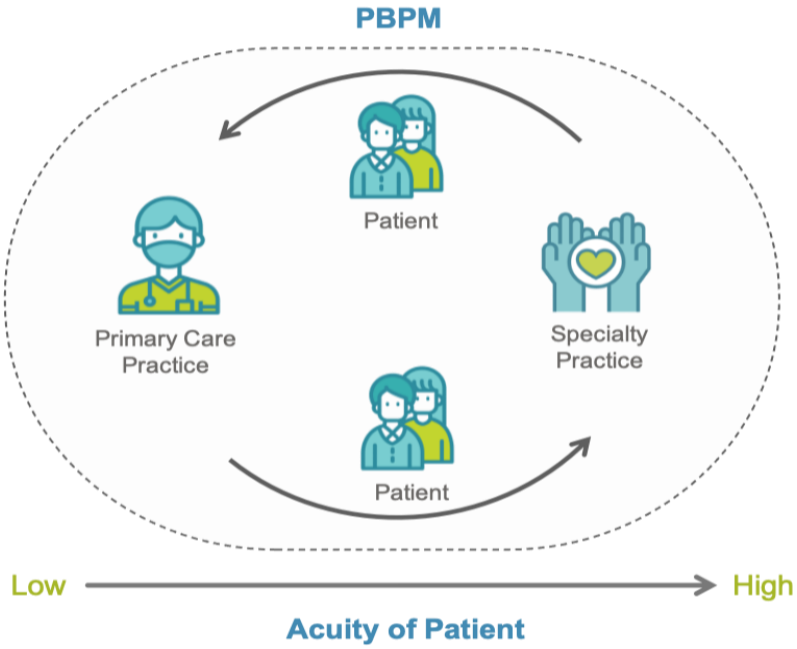


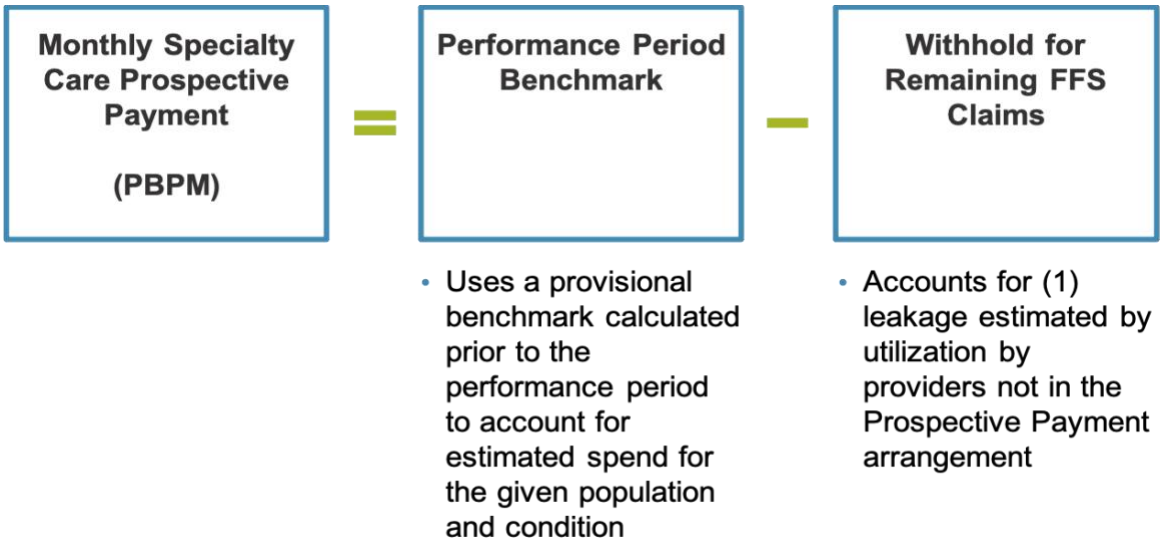
Figure 12: This table shows an example of how the Specialty Care Bundle PBPM could be split between the PCP and the Specialist. The beneficiaries in the bottom 50th percentile of spend represent those with lower acuity conditions that could be managed by a PCP. Like Direct Contracting, it is up to the SCE to distribute payment to the PCP

	Total		Bottom 50th Percentile PBPM		Top 50th Percentile PBPM	
	Member Count	PBPM	Member Count	PBPM	Member Count	PBPM
Cardiac	33,885	$195	14,810	$20	19,075	$330
Ortho	25,662	$134	9,880	$18	15,782	$207
GI	11,665	$69	3,605	$9	8,060	$96
Total	**48,020**	**$1,153**	**24,010**	**$162**	**24,010**	**$2,144**

SCE Payment Mechanisms

Similar to Direct Contracting, this program offers a Specialty Care prospective payment mechanism so that SCEs can receive stable monthly payments from CMS. This is based on the thesis that having control of the flow of funds with the participating providers will enable and incentivize SCEs to improve care coordination and delivery, and to better manage the health needs of their aligned population, resulting in reduced costs and better outcomes.

Figure 13: Prospective Payment amounts received by SCEs



SCE Payment Mechanism	
Prospective Payment Mechanism	SCE receives a monthly prospective payment from CMS on a PBPM basis. Monthly Specialty Care Prospective Payment = (Performance Period Benchmark) minus (withhold for remaining FFS claims).
Performance Period Benchmark	The benchmark is a per beneficiary per month (PBPM) dollar amount against which a SCE is held accountable for performance period expenditures for its aligned beneficiaries. The Performance Period Benchmark is established by starting with the historical baseline, and adjusting it for trending and risk and case mix adjustment. Reference the Performance Period Benchmark section below. Notably: ● The benchmark is inclusive of Medicare parts A and B spend for the selected Clinical Condition Category (CCC). ● The historical baseline expenditure is calculated using a weighted average of historical Medicare expenditures for beneficiaries that would have been aligned to the SCE in the base years (a fixed 3-year period, prior the first performance period, with the most recent years more heavily weighted).
Global Discount	See Figure 7. Starts at 2% and increases to 3% by performance year 3. Include the following discount adjustment: ● **Early Participant Adjustment** for SCEs that join during the first two performance years. ● **High Performance Adjustment** for SCEs that are in the top two deciles of performance -- meaning that their historical costs are lower than most other providers. ● **Low Performance Adjustment** for SCEs below the top two deciles of performance. ● **Underserved Population Adjustment** for SCEs that serve a high proportion of underserved beneficiaries.

Shared Savings or Losses	Shared Savings or Shared Losses: ● Will be determined by CMS after comparing actual Medicare expenditures delivered to aligned beneficiaries against the SCE's benchmark to determine shared savings or losses. ● Medical expenditures include PBPM payments and FFS claim amounts paid by CMS directly for the selected Clinical Condition Category. ● Discount is applied to the Performance Period Benchmark for CMS to obtain savings. ● 10% quality withhold is applied to Performance Period Benchmark to incentivize quality performance. Shared losses would initially be collected from the remainder CMS withholds. Losses that exceed the balance of the quality withhold would be collected as a claw back from future payments or repayment, similar as managed in the Direct Contracting program.
Reconciliation, spending calculation, disbursement, and post-episode monitoring period:	Final Financial Reconciliation ● Conducted after the end of the Performance Period and sufficient time has passed for claims processing and full claims run out and data availability to reflect the complete Performance Period. Disbursement ● CMS to disburse payment to SCE, who is responsible for payment to downstream sub-contracted providers. Post-Episode Monitoring Period: ● 30 days.
Health Equity Reward	A global administrative bonus / reward to SCEs for reporting outcome-related health equity data and metrics across their populations for the first two Performance Periods. Subsequently for the following Performance Periods, data will be used to establish pay for performance rewards that focus on rewarding SCEs who improve outcomes in disadvantaged populations and generally reduce health inequities.

Performance Period Benchmark

Based on the experience of past programs, the Innovation Center's Innovation Strategy Refresh[24] identified the need to refine benchmark methodologies based on lessons learned and stakeholder input in order to: maximize provider participation, generate savings and limit spending growth, and motivate continuous improvement. Complementing these requirements, established benchmarks for SCEs must be stable and predictable over time and, most critically, fairly balance the interests of different program stakeholders, such as between different types of SCEs or between SCEs and CMS.

In order to meet these objectives, the methodology for establishing the Performance Period Benchmark for the SCB program would be similar to the standard claims-based alignment benchmarking methodology used in the Global and Professional Direct Contracting (GPDC) program[25] with several key differences across: the historical expenditure calculation, baseline trend, adjustment for risk and case-mix, and global discount, some of which have been articulated in a recent paper[26]:

Calculation of Historical Expenditures:

- *Clinical Condition Category Baseline*: Like the GPDC program, baselines are calculated as a per beneficiary per month (PBPM) amount based on a weighted average of the SCE's 3-year historical and regional expenditures, with the most recent year weighted more heavily. However, instead of total beneficiary costs, baseline and expenditures would reflect the costs of the specific clinical category as defined in Episode Definition section;
- *Fixed historical benchmarks throughout an SCE's participation:* Re-basing the historical baseline between contract periods creates a ratchet effect in which today's program successes (i.e., lower costs) begets tomorrow's failures. This invariably leads to program attrition, particularly among higher, more efficient performers. In the SCB program, all historical benchmarks would remain fixed and based on the same three years of historical data throughout an SCE's participation in the program. Fixing benchmarks in this way would no doubt accrue greater savings to providers relative to CMS in later years, however CMS would still continue to maintain program-level savings as compared to the absence of any program at all.

Trending Baseline

- *Prospective trends with explicit adjustments in outyears to re-balance program costs*: Developing methodologies that accurately predict trends at the condition- or episode-level is notoriously difficult. This is especially true as time progresses because factors such as changes to standards of practices, the introduction of new health care technologies, or external shocks can lead to wide differences between predicted and observed trends. In existing programs like BPCI Advanced, CMS has attempted to reconcile these differences by applying a retrospective adjustment at the end of each

[24]https://innovation.cms.gov/strategic-direction-whitepaper#:~:text=As%20part%20of%20its%20strategy,role%20in%20achieving%20these%20goals
[25] https://innovation.cms.gov/files/slides/dc-model-options-paymenttwo-slides.pdf
[26] The Merits of Administrative Benchmarks for Population-Based Payment Programs, AJMC: https://www.ajmc.com/view/the-merits-of-administrative-benchmarks-for-population-based-payment-programs

performance period. These adjustments allow CMS to maintain cost neutrality for the program year-to-year but pose significant challenges for participants because they produce highly unstable and unpredictable swings in benchmarks at the point of reconciliation.

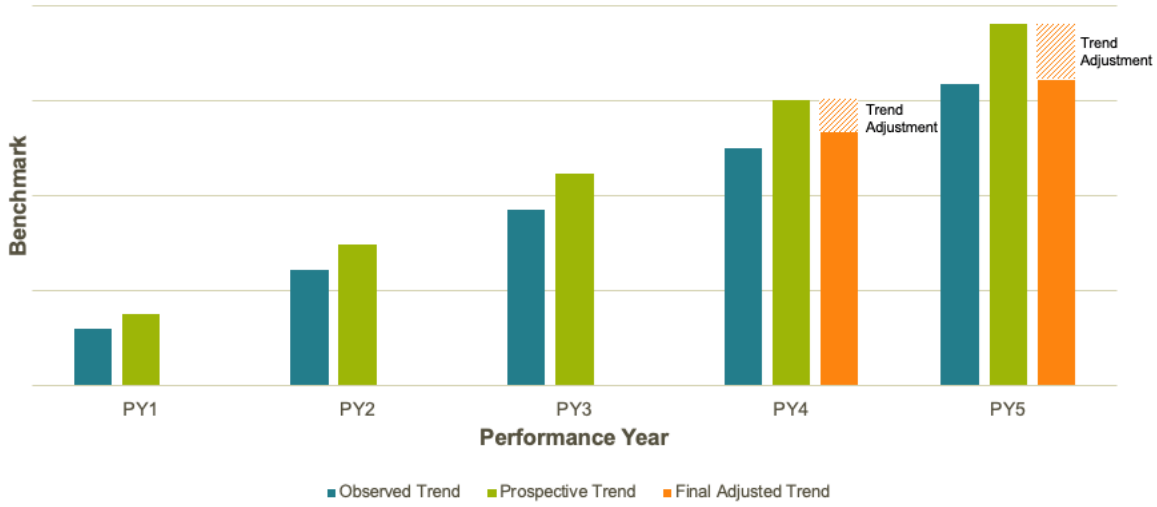
CMS must appropriately close gaps between predicted and observed trends over time to more closely balance the program's overall costs and savings. But this must be weighed against participants' interests in maintaining stable and predictable pricing from one Performance Period to the next. The SCB program would do this by building any necessary trend adjustments into benchmark discounts in later years of the contract period. Specifically, prospective trends would be determined on an annual basis by clinical condition category in Performance years 1-3 based on a consistent methodology. However, an adjustment would be applied to prospective trends in Performance Years 4 and 5 based on the observed gaps between the predicted and actual trends in the previous years.[27]

A simplified illustration showing this adjustment in the figure below. In the example, prospective trends are consistently higher than actual trends during PY1-3. This results in a downward adjustment to the actual prospective trends in the final two years of the contract period to bring them more in line with "true" growth rate. Note that the adjustment is based on the direction of the observed gaps between predicted and actual trends. If, unlike in the figure, there was a scenario in which actual trends exceeded prospective trends in PY1-3, trends in PY4 and 5 would be upwardly adjusted instead.

With this methodology it is also important that guardrails be in place to prevent the adjustment from drastically increasing/decreasing benchmarks when prospective trends are found to be significantly higher or lower from observed. In the SCB program the magnitude of any trend adjustments would be capped at +/-2 percentage points from what the prospective trend would have been. In other words, if the initial prospective trend is +4% and adjustments would reduce it to +0.5%, the final prospective trend for the performance period trend would be limited to +2% due to the cap.

[27] Page 56: As a safeguard for CMS, Conveners and Specialists Contracting Entity participants should incur a penalty for dropping out of the program early.

Figure 14: Proposed trend adjustment illustration



Adjusting for Risk

- *Risk and case-mix adjustments should be calibrated to the individual clinical condition category:* Risk adjustment models and the risk scores derived from them for purposes of SCE case-mix adjustment should be tailored to each individual clinical condition category as opposed to models that combine multiple conditions or are based on total beneficiary cost of care. This ensures the contribution of any clinically important co-morbidity or risk factor to expected resource use represents its 'true' condition-specific effect and produces a more accurate measure of patient risk for the condition overall.

Discount Application

- *Discount Adjustments:*
    - *Lower global discounts over the 5-year contract period*: While the global discount would be phased in over the 5-year contract period like in the current DC program, it would be capped at -3% (See figure below). Although high discount rates maximize savings to CMS, the experience of past programs shows that high discount rates hinder providers' ability to be financially viable and qualify for shared savings, especially when start-up and administrative costs are factored in. High discount rates also discourage provider participation from the historically better performers. The lower global discount helps to appropriately balance between program savings for CMS and potential savings for individual SCEs;

    - *Preferential discounts for early entrants*: The program must aim to encourage early participation and discourage providers from entering in later years only after they've had time to "wait and see" how the program takes shape. To avoid this behavior and incentivize participation at the outset of the program, SCEs entering in the first two years of the program would be given a lower global discount in Performance Years 3-5 relative to those entering later by 0.5 percentage points (See figure below)

- *Discount adjustments for high / low performing participants:* Fixed global discounts disproportionately reduce high performing efficient providers' likelihood of achieving program savings given their marginal opportunities to reduce costs, even at minimal discount rates. The SCB Program would give a +0.5% adjustment to the global discount for all providers with risk-adjusted costs that are in the top two deciles of performance. This would be applied beginning in PY2 and be assessed annually based on the prior year's performance (See Figure 15 below). In order to offset these lower discounts at the program-level, an equal downward adjustment of -0.5% would be applied to the discount for SCEs in the bottom two deciles of the prior year's performance. The high performance adjustment would replace the High Performers Pool in the existing DC program.

- *Reduced discounts for providers that primarily care for underserved populations:* In keeping with its goal to advance health equity, in order to incentivize participation of providers that disproportionately care for underserved populations and are often under-resourced, such as Federally Qualified Health Centers and rural health clinics, the SCB program would reduce the size of the discount for these providers by 0.5%.

Figure 15: Discount schedule during 5-year contract period

	Year 1	Year 2	Year 3	Year 4	Year 5
Global Discount Rate	-2%	-2%	-3%	-3%	-3%
*Discount Adjustments**					
Early Participant (PY1/2)			+0.5%	+0.5%	+0.5%
High Performer^		+0.5%	+0.5%	+0.5%	+0.5%
Low Performer^		-0.5%	-0.5%	-0.5%	-0.5%
Underserved Population	+0.5%	+0.5%	+0.5%	+0.5%	+0.5%

**Added to global discount rate; ^Determined annually based on performance in prior performance year*

Quality

Over the past decade, CMS has made meaningful progress in advancing quality measurement across a wide range of conditions. These efforts have resulted in robust activities across the healthcare ecosystem in collecting, tracking, and reporting a diverse range of metrics. Although some of these efforts have made a meaningful impact on patients' health outcomes, many other activities have not had a direct impact on patient care, while adding significant reporting and tracking burden on health care providers and organizations.

Recently, CMS has started to make changes to simplify and streamline quality measures across the various quality programs. For the next generation of value-based care episodes of care and specialty-based models, we recommend that the Innovation Center consider the following:

- Consider a limited set of high-impact, outcome-focused, population health measures that broadly apply to condition-specific episodes and can be impacted through meaningful structure and process measures.
- Align measures with other VBC programs (e.g., DC, ACO, PCF) and professional associations (e.g., ACC) where possible.
- Ensure measures are claims-based (NQF, NCQA endorsed) and do not put significant tracking and reporting burden on providers and participants.
- Ensure measures help advance focus on key clinical, patient care, and equity objectives that can be impacted by participants.

In alignment with these considerations, we recommend the following quality measures.

Quality Measures	Measure Overview	Data Submission
Risk-Standardized All- Cause Unplanned Readmission (ACUR) NQF 1789	Measures how many index acute episodes result in subsequent, unplanned readmissions within 30 and 90 days, depending on acute (30 day) or procedural (90 day) episodes.	CMS Calculates from claims
Hospital-Wide Risk-Standardized All Cause Mortality Rate (HWRM) NQF Pending	Measures unplanned all-cause 30-day mortality for all acute and procedural episodes attributed to providers in the program.	CMS Calculates from claims

Timely Follow-Up After Acute Exacerbations of Chronic Conditions (Timely Follow-Up) **NQF Pending**	Measures the percentage of acute events related to one of six chronic conditions where follow-up was received within the timeframe recommended by clinical practice guidelines in a non-emergency outpatient setting. Acute events are those that require either an emergency department visit or hospitalization. The six chronic conditions include hypertension, asthma, heart failure, coronary artery disease, chronic obstructive pulmonary disease, and Type I/II diabetes mellitus.	CMS Calculates from claims
Controlling High Blood Pressure (BP) **NQF 0018**	Measures percentage of patients 18 - 85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	CMS Calculates from claims; providers use G codes to track on Part B claim
Diabetes: Hbg A1C Poor Control (A1C) **NQF 0059**	Measures percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	CMS Calculates from claims; providers use G codes to track on Part B claim
Preventive Care and Screening: Screening for Depression and FollowUp Plan (Depression) **NQF 0418e**	Percentage of patients aged 12 years and older screened for depression using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	CMS Calculates from claims; providers use G codes to track on Part B claim
Average Days at Home (ADH) **TEP Report**	Measures days at home, defined as the total number of eligible patient days minus the number of days spent in specified acute care settings (that is, a “day at home” is any day alive and not in an institutional care setting).	CMS Calculates from claims

Functional Outcomes Assessment (Function)[28] NQF 2624	Measures percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	CMS Calculates from claims; providers use G codes to track on Part B claim
CAHPS Survey (CAHPS)	Measures patient reported outcomes to improve patient engagement and decision-making in the care provided. Existing efforts to collect CAHPS responses from hospitals, MIPS eligible clinicians, ACO participants, or DC participants can be leveraged to measure performance for bundle participants without additional reporting burden.	Participants selects from existing efforts to report
Condition-specific Patient Reported Outcomes Measures (PROMs)	The International Consortium for Health Outcomes Measurement (ICHOM)[29] has developed a number of condition-specific outcomes measures that are reported by the patient and collected systematically and independently. While this constitutes a net new measurement for providers, we believe that it is one of the only objective ways to ensure that care pathways are implemented for the complete benefit of the patient.	CMS selects a PROM for each condition and manages the data collection and reporting

[28] There are two new PRO-PMs related to hip/knee OA that were recently added to the CMS Measures Under Consideration list that would be appropriate to add here.
[29] See measurement tools and dimensions at https://www.ichom.org/

Quality Withhold

Performance on quality will impact 10% of positive or negative savings in the program, similar to BPCI-A. In each performance period, 10% of positive savings will be held "at risk" and can be earned back, in part or in full, subject to quality performance. Some or all of the 10% Quality Withhold will be tied to either quality reporting or quality performance in each PY as described below.

Figure 16: Portion of quality withhold tied to P4R vs. P4P by performance period

PY	Quality Withhold	Pay for Reporting (P4R)	Pay for Performance (P4P)
PY 1	10%	5%	5%
PY 2	10%	4%	6%
PY 3	10%	1%	9%
PY 4	10%	0%	10%
PY 5	10%	0%	10%

The quality performance will be measured as an improvement over baseline for each of the 14 recommended quality metrics. As described below in the section on Promoting Health Equity, beginning in Year 3, the derivation of the rates for each metric will place emphasis on improvements achieved for patients categorized as disadvantaged.

The below figure outlines the measures by performance periods. The first two years, program participants will get full quality credit for reporting complete data on some of the measures, including Timely Follow-up, BP, A1C, and CAHPS measures. As participants gain experience reporting complete data on all participants, performance will be based on improvements achieved compared to baseline across all measures.

We recognize that there is also a need for supplemental technical appendices, especially on addressing SDOH, inequities and disparities, that could provide specialty practices in each targeted clinical condition category with models, tools and resources that could be useful in model engagement. As such, we will be providing the Innovation Center with these additional appendices in early 2022.

Figure 17: P4R vs. P4P by performance period

Measure	PY 1	PY 2	PY 3	PY 4	PY 5
ACUR	P4P	P4P	P4P	P4P	
ADH	P4P	P4P	P4P		
Follow-up	P4R	P4R	P4P		
BP	P4R	P4R	P4P		
A1C	P4R	P4R	P4P		
Depression	P4R	P4R	P4P		
HWRM	P4P	P4P	P4P		
CAHPS	-	P4R	P4R		
Health Equity	P4R	P4R	P4P		

Promoting Health Equity

Many analyses have been conducted on instances of racial and socio-economic health disparities in the United States. As recognized in the *CMS Equity Plan for Improving Quality in Medicare,*[30] low-income Americans and racial and ethnic minorities experience disproportionately higher rates of disease, fewer treatment options, and reduced access to care. One of the most glaring disparities is apparent in the African American community, where 48% of adults suffer from a chronic disease compared to 39% of the general population.[31]

Many of the proposed quality measures can be used to advance the broader health equity agenda. Measures such as BP and A1C control and timely follow-up care are disparity-sensitive measures and can provide a more nuanced understanding of gaps in care for vulnerable populations if performance is stratified by race/ethnicity and socioeconomic factors. Disparities can be found in the majority of the proposed quality measures.

[30] https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf
[31] https://smhs.gwu.edu/rodhaminstitute/sites/rodhaminstitute/files/HCReform%20-%20Disparities%20Report.pdf

- After adjustment for all factors, black patients had a higher risk of readmission compared with white patients.[32]
- Findings from a cross-sectional study, *Comparison of All-Cause Mortality Rates and Inequities Between Black and White Populations Across the 30 Most Populous US Cities* suggest that mortality in the US is associated with one's skin color and city of residence.[33]
- There are well-documented racial disparities in hypertension morbidity and mortality, with African Americans faring worse than other racial and ethnic groups in the US. Although several risk factors have been associated with hypertension, they do not appear to fully explain the racial differences.[34]
- In one study, *Disparities in HbA1C Levels Between African-American and Non-Hispanic White Adults with Diabetes*, higher A1C levels were observed for African-American patients vs white adults with diabetes. The cause of the disparity in glucose control is multifactorial.[35]
- Research shows that men, adults age 75+, minorities (Hispanic, Black, and Asian), adults receiving a high school diploma or less, and those who are uninsured are less likely to have been assessed for depression.[36]

Rewarding Quality Improvement for Disadvantaged Populations

To incent improvements that will address health inequities, we recommend deriving the quality improvement scores with a methodology that provides greater weight to improvements achieved for disadvantaged populations. Disadvantaged populations would be defined by available race, ethnicity and socio-demographic factors. Although disparities have been proven to be prevalent for certain of the proposed measures in particular, we recommend that all 14 quality improvement metrics be measured with a more significant weight placed on improvements for the disadvantaged population.

Providers should be rewarded for reporting race and ethnicity data as well as certain socio-demographic information such as those represented by Z codes. This can be incented through a pay for reporting program throughout performance periods 1 and 2.

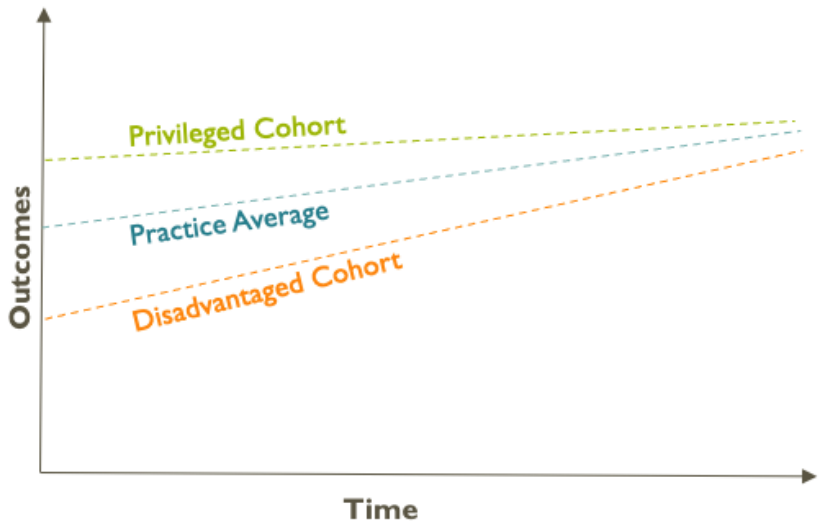
[32] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2752820
[33]https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2775299
[34]https://www.ahajournals.org/doi/10.1161/HYPERTENSIONAHA.119.14492
[35] https://care.diabetesjournals.org/content/29/9/2130
[36]https://www.jabfm.org/content/31/3/389

Figure 18: Example socio-economic factors for reporting

Z-Code	Description
Z55	Problems related to education and literacy
Z56	Problems related to employment and unemployment
Z57	Occupational exposure to risk factors
Z59	Problems related to housing and economic circumstances
Z60	Problems related to social environment
Z62	Problems related to upbringing
Z63	Other problems related to primary support group
Z64	Problems related to certain psychosocial circumstances
Z65	Problems related to other psychosocial circumstances

Beginning in performance period 3, quality improvement over baselines can be measured for the overall population with particular emphasis on the disadvantaged population. We recommend beginning in performance period 3 to use available race, ethnicity and socio-demographic information to segment populations into disadvantaged vs. non-disadvantaged populations and overweight changes in performance for the disadvantaged group in a composite measure.[37]

Illustration of how differences between advantaged and disadvantaged cohorts close over time



[37] "Will Pay-For-Performance And Quality Reporting Affect Health Care Disparities?" Health Affairs, https://doi.org/10.1377/hlthaff.26.3.w405

Since performance specific to improving quality for disadvantaged populations will be measured beginning in performance year 3, data from performance years 1 and 2, and/or prior years to the extent the race, ethnicity and socio-demographic information is available, can provide the baseline against which performance years 3, 4 and 5 will be measured. Patient cohorts can be designated based on race and ethnicity and on the presence or absence of major socio-economic factors. The quality outcomes can be derived within each cohort and comparisons within each cohort made between the performance year and the baseline. The overall improvement can be derived by placing greater weight on the change in the disadvantaged cohort. To the extent that more significant improvements are achieved for the disadvantaged cohort, this will be reflected in the final improvement score. Alternatively, lesser improvement in scores for the disadvantaged cohort will result in a disproportionately lower improvement outcome. By placing greater emphasis on improvements for disadvantaged populations, providers will have an incentive to make strides in improving outcomes for this population, thereby impacting health equity.

Model Evaluation

Program Evaluation	
Evaluate performance by type of treatment and by type of participant	Analyze program outcomes by clinical condition category (e.g., Orthopedics, Cardiology, Gastrointestinal) and by type of participant subgroup. Example participant subgroups: ● SCE only ● PCP ACO ● Health system/PGP ACO
Measure Success based on Gross Savings	Use Gross Savings, rather than Net Savings, as one factor to consider in assessing future promise.
Mandatory Geographies for Evaluation	MedPAC has recognized that one way to account for measuring model success across geographies may be to randomly assign providers to treatment and control groups. This will reduce the regional differences in health care spending and may enable target prices to be set regionally with only the differences in the production costs of workforce and labor (e.g. salary and wages) to account for cost variation.
Hold Providers accountable for Health Outcomes and Quality	Holding providers accountable for health outcomes decreases the incentive for withholding appropriate care as a mechanism to improve financial performance, which could occur under capitation. Models should be evaluated against standardized and relevant metrics that demonstrate achievement in stated cost and quality goals. These metrics should consider: ● Quality of care from a patient's perspective. ● Optimal utilization of resources - not just lower costs of care, but the optimal incorporation of costs which contribute to better care, particularly care that contributes to patient value. ● A reduction in adverse events and preventable harms (e.g. hospital readmissions, procedure complications, patient discharge to skilled nursing facilities), as success in reducing adverse events will translate into better resource optimization.

Legal Considerations

Legal Considerations	
Contractual vs. Regulatory Model	While the Innovation Center could establish the Medicare Specialty Care Bundles program via a Final Rule, a key lesson of the BPCI and BPCIA program has been that a contractual model can encourage participation in a program with sophisticated, robust legal and compliance requirements. To minimize the burden on the Innovation Center to construct the Medicare Specialty Care Bundles program, encourage and ensure collaboration among participants (including relationships between conveners and providers who might otherwise not participate), and to preserve the Innovation Center's flexibility in growing and improving the program, a contractual model should be employed. However, to evaluate the success across geographies and to address underserved areas, one or two mandatory regions should be considered, beginning in performance year two.
Legal Entity. Governance, Leadership & Representation	A key tenet of these recommendations concerning the Medicare Specialty Care Bundles program is flexibility, which in turn will enable the program to engage a wide variety of specialist participants to address a myriad of conditions. In furtherance of those goals, the program should retain the flexibility currently reflected in the BPCIA model, which shall in turn enable conveners to engage with a variety of specialist participants across a spectrum of episodes. This approach should be employed, rather than the mandated minimum levels of provider participation in governance and leadership included in the Global and Professional Direct Contracting and Kidney Care Choices models, which are focused on particular types of healthcare providers. Participants, including conveners, should, however, continue to receive input and support from specialist participants by and through contractually mandated clinical input, particularly with regard to the requisite care redesign plans. Relatedly, beneficiary input should be similarly flexible. Rather than required at the governing body level, participants, including conveners, should be permitted to obtain beneficiary input through an established, publicized mechanism (e.g., web form, email address, telephone number) for beneficiaries or beneficiary advocates to provide such input.

AKS/Stark Waivers/CMP Beneficiary Incentives	To enable the success of the Medicare Specialty Care Bundles program, CMS should continue to issue Model-specific fraud and abuse waivers for financial sharing arrangements among providers or utilize the CMS-Sponsored Model Safe Harbor contained in the Stark and AKS Final Rules. Such CMP/Beneficiary Incentive waivers should continue the broad flexibilities included in the BPCIA program, and should further be expanded to permit participants to provide Medicare covered services and waivers of cost-sharing amounts as beneficiary incentives.
Application Process & Flexibility to Add Participants, Convener, Episodes, etc.	**Enable Participation Semi-Annually**: For the Medicare Specialty Care Bundles program to improve upon and expand the success of the BPCIA program, participant providers must have the ability, on a more frequent basis, to join the program, add clinical episodes, and add financial sharing partners. At a minimum, these opportunities, particularly the opportunity to add financial sharing partners, should occur semi-annually (i.e., every six months). Provided, however, that in participating in the program, a Specialist Contracting Entity should participate in (i.e., elect risk for) all clinical episodes within a particular Clinical Condition Category or "CCC." Put more simply, the given CCC episode definition cannot be modified by Specialist Contracting Entity, therefore individual, underlying episodes may not be added or dropped within such CCC. **Early Termination Penalty:** Conveners and Specialists Contracting Entity participants should incur a penalty for dropping out of the program early, when that action could be construed as adverse selection against Medicare. For example, if a SCE has experienced substantial savings and expects those savings to taper off or worse and decides to drop, that would be considered adverse selection for Medicare. In those instances, Conveners or Specialists could forfeit a portion of any shared savings in the final performance period preceding an early termination. This type of penalty would not apply to Conveners or SCEs that drop out after experiencing losses. Overall, this should encourage more sustainable commitment to the program from participants and incentivize participants to continue to improve care delivery and performance across the years, as experience in the BPCI-A and other models has demonstrated that care redesign, and thus the resultant reductions in costs and improvements in quality, tends to increase with time. Beyond encouraging continued care redesign, an early termination penalty would minimize participants dropping out early, seeking to benefit from initial savings but anticipating, rightly or wrongly, that the potential for shared savings may decrease over time (e.g., as a result of price re-basing).

Model Transparency	To promote increased transparency, to facilitate participant compliance, and to encourage additional participation, CMS/the Innovation Center should make all program documents and guidance materials widely available on the Medicare Specialty Care Bundles program website, as opposed to posting materials exclusively to provider portals. In addition, the Specialists Contracting Entities participating in the program should have access to on-going full Part A and Part B claims data for all attributed beneficiaries.
Quality Metrics	As set forth in greater detail in the Quality Section, CMS should assess quality during reconciliation (i.e., prior to issuing shared savings), employing standard, meaningful quality measures that can be assessed on a claims basis, rather than requiring disparate quality measures to flow through every financial sharing arrangement in piecemeal fashion. This permits the program to have standard, meaningful quality measures set by CMS, which in turn also creates consistency, enhances transparency, and encourages participation.