



ACO Primary Care Flex Model

Request for Applications

05/30/2024

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I. Background and Introduction

The ACO Primary Care Flex Model (ACO PC Flex Model) provides an opportunity for the Centers for Medicare & Medicaid Services (CMS) to test new payment mechanisms to support primary care for low revenue Accountable Care Organizations¹ (ACOs) participating in the Medicare Shared Savings Program (Shared Savings Program). These payment arrangements leverage lessons learned from other Medicare ACO initiatives, such as the Shared Savings Program, the Next Generation ACO (NGACO) and ACO Realizing Equity, Access, and Community Health (ACO REACH) Models as well as advanced primary care models such as Comprehensive Primary Care Plus and Primary Care First. The ACO PC Flex Model seeks to reduce program expenditures and improve quality of care and health care outcomes for Medicare beneficiaries through the alignment of financial incentives for primary care, an emphasis on flexibility and primary care innovation, and strong monitoring to ensure that beneficiaries receive access to high-quality, personcentered primary care. This model is part of a strategy by the CMS Center for Medicare and Medicaid Innovation (the CMS Innovation Center) to use the redesign of primary care as a platform to drive broader health care delivery system reform. The model provides more flexibility in the use of funds for primary care providers (defined in Appendix A), increases resources for primary care, and strengthens incentives for organizations to participate in ACOs, the Shared Savings Program, or both. This includes, for example, newly formed low revenue ACOs and ACOs that include federally qualified health centers (FQHCs) or rural health clinics (RHCs) as ACO participants.

The ACO PC Flex Model is a 5-year voluntary primary care payment model that will be tested within the Shared Savings Program beginning January 1, 2025. ACOs that participate in the ACO PC Flex Model (PC Flex ACOs) will jointly participate in the Shared Savings Program. The model will test whether alternative payment for primary care services will empower ACOs participating in the Shared Savings Program and their primary care providers to use more innovative, team-based, person-centered, and proactive approaches to care that positively impacts health care outcomes, quality, and costs of care.

The ACO PC Flex Model is designed to help realize the National Academies of Sciences, Engineering, and Medicine's (NASEM) vision of advanced, high-quality primary care—"whole person, integrated, accessible, and equitable health care by interprofessional teams who are accountable for addressing the majority of an individual's health and wellness needs across settings and through sustained relationships with patients, families, and communities." Specifically, the ACO PC Flex Model will test if prospective primary care payments (PPCP) that are, on average, greater than historical primary care payments will:

- Improve individuals' experience and access to care while supporting primary care to deliver on key outcomes;
- Grow participation in the Shared Savings Program to reach CMS' accountable care goal of placing 100% of Medicare beneficiaries in an accountable care relationship by 2030;
- Reduce disparities in health care outcomes and access to primary care;
- Lower costs while enhancing quality of care for individuals in the Shared Savings Program; and
- Empower PC Flex ACOs and their providers to use innovative care delivery approaches that are

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¹ Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to the Medicare patients they serve as defined at 42 C.F.R. § 425.20.

² National Academies of Sciences, Engineering, and Medicine (NASEM); Robinson, S. K., Meisnere, M., Phillips, R. L., Jr., & McCauley, L. (Eds.). (2021). Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/34251766/.

team-based, person-centered and proactive – rather than visit-driven – to improve health care outcomes and quality of care.

The model will focus on and invest in low revenue ACOs, which are usually ACOs that are mainly made up of physicians, tend to be smaller, and may include a small hospital or serve rural areas. Only low revenue ACOs as defined by Shared Savings Program regulations³ will be eligible to participate in the ACO PC Flex Model. See section III.B Applicant Eligibility for more details. Low revenue ACOs have historically performed better than high revenue ACOs in the Shared Savings Program, demonstrating more savings and stronger potential to improve the quality and efficiency of care delivery. The Congressional Budget Office recently reported that ACOs with a larger proportion of primary care providers, or those led by an independent physician group rather than a hospital, achieved greater savings in the Shared Savings Program.⁴ In comparison to high revenue ACOs, low revenue ACOs often face greater financial challenges, dedicating a significant portion of their revenue to cross-subsidize the costs of more comprehensive primary care because they tend to have fewer resources and have greater difficulty assuming higher levels of financial risk.

The ACO PC Flex Model will provide new payment mechanisms for low revenue ACOs participating in the Shared Savings Program. Specifically, it includes a one-time Advance Shared Savings Payment to help cover costs associated with forming an ACO (where relevant) and administrative costs for model activities. It also includes the PPCP which are monthly prospective, population-based payments. ACOs will distribute the PPCP to primary care providers in the PC Flex ACO. In doing so, PC Flex ACOs will be encouraged to move away from fee-for-service, visit-based payment approaches in their payment arrangements with PC Flex ACO Participants towards population-based mechanisms, such as capitation. CMS will assess the PC Flex ACO's payment mechanisms with primary care providers during the application process as well as during model implementation. As part of the ACO PC Flex Model application process, applicant ACOs will be asked questions specific to their proposed implementation of the model payment mechanisms. CMS will also assess the degree to which an applicant ACO promotes the model goals of enhancing the predictability, amount of funding, and flexibility for participating primary care providers. Routine reporting, monitoring and compliance activities will be conducted related to the use of the PPCP. Details can be found in section V. Monitoring and Oversight.

II. **Statutory Authority**

A. General Authority to Test Model

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

Section 1115A(b)(2) provides a non-exhaustive list of examples of models that the Secretary may select to test, which includes models under which the CMS Innovation Center contracts directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment (see section 1115A(b)(2)(B)(ii) of the Act); and models

³ 42 C.F.R. § 425.20.

⁴ Congressional Budget Office. (2024). Medicare Accountable Care Organizations: Past Performance and Future Directions. https://www.cbo.gov/system/files/2024-04/59879-Medicare-ACOs.pdf.

under which the CMS Innovation Center promotes care coordination between providers of services and suppliers that transition health providers away from fee-for-service based payment and toward salary-based payment (see section 1115A(b)(2)(B)(iv) of the Act).

Consistent with the Medicare ACO Track 1+ Model, the ACO Investment Model (AIM) and the Advanced Payment (AP) ACO Model, CMS will test the ACO PC Flex Model in accordance with the authority granted to the CMS Innovation Center under section 1115A of the Act with Shared Savings Program ACOs. Testing this model within the Shared Savings Program advances CMS' vision for ACOs and larger strategy of testing payment and service delivery models within the framework of the Shared Savings Program where possible to better harmonize policies across Medicare ACO initiatives and more easily and rapidly scale relevant findings. Unless stated otherwise in the model's governing documents, the Shared Savings Program regulations⁵ and guidance issued by CMS will be applicable to PC Flex ACOs.

B. Authority to Waive Medicare Program Requirements

Section 1115A(d)(1) of the Act authorizes the Secretary to waive the requirements of Title XVIII of the Act as may be necessary solely for purposes of carrying out the testing by the CMS Innovation Center of an innovative payment and service delivery model, including the ACO PC Flex Model.

C. Waiver and Safe Harbor Authority

The ACO PC Flex Model is authorized by section 1115A of the Act. Under section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b).

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

In addition to or in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, CMS may determine that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives⁶ is available to protect remuneration exchanged pursuant to certain financial arrangements or patient incentives permitted under ACO PC Flex Model participation documentation. No such determination is being issued in this document. Such determination, if any, would be set forth in documentation separately issued by CMS.

CMS may waive certain Shared Savings Program payment rules or other Medicare requirements as determined necessary to make payments under the ACO PC Flex Model.

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⁵ 42 C.F.R. § 425.

^{6 42} C.F.R. § 1001.952(ii).

At this time, CMS is not planning to add waivers to Medicare program requirements, fraud and abuse provisions, or safe harbor authority for the ACO PC Flex Model beyond the waivers permitted under the Shared Savings Program⁷ or final waivers in connection with the Shared Savings Program.⁸

III. Scope and General Approach

A. Model Performance Period

The ACO PC Flex Model will be tested over five performance years, from January 2025 – December 2029. All performance years will occur in the calendar years of 2025, 2026, 2027, 2028, and 2029, respectively. A Shared Savings Program ACO participating in the ACO PC Flex Model will start a new Shared Savings Program agreement period (see section III.D. Application Process) and will have a new participation agreement for the performance years January 2025 through December 2029. In addition, the ACO will have a separate ACO PC Flex Participation Agreement for performance years January 2025 through December 2029. This RFA is for applications for ACOs to begin participation in the ACO PC Flex Model on January 1, 2025.

B. Applicant Eligibility

An ACO is eligible to participate in the ACO PC Flex Model if CMS determines that all of the following criteria are met:

- Shared Savings Program eligibility: CMS has determined that the ACO is eligible to participate in
 the Shared Savings Program.⁹ Details on the regulations governing the Shared Savings Program,
 including changes to the regulations, are specified in Federal Register publications that can be
 accessed through the <u>Program Statutes & Regulations webpage</u> of the Shared Savings Program
 website.
- 2. Revenue status: The ACO is a low revenue ACO as defined by the Shared Savings Program. 10
- 3. Program integrity: CMS has determined that a program integrity (PI) review of the ACO or any other relevant individuals or entities associated with the ACO has produced satisfactory results, meaning information found during the PI review does not warrant a denial of model participation for the ACO. See sections V.B. General Monitoring Activities and VIII. Application Review, Scoring and Selection for more information.
- 4. **Participation in other shared savings initiatives:** An ACO does not receive prepayments of shared savings, such as advance investment payments under the Shared Savings Program, or simultaneously participate in another Medicare initiative that involves shared savings payments. See section III. E Program Overlaps and Synergies for more information on model overlaps.
- 5. **Ability to repay:** The ACO has the ability to repay amounts for which it may be liable under the ACO PC Flex Model, as demonstrated through the establishment of a repayment mechanism for the model. This requirement is distinct from repayment requirements under the Shared Savings Program regulations. See section III.I. Repayment Mechanism for more information.

A determination regarding whether an ACO is eligible to participate in the ACO PC Flex Model will be made

⁷ 42 C.F.R. § 425.612.

^{8 80} FR 66745.

⁹ 42 C.F.R. § 425 Subpart B.

¹⁰ 42 C.F.R. § 425.20.

based in part on data from the ACO's Shared Savings Program application. For example, the high or low revenue designation is determined by CMS from the ACO participant list submitted by the ACO during phase 1 of the Shared Savings Program application. The Shared Savings Program provides revenue determinations to ACOs in the ACO Management System (ACO-MS) with the release of each Shared Savings Program phase 1 request for information (RFI; RFI-1 and RFI-2) and during the Shared Savings Program phase 1 final dispositions on October 17, 2024. Eligibility for the ACO PC Flex Model will be based on final revenue determinations provided by CMS during phase 1 final dispositions. Applicant ACOs that are determined to be high revenue during the Shared Savings Program RFI-1 or RFI-2 but meet all other ACO PC Flex Model eligibility criteria will be considered eligible for the ACO PC Flex Model until final revenue determinations are communicated by CMS.

C. Participation Requirements

CMS will evaluate an applicant ACO's application to determine whether the applicant ACO is eligible to participate in the model based on the eligibility criteria outlined in section III.B. above. A PC Flex ACO must adhere to the following participation requirements for the duration of their participation in the model:

- 1. **Shared Savings Program participation:** A PC Flex ACO must adhere to Shared Savings Program participation requirements;¹¹
- 2. **ACO PC Flex Model eligibility criteria:** A PC Flex ACO must continue to meet the eligibility criteria outlined in section III.B. Applicant Eligibility;
- 3. **Model Participation Agreement:** A PC Flex ACO must enter into an ACO PC Flex Participation Agreement with CMS for a period of not less than 5 years; and
- 4. **Required reporting:** A PC Flex ACO must submit information, inclusive of Spend Plan data, data necessary for quality reporting, and data requirements for model monitoring activities (as outlined in section <u>V.B. General Monitoring Activities</u>) in the form and manner required by CMS for each performance year of the agreement period.

CMS will monitor a PC Flex ACO annually for changes that may cause the PC Flex ACO to no longer meet the model eligibility or participation requirements and will take any appropriate action CMS deems necessary, including termination of the ACO PC Flex Participation Agreement. For example, during the annual change request cycle for the Shared Savings Program, ACOs may modify their Shared Savings Program ACO participant list by adding or deleting ACO participants. If CMS determines that a PC Flex ACO has a change in revenue status due to changes made during the Shared Savings Program annual change request cycle and meets the definition of a high revenue ACO during any performance year, CMS will cease paying PPCP no later than the quarter after the PC Flex ACO became ineligible and may take compliance action. Compliance action will be further described in the ACO PC Flex Participation Agreement.

Provider Participation

Participation in the ACO PC Flex Model is at the ACO level. Consistent with Shared Savings Program requirements, ¹² a PC Flex ACO may add ACO participants vetted through the CMS screening process effective on January 1 of the following performance year and remove PC Flex ACO Participants no later than 30 days after the termination of their ACO participant agreement. The PC Flex ACO must submit changes in the form and manner and according to the timeline established by CMS annually. For more information see the Shared Savings Program ACO Participant List and Participant Agreement Guidance.

¹¹ 42 C.F.R. § 425 Subpart C.

^{12 42} C.F.R. § 425.118.

Consistent with the Shared Savings Program requirements for "whole TIN" participation, PC Flex ACOs cannot select which ACO participants or ACO professionals participate in the ACO PC Flex Model. The ACO PC Flex Model fee reductions for primary care services (see section IV.D. Fee Reductions) will apply to each PC Flex ACO Participant that includes a primary care provider. CMS will identify for fee reduction the PC Flex ACO Participants and their primary care providers based on the ACO participant list submitted as part of the ACO's Shared Savings Program application. To apply fee reductions, CMS will identify the TIN and CCN (if applicable) of each PC Flex ACO Participant and National Provider Identifiers (NPI) of each eligible primary care provider, such that CMS understands each primary care provider as a TIN/NPI combination.

A PC Flex ACO will be subject to the Shared Savings Program exclusivity rule.¹³ Any Shared Savings Program ACO participant that bills Medicare for primary care services used in assignment must be exclusive to a single Shared Savings Program ACO, and thus to a single PC Flex ACO. However, individual primary care providers, identified by individual NPIs, may participate in multiple ACOs if they bill under different TINs.

D. Application Process

Application Procedure

To apply to the ACO PC Flex Model, an applicant ACO must first apply to the Shared Savings Program. This includes applicant ACOs applying to participate in the Shared Savings Program as initial applicant ACOs or re-entering applicant ACOs, and ACOs applying to enter a new participation agreement for the Shared Savings Program as renewal applicant ACOs or early renewal applicant ACOs. For example, an ACO that is currently participating in the Shared Savings Program and is interested in also participating in the ACO PC Flex Model must apply to the Shared Savings Program as an early renewal/renewal applicant ACO and begin a new Shared Savings Program agreement period. Shared Savings Program applications are open May 20, 2024 - June 17, 2024. The Shared Savings Program Application Reference Manual provides guidance to help ACOs complete the Shared Savings Program application. For more detailed information and sample applications, review the additional resources and guidance available in the application toolkit. In addition to the reference manual, please refer to the Shared Savings Program's regulations¹⁴ and discussions in the previous rulemaking of the program requirements.

In addition to submitting an application to participate in the Shared Savings Program, an applicant ACO must submit supplemental ACO PC Flex Model application information. An ACO can indicate interest in receiving details regarding the supplemental ACO PC Flex Model application information via email by selecting "yes" on the relevant question in their Shared Savings Program application but doing so is not required to apply to the ACO PC Flex Model.

Submission of supplemental ACO PC Flex Model application information will consist of three phases, the phase 1 application submission period, phase 2 application submission period, and the final submission period. See Table 1 below for a summary of the application timeline.

CMS will offer one application cycle for the ACO PC Flex Model.

Application Contents and Review

An applicant ACO must submit supplemental application information sufficient for CMS to determine

¹³ 42 C.F.R. § 425.306.

¹⁴ 42 C.F.R. Part 425.

whether the applicant ACO is eligible to participate and likely to succeed in the ACO PC Flex Model. See section <u>VIII. Application Review, Scoring and Selection</u> for more information. Key components of the model supplemental application information include:

- 1. **ACO PC Flex Model application questionnaire:** To complete the ACO PC Flex Model application questionnaire, an existing or applicant Shared Savings Program ACO can navigate to https://app.innovation.cms.gov/PCFlex. The questionnaire is available in Appendix B.
- 2. **Spend Plan:** The applicant ACO must submit a proposed Spend Plan that specifies how the applicant ACO intends to spend the PPCP and Advance Shared Savings Payment in the performance year. See section V.A. Allowable Uses of PPCP, Reporting, and Monitoring.
- 3. **Roster of Non-Physician Practitioner data (NPP):** Applicant ACOs must submit a roster that includes each ACO professional by NPI who is an NPP (NPPs include nurse practitioners (NP), physician assistants (PA), clinical nurse specialists (CNS)) designating each as "primary care" or "specialty care." See section D.ii. Claims payments excluded from Prospective Primary Care Payments.
- 4. **Assurance of ability to repay:** The applicant ACO must secure a repayment mechanism to ensure CMS is able to recoup amounts owed to CMS under the ACO PC Flex Model. This repayment mechanism is separate from and in addition to repayment requirements under the Shared Savings Program regulations. The applicant ACO must submit draft and final repayment mechanism documentation for CMS review and approval. See section III.I. Repayment Mechanism for more information.

PC Flex ACOs will be required to comply with rigorous safeguards that will be specified in the ACO PC Flex Participation Agreement. PC Flex ACOs will be required to complete additional actions as part of the ACO PC Flex Participation Agreement signing event and final submission period from December 6, 2024 – December 12, 2024. For example, under the terms of the ACO PC Flex Participation Agreement, a PC Flex ACO will be required to establish fee reduction agreements with each of its PC Flex ACO Participants (i.e., their billing taxpayer identification numbers (TINs) or CMS certification numbers (CCNs)) that include a primary care provider. Each fee reduction agreement must expressly state that the PC Flex ACO Participant agrees to reductions to their fee-for-service payments for primary care services under the ACO PC Flex Model. See section IV.D. Fee Reductions for additional information. A full list of additional actions will be provided to applicant ACOs during the phase 1 final disposition on October 17, 2024.

i. Phase 1 Application Submission Period

ACO PC Flex Model application questionnaires must be submitted during the phase 1 application submission period from May 30, 2024 – August 1, 2024. An applicant ACO may apply to the ACO PC Flex Model without impact to their Shared Savings Program application. For example, an applicant ACO may choose to withdraw their consideration for the ACO PC Flex Model without impacting their overall Shared Savings Program application. Similarly, an applicant ACO that is not selected to participate in the ACO PC Flex Model may choose to either complete or withdraw their Shared Savings Program application. ¹⁵ See the next section for more information on withdrawal of an ACO PC Flex Model application.

CMS will estimate an applicant ACO's PPCP amount and repayment mechanism amount using Shared

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¹⁵ An applicant ACO will be notified whether CMS has selected them for participation in the ACO PC Flex Model during the phase 1 final disposition on October 17, 2024. Final application dispositions for the Shared Savings Program are communicated on December 5, 2024.

Savings Program beneficiary assignment estimates¹⁶ and other relevant data. CMS anticipates this information will be provided to applicant ACOs as a report prior to phase 1 final dispositions on October 17, 2024. More information on payment calculations and the payment schedule can be found in section IV. Model Design Elements. All payment amounts, calculations, and schedules, including repayment mechanism amounts, provided during the application process are estimates, should not be considered final, and may be subject to change.

ACO Application Disclosure Requirements

To support the model program integrity review (see section VIII. Application Review, Scoring and Selection), an applicant ACO will be required to disclose as part of their ACO PC Flex Model application questionnaire the following with respect to the applicant ACO, Persons With An Ownership Or Control Interest in the applicant ACO, Key Executives, equity partners, and individuals and entities the ACO applicant expects to be PC Flex ACO Participants: (1) any sanctions or corrective action plans imposed under Medicare, Medicaid, or state licensure authorities within the last five years (including corporate integrity agreements); (2) any fraud investigations initiated, conducted, or resolved within the last five years; (3) any outstanding Federal debts, including debts owed to Federal healthcare programs and any debts owed under a CMS model or to any agency of the federal government; (4) any awards of a CMS contract in the past five years, and, if applicable, the contract number and period of performance for such award; (5) whether any such individuals or entities are on a government suspension, debarment, or exclusion list relating to procurement and non-procurements; (6) any instances of criminal conduct; and (7) any bankruptcy filings. An ACO will be required to notify CMS of any changes to these disclosures. This screen will occur annually thereafter and at the time of any change in the PC Flex ACO's organizational structure (e.g. merger, acquisition). See section V.B. General Monitoring Activities section VIII. Application Review, Scoring and Selection and Appendix B for more information.

ii. Phase 1 Final Dispositions and Phase 2 Application

An applicant ACO will be notified whether CMS has selected them for participation in the ACO PC Flex Model during the phase 1 final disposition on October 17, 2024. The model's phase 1 final disposition will align with the Shared Savings Program phase 1 final disposition, which includes the advance investment payments eligibility final disposition. CMS anticipates that monthly payment estimates and final repayment mechanism amounts will also be released during the phase 1 final disposition for the model.

Phase 2 of the application will begin on October 18, 2024 and will include the phase 2 application submission period from October 18, 2024 – October 29, 2024 and the phase 2 request for information period from November 8, 2024 – November 18, 2024.

iii. Phase 2 Application Submission Period

If an applicant ACO is selected to participate in the model, a participation question will be available in their ACO PC Flex application portal during the phase 2 application submission period from October 18, 2024 –

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¹⁶ The approach used to produce the assignment estimates will generally overestimate an ACO's assigned beneficiary population. The overestimation occurs because there are limitations to assignment estimates that do not allow CMS to reflect all the beneficiary eligibility and exclusion criteria that are incorporated into the assignment methodology used for operational purposes. An ACO's assigned beneficiary population can be affected by several factors including: changes to the ACO's participant list, Changes to other ACOs' participant lists or selected assignment methodology. See the Shared Savings Program Application Manual for more details: https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/ssp-application-reference-manual.pdf.

October 29, 2024. Only selected applicant ACOs will see this participation question. An applicant ACO that wishes to participate in the model should answer "yes" to the participation question. An applicant ACO that does not wish to participate in the model should answer "no" to the participation question. If the applicant ACO does not respond to the participation question by the end of the phase 2 application submission period on October 29, 2024, CMS will interpret the non-response as declining to participate in the model.

An applicant ACO that answers "yes" to the participation question during the phase 2 application submission period must submit additional materials, listed below. An applicant ACO may begin submitting these materials on October 18, 2024. Required materials and their associated due dates include:

- 1. **Spend Plan:** Due October 29, 2024 (the end of the Phase 2 application submission period). See section <u>V.A. Allowable Uses of PPCP</u>, <u>Reporting</u>, <u>and Monitoring</u> and section <u>V.A.iv</u>. <u>Spend Plan Reporting and Monitoring</u> for more information.
- 2. **NPP Roster:** Due October 29, 2024 (the end of the Phase 2 application submission period). See section D.ii. Claims payments excluded from Prospective Primary Care Payments.
- 3. **Draft Repayment Mechanism Documentation:** Due November 18, 2024 (the end of the Phase 2 request for information period). See section III.1. Repayment Mechanism for more information.
- 4. **Final Repayment Mechanism Documentation:** Due December 12, 2024 (the end of the final submission period). See section III.I. Repayment Mechanism for more information.

An applicant ACO that answers "yes" to the participation question must submit a Spend Plan and NPP roster during the phase 2 application submission period. The Spend Plan must specify how the applicant ACO intends to spend the PPCP and Advance Shared Savings Payment in the performance year. Guidance on Spend Plan reporting will become available on the <u>model website</u> before or at the time of the phase 1 final dispositions. The NPP roster must designate each ACO professional by NPI who is a NPP as a "primary care" NPP or a "specialty care" NPP. If an applicant ACO fails to submit a Spend Plan or NPP roster by the end of the phase 2 submission period on October 29, 2024, the applicant ACO will have one opportunity to correct any deficiency as part of the phase 2 request for information period. If the applicant ACO fails to submit the Spend Plan or the NPP roster by the end of the phase 2 request for information period on November 18, 2024, CMS will interpret the omission as the applicant ACO declining to participate in the model and CMS will remove the applicant ACO's application from consideration for the model.

iv. Phase 2 Request for Information Period

During the RFI period from November 8, 2024 – November 18, 2024, CMS will review the phase 2 application submission and make supplemental requests for information necessary to complete the phase 1 and 2 applications. During this period an applicant ACO will receive a notification summarizing CMS' review of the submitted information along with a request for information. The applicant ACO should carefully review any request sent by CMS because it will have only one opportunity to correct any deficiencies identified in previously submitted application materials. If an applicant ACO has not submitted draft documentation of the applicant ACO's compliance with the model repayment mechanism (see section III.I. Repayment Mechanism), Spend Plan or the NPP roster (See section D.ii. Claims payments excluded from Prospective Primary Care Payments), the RFI will include a request to submit these materials by the close of the phase 2 request for information period on November 18, 2024. Guidance on ACO PC Flex Model repayment mechanism arrangements will become available on the model website at the time of the phase 1 final dispositions.

v. Final Application Dispositions, Signing Event, and Final Submission Period

The final application disposition for the model will be communicated on December 5, 2024. During the signing event from December 6, 2024 – December 12, 2024, an applicant ACO must review, certify, and electronically sign required documents. An applicant ACO must also submit final documentation of their compliance with the model repayment mechanism. Once the signature period for ACOs to sign all required documents ends, CMS will countersign certain required documents related to applicant ACOs' participation in the ACO PC Flex Model. Applicant ACOs will receive an email notification once CMS countersigns their documents. This notification is the final step of the ACO signing event and final submission period. A summary of key application period dates is listed in the table below.

Table 1. List of Key Application Dates for the ACO PC Flex Model

ACO PC FLEX MODEL KEY APPLICATION DATES	DETAILS	
PHASE 1 APPLICATION SUBMISSION PERIOD MAY 30, 2024 – AUGUST 1, 2024	ACO will submit an ACO PC Flex Model application questionnaire.	
PHASE 1 FINAL DISPOSITIONS OCTOBER 17, 2024	ACO will receive ACO PC Flex Model application phase 1 dispositions. Aligns with Shared Savings Program phase 1 final dispositions.	
PHASE 2 APPLICATION SUBMISSION PERIOD OCTOBER 18, 2024 – OCTOBER 29, 2024	ACO will submit their Spend Plan and NPP roster. Aligns with Shared Savings Program phase 2 submission period.	
PHASE 2 REQUEST FOR INFORMATION PERIOD NOVEMBER 8, 2024 – NOVEMBER 18, 2024	ACO will submit their draft ACO PC Flex Model repayment mechanism documentation. ACOs will receive requests to correct any deficiencies identified by CMS on earlier application elements. Aligns with Shared Savings Program phase 2 RFI.	
FINAL APPLICATION DISPOSITIONS DECEMBER 5, 2024	ACO will receive ACO PC Flex Model final application dispositions. Aligns with Shared Savings Program final application dispositions.	
SIGNING EVENT AND FINAL SUBMISSION PERIOD DECEMBER 6, 2024 – DECEMBER 12, 2024	ACO will submit ACO PC Flex Model final repayment mechanism amount documentation. ACO will review, certify, and electronically sign required documents. Aligns with Shared Savings Program ACO signing event.	

vi. Withdrawal of ACO PC Flex Model Application

An applicant ACO may withdraw its ACO PC Flex Model application from consideration at any time prior to signing the ACO PC Flex Participation Agreement with CMS during the signing event from December 6, 2024 – December 12, 2024. ACO PC Flex Model application questionnaires that are not submitted prior to August 1, 2024 will be considered incomplete and will not be considered for participation in the model.

An applicant ACO can withdraw their ACO PC Flex Model application by submitting an electronic withdrawal request to CMS via the ACO PC Flex Model mailbox, <u>ACOPCFlex@CMS.HHS.GOV</u>. The request must be submitted as a PDF on the organization's letterhead and signed by an official authorized to act on behalf of the organization. It should include the applicant ACO's legal name; the ACO's primary point of contact; the full address of the organization; and a description of the reason for the withdrawal.

Applicant ACOs can choose to withdraw their ACO PC Flex Model applications without impacting their Shared Savings Program application. A currently participating Shared Savings Program ACO in an existing Shared Savings Program agreement period that applies to and subsequently withdraws its ACO PC Flex Model application may either complete or withdraw its Shared Savings Program application. Applicant ACOs that are also early renewal applicant ACOs can withdraw their early renewal Shared Savings Program application and return to their current Shared Savings Program agreement period. Additional information on withdrawing a Shared Savings Program application is available in the Shared Savings Program Application Reference Manual.

E. Program Overlaps and Synergies

In general, during an ACO PC Flex Model performance year, PC Flex ACO Participants and their primary care providers may not simultaneously participate in another model tested or expanded under section 1115A of the Act that involves shared savings, or any other Medicare initiative that involves shared savings unless otherwise permitted by CMS. In addition, overlap is prohibited with certain programs that are not Shared Savings initiatives but feature similar payment structures to the ACO PC Flex Model.

CMS may issue guidance that assists ACOs in determining how participation in certain demonstrations or models can be combined with participation in the ACO PC Flex Model, and whether a beneficiary may be assigned to more than one initiative and, in such cases, whether there is any adjustment made to account for the potential overlap at financial settlement. These overlap policies may be adjusted by CMS if or when CMS makes changes to existing models/initiatives or implements new models/initiatives. Additional details can be found in Appendix C.

CMS Initiatives that Include Prepayments of Shared Savings

A PC Flex ACO may not simultaneously receive prepayments of shared savings, such as advance investment payments under the Shared Savings Program. If an ACO began a new agreement period in 2024 to start advance investment payments but wants to participate in the ACO PC Flex Model beginning in 2025, the ACO must apply to enter into a new agreement period beginning in 2025. The ACO would not receive advance investment payments beginning in 2025 if they agree to participate in the ACO PC Flex Model. An ACO that terminates its Shared Savings Program participation agreement during the agreement period in which it received an advance investment payment must repay all advance investment payments it received, consistent with the Shared Savings Program rules for recoupment and recovery of advance investment payments.¹⁷

CMS Innovation Center Shared Savings Initiatives and Other Prohibited Overlaps

Innovation Center models in which participation by a PC Flex ACO is prohibited due to overlap with the ACO PC Flex model include:

• ACO Realizing Equity, Access, and Community Health (REACH) Model (both ACO REACH Participant

¹⁷ 42 C.F.R. § 425.630(g).

Providers and Preferred Providers cannot overlap with the ACO PC Flex Model)

- Vermont All-Payer ACO Model
- Making Care Primary (MCP) Model
- All-Payer Health Equity Advancement and Development (AHEAD) Model
- Primary Care First Model
- Independence at Home demonstration
- Maryland Primary Care Program
- Kidney Care Choices Model (KCC)

CMS Innovation Center Non-Shared Savings Initiatives and Other Allowed Overlaps

PC Flex ACOs may participate in other CMS Innovation Center initiatives that do not involve Shared Savings. These include:

- Bundled Payments for Care Improvement (BPCI) Advanced Model;
- Enhancing Oncology Model (EOM);
- End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model;
- Financial Alignment Initiative for Medicare-Medicaid Enrollees; and
- Guiding an Improved Dementia Experience (GUIDE) Model (scheduled to begin July 1, 2024).

F. Advanced APM Determination

The BASIC track Level E and the ENHANCED track of the Shared Savings Program meet the criteria to be Advanced Alternative Payment Models (APMs) under the model for performance year 2025, and CMS anticipates they will continue to meet such criteria for all subsequent performance years, subject to annual Advanced APM determinations. Advanced APM status in the ACO PC Flex Model will be consistent with CMS' Advanced APM determination for each Shared Savings Program risk track, where CMS has determined that Level E of the BASIC track and the ENHANCED track are Advanced APMs for performance year 2025. Eligible providers who are included on the participant list participating in the Level E of the BASIC track or the ENHANCED track will be eligible for Qualifying Quality Program (QPP) Participant (QP) determinations.

G. MIPS APM Qualification

Each risk track available in the ACO PC Flex Model is considered a Merit-Based Incentive Payment System (MIPS) APM.¹⁹ Eligible clinicians that do not attain QP status are eligible to be scored in a MIPS APM for that performance year.²⁰ PC Flex ACOs may report the APM Performance Pathway (APP), a MIPS reporting and scoring pathway designed to reduce reporting burden and create new scoring opportunities for MIPS APM participants that are not qualified professionals. More information about the APP and the QPP is available at https://qpp.cms.gov/about/qpp-overview.

H. Focus on Health Equity

The ACO PC Flex Model seeks to improve quality of care and health care outcomes for all assigned beneficiaries. Research shows that certain underserved communities experience worse health care

¹⁹ 42 C.F.R. § 414.1305.

¹⁸ 42 C.F.R. § 414.1410.

²⁰ 42 C.F.R. §§ 414.1317; 414.1367.

outcomes and lower quality of care than the general population.^{21,22,23} To improve the quality of care and outcomes for all assigned beneficiaries, the ACO PC Flex Model will test ways to address these health care inequities.

Equitable care is a key component to achieving high-quality care for Medicare beneficiaries and is therefore critical to the ACO PC Flex Model's success. The ACO PC Flex Model defines the term "equity" as it was defined in the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (Executive Order 13985): "the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American individuals, Asian Americans and Pacific Islanders and other individuals of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals; individuals with disabilities; individuals who live in rural areas; and individuals otherwise adversely affected by persistent poverty or inequality." The term "underserved communities" refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by the list in the definition of "equity."

Equitable care is one of the six domains of health care quality developed by the Institute of Medicine and promoted by the Agency for Healthcare Research and Quality (AHRQ), defined as providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, or socioeconomic status. In line with the CMS Framework for Health Equity 2022-2032, and findings of the NASEM Report on Implementing High Quality Primary Care,²⁴ the ACO PC Flex Model will deliberately address health equity from model design through implementation to reach a diverse group of beneficiaries and to reduce disparities in health care outcomes. The ACO PC Flex Model includes the following equity promoting policies:

- 1. PPCP rate setting methodology;
- 2. PPCP County Enhancement;
- 3. PPCP health equity adjustment;
- 4. PPCP add-on for beneficiaries with FQHC / RHC Focused Care
- 5. Health equity plan requirements;
- 6. Health equity data collection requirement; and
- 7. Health equity questions in application and scoring for health equity experience.

These policies are expected to reduce disparities in health such that those with the greatest needs and least resources receive the care they need. The equity promoting aspects of each of these policies is discussed in

²¹ Fredriksen-Goldsen KI, Hoy-Ellis CP, Muraco A, Goldsen J, Kim H-J. The health and well-being of LGBT older adults: Disparities, risks, and resilience across the life course. The lives of LGBT older adults: Understanding challenges and resilience. Washington, DC, US: American Psychological Association; 2015:25-53.

²²Krahn GL, Walker DK, Correa-De-Araujo R. Persons with disabilities as an unrecognized health disparity population. Am J Public Health. 2015;105 Suppl 2(Suppl 2):S198-S206. doi:10.2105/AJPH.2014.302182.

²³ Douthit N, Kiv S, Dwolatzky T, Biswas S. Exposing some important barriers to health care access in the rural USA. Public Health. 2015;129(6):611-620. doi:10.1016/j.puhe.2015.04.001.

²⁴ National Academies of Sciences, Engineering, and Medicine (NASEM); Robinson, S. K., Meisnere, M., Phillips, R. L., Jr., & McCauley, L. (Eds.). (2021). Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care. National Academies Press (US). https://pubmed.ncbi.nlm.nih.gov/34251766/.

greater detail below. CMS reserves the right to amend the ACO PC Flex Model health equity strategy and related financial methodology, as needed, to account for any relevant changes in the Shared Savings Program's regulations issued as part of future rulemaking.

i. Health Equity Promoting Aspects of the PPCP Rate Setting Methodology

For ACOs serving underserved communities, payments for primary care services that are based on historically observed primary care spending may reflect inequities in access to and the provision of high-quality primary care which may entrench inappropriately low levels of primary care spending. ²⁵ The ACO PC Flex Model will address this problem by using a risk-standardized County Base Rate for primary care, rather than ACO-specific historical spending as the basis for payment. The intent is to pay the same rate for a given beneficiary in a given region, regardless of which PC Flex ACO a beneficiary is assigned to, before social and clinical risk factors are applied, to increase payment for providers that have entrenched patterns of low spending for underserved groups. Risk adjustment will be applied to both the County Base Rate and the Enhanced Amount (see section IV.C.ii.b.. Prospective Primary Care Payment Enhanced Amount below for operationalization of the Enhanced Amount). Risk adjusting the Enhanced Amount aims to ensure the enhancement dollars are allocated according to need and reduces disincentives for PC Flex ACOs to serve complex patients.

ii. Health Equity Promoting Aspects of the PPCP County Enhancement

Where appropriate, the PPCP County Base Rate amount will be increased via a County Enhancement. The County Enhancement is applied at the county level in counties designated as low spending counties (defined in section IV.C.ii.b Prospective Primary Care Payment Enhanced Amount below) relative to standardized spending nationally. The County Enhancement will enhance payment to PC Flex ACOs in counties with historically low levels of primary care spending, evidence of underuse of medical services, and socioeconomic disadvantage. The purpose of the County Enhancement is to reduce geographic variation in primary care utilization nationally by directly increasing county-level funding for primary care in underserved counties. In these counties, historic and current levels of Medicare spending are likely inadequate to deliver advanced primary care and improve the overall health of the population. People who experience social disadvantage may use fewer health care services and have lower spending than others with the same clinical needs. As a result, providers in these counties may lack sufficient resources to improve quality of care or provide support services (e.g., case management) that could otherwise mitigate the adverse impact of social determinants of health (SDOH) on care use and outcomes. A County Enhancement that ensures payment for all PC Flex ACOs is above the historical and current county average can avoid entrenching low levels of primary care spending in these counties.

iii. PPCP Health Equity Adjustment

The PPCP will be adjusted by a per-beneficiary per-month (PBPM) amount based on the PC Flex ACO's mix of beneficiaries living in underserved communities, measured by the ACO PC Flex Model equity scores (see section IV.C.iii.f Beneficiary Enhancements). While the County Enhancement increases primary care funding in entire regions, a beneficiary-specific health equity adjustment incentivizes assignment of underserved

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²⁵ Lewis VA, Spivack S, Murray GF, Rodriguez HP. FQHC designation and safety net patient revenue associated with primary care practice capabilities for access and quality. J Gen Intern Med. 2021;36(10):2922-2928. doi:10.1007/s11606-021-06746-0. ²⁶ McWilliams JM, Weinreb G, Ding L, Ndumele CD, Wallace J. Risk adjustment and promoting health equity in population-based payment: Concepts and evidence. Health Aff (Millwood). 2023 Jan;42(1):105-114. doi: 10.1377/hlthaff.2022.00916.

beneficiaries within such a region.

iv. Health Equity Promoting Aspects of the PPCP Add-On for Beneficiaries with FQHC / RHC Focused Care

The ACO PC Flex Model includes special considerations for RHCs and FQHCs, which are not paid fee-for-service like other primary care providers. A beneficiary level add-on for FQHC / RHC Focused Care is included in the PPCP for beneficiaries who receive the plurality of primary care services based on allowable charges at FQHCs or RHCs. Because the all-inclusive payment rate is different for FQHCs and RHCs, there will be a different primary care PBPM add-on payment for each of these settings to encourage FQHCs and RHCs to participate in the ACO PC Flex Model. The plurality of primary care services is determined by comparing the total Medicare allowed amounts for primary care services during the assignment window billed by the various TINs and CCNs in the PC Flex ACO. If the entity with the greatest allowed amount is an FQHC or an RHC, then the beneficiary is considered to have received the plurality of their primary care services at an FQHC or RHC.

v. Health Equity Plan Requirements

As outlined in the <u>Paving the Way to Health Equity 2015-2021 Report</u>, CMS has piloted agency-wide initiatives such as the <u>CMS Disparities Impact Statement</u>, Medicare SDOH data collection, the <u>Mapping Medicare Disparities Tool</u>, and the <u>CMS Health Equity Awards</u> to promote health equity. PC Flex ACOs will develop and implement a health equity plan based on the CMS Disparities Impact Statement. CMS will provide PC Flex ACOs with a template based on the Disparities Impact Statement to support identification of health disparities,²⁷ defining health equity goals, establishing a health equity strategy, planning for implementing the health equity strategy and monitoring and evaluating progress to achieve health equity for underserved communities.

PC Flex ACOs will submit a health equity plan to CMS in a form and manner, and by a date specified by CMS. In advance of a submission deadline, CMS will provide the PC Flex ACO with a list of components that the PC Flex ACO shall include in its health equity plan and the requirements regarding the content and use of the health equity plan will be described in the ACO PC Flex Participation Agreement. PC Flex ACOs must use the template language provided by CMS to develop their health equity plan. PC Flex ACOs will be required to report to CMS their progress in implementing their health equity plan and achieving their health equity goals, including certain health equity metrics identified by the PC Flex ACO, outcomes resulting from an entity's health equity plan, and updates to an entity's health equity strategy.

vi. Health Equity Data Collection Requirement

Consistent with CMS' commitment to addressing health equity and health disparities, CMS requires current and future value-based payment models collect and utilize self-reported sociodemographic data. The ACO PC Flex Model will include a health equity data reporting (HEDR) requirement,²⁸ which represents a policy initiative that emerged from the 2021 update of the CMS Innovation Center's strategic plan, and derives

²⁷ For disparities and recommended mitigating actions involving protected classes of beneficiaries, ACOs will be required to submit data substantiating the disparity and demonstrating that the data supports the need for protected class-conscious interventions, and that there is no protected class-neutral intervention that will address the disparity.

²⁸ Because HEDR reporting continues to evolve, we will revise as needed, but intend to require either individual or aggregate level data for PC Flex HEDR submission.

from the CMS Framework for Health Equity.²⁹ The HEDR requirement will ensure that important self-reported beneficiary characteristics, including expanded demographic characteristics and health related social needs data that are currently not systematically captured through Medicare enrollment by the Social Security Administration, are captured and submitted by PC Flex ACOs.³⁰

vii. Health Equity Questions in Application and Scoring for Health Equity Experience

CMS has designed the application for the ACO PC Flex Model to encourage participation by ACOs with direct patient care experience (vs. providing supportive services to Medicare healthcare providers) and / or experience furnishing high quality care to underserved communities with identified health care disparities. Research suggests that, historically, access to providers participating in ACOs has not been equally shared across patients of differing backgrounds, with ACOs more likely present in non-rural communities with higher socioeconomic status. ACOs serving high proportions of racial and ethnic minorities tend to perform worse on quality metrics compared to other ACOs.³¹ While this particular research concerns rurality, socioeconomic status, race, and ethnicity, these characteristics are not the only ones that could be considered under the ACO PC Flex Model definition of "underserved communities."

In the ACO PC Flex Model application questionnaire, applicant ACOs will be asked to provide information regarding their experience with (1) providing direct patient care and / or (2) furnishing high-quality care to patients with conditions that are linked to identified health disparities (as outlined in section VIII. Application Review, Scoring, and Selection). While CMS will not determine whether a given applicant ACO is selected for participation in the ACO PC Flex Model based solely on this experience, by attaching discrete points separately to questions relating to each category of experience, CMS hopes to ensure that selected applicant ACOs are well positioned to improve quality outcomes for all assigned beneficiaries, including those in underserved communities.

I. Repayment Mechanism

A PC Flex ACO, regardless of their Shared Savings Program risk track, must repay Other Monies Owed, as that term is defined in <u>Appendix A</u>, for which it may be liable under the model. If a PC Flex ACO terminates from the model early (discussed in section <u>XII. Remedial Action and Termination</u>) the ACO must repay as Other Monies Owed the enhanced portion of the PPCP and the Advance Shared Savings Payment it received (subject to a proration schedule). To ensure an ACO's ability to repay any Other Monies Owed, each PC Flex ACO must obtain a repayment mechanism to participate in the ACO PC Flex Model. The repayment mechanism for the model is separate from and in addition to the repayment obligations an ACO may have under the Shared Savings Program regulations.

PC Flex ACOs participating in two-sided risk tracks of the Shared Savings Program must secure two repayment mechanisms. Separate from and in addition to the ACO PC Flex Model repayment mechanism

²⁹ CMS Framework for Health Equity. (2023, Dec 11). CMS.gov.

³⁰ Costs associated with health equity data reporting vary according to the PC Flex ACO's circumstances, readiness, and existing investments. In line with the ACO REACH Health-Related Social Needs Screening, Referral, & Navigation in CMMI. Models: Implementation Guide, the use of 1115A funds disbursed via a Cooperative Agreement could be explored to support PC Flex ACOs with data reporting in select cases where costs represent a significant barrier. The Accountable Health Communities Model used cooperative agreement funds to support the implementation of HRSN, screening, referral, and (for a select population of screened individuals) navigation.

³¹ Lewis VA, Fraze T, Fisher ES, Shortell SM, Colla CH. ACOs serving high proportions of racial and ethnic minorities lag in quality performance. Health Aff (Millwood). 2017 Jan 1;36(1):57-66. doi: 10.1377/hlthaff.2016.0626.

discussed above, the Shared Savings Program requires ACOs participating in a two-sided model to establish a repayment mechanism to assure CMS that they can repay losses for which they may be liable upon reconciliation for each performance year under which they accept Performance-based Risk.³² The repayment mechanism established as part of the Shared Savings Program application ensures the ACOs ability to repay shared losses for which it may be liable under a two-sided Performance-based Risk arrangement. The ACO PC Flex Model repayment mechanism ensures the PC Flex ACO's ability to repay any Other Monies Owed to CMS, which may include the Advance Shared Savings Payment and the PPCP Enhanced Amounts. A PC Flex ACO participating in a two-sided risk track of the Shared Savings Program may not obtain a single repayment mechanism to meet its obligations to obtain an ACO PC Flex Model repayment mechanism and a Shared Savings Program repayment mechanism.

PC Flex ACOs participating in one-sided tracks of the Shared Savings Program must establish a single repayment mechanism to repay Other Monies Owed.

The ACO PC Flex Model repayment mechanism must be in one of the following three forms: (1) funds placed in escrow, (2) a line of credit, or (3) a surety bond. As part of its application, the applicant ACO must submit draft documentation of its compliance with the repayment mechanism requirements during the RFI period from November 8, 2024 – November 18, 2024, and final documentation of its compliance during the final submission period from December 6, 2024 – December 12, 2024. CMS will annually notify the PC Flex ACO of the amount that must be funded by its repayment mechanism for the relevant performance year.

If CMS does not receive payment for Other Monies Owed by the date payment of Other Monies Owed is due, CMS will pursue payment under the repayment mechanism and may withhold payments otherwise owed to the PC Flex ACO under this model or any other CMS program or initiative.

IV. Model Design Elements

Unless stated otherwise in the model's governing documents, the ACO PC Flex Model will align with the Shared Savings Program regulations.³³ In addition, unless stated otherwise, guidance issued by CMS related to the Shared Savings Program will be applicable to PC Flex ACOs. CMS reserves the right to amend the ACO PC Flex Model methodologies, as needed, to account for changes in the Shared Savings Program's regulations issued as part of future rulemaking.

A. Beneficiary Eligibility and Assignment

Before calculating a PC Flex ACO's PPCP, beneficiaries must be assigned to a PC Flex ACO. The ACO PC Flex Model will rely on the criteria and other factors CMS uses to determine a beneficiary's eligibility for assignment under the Shared Savings Program.³⁴ Eligible beneficiaries will be assigned to the ACO PC Flex Model by the Shared Savings Program annual assignment processes, which is determined based on voluntary assignment or claims-based assignment.

Details about how assignment options affect the PPCP can be found in Appendix E.

While the ACO PC Flex Model will follow the Shared Savings Program annual assignment process, CMS will

^{32 42} C.F.R. § 425.204(f).

^{33 42} C.F.R. Part 425.

^{34 42} C.F.R. § 425.401.

identify beneficiaries receiving a plurality of primary care services based on allowable charges at FQHCs and/or RHCs to extend the Shared Savings Program beneficiary assignment methodology to the CCN – level.

B. Beneficiary Engagement and Marketing

The ACO PC Flex Model will follow Shared Savings Program requirements for beneficiary notification and marketing.³⁵

C. ACO PC Flex Model Payment Mechanisms and Financial Methodology

Overview

The ACO PC Flex Model will provide new payment mechanisms for ACOs participating in the Shared Savings Program, including PPCP and a one-time, upfront Advance Shared Savings Payment. The calculation of the benchmark for PC Flex ACOs will be unchanged from the Shared Savings Program's methodology for the duration of the ACO PC Flex Model.^{36,37} The ACO PC Flex Model will apply adjustments to the calculation of performance year expenditures and the calculation of shared savings and shared losses under the Shared Savings Program to account for the model's unique features. See section IV.E. Financial Settlement for details.

The ACO PC Flex Model's PPCP and Advance Shared Savings Payment are designed to support population health management. The model tests how patient care and practice patterns evolve as a result of the PPCP, which will shift payment for primary care away from fee-for-service, visit-based payment and will increase the predictability of primary care funding for low revenue ACOs. More predictable cash flows may offer more flexibility and a stronger incentive for health care providers to coordinate care with the potential to improve outcomes and lower costs. The regionally consistent rate for primary care spending will increase payment for providers that have entrenched patterns of inappropriately low spending for underserved communities and populations.

Context

The PPCP will allow for prospectively determined and more predictable revenue streams for primary care that are paid on a monthly basis to PC Flex ACOs. It builds on payment policies tested in CMS Innovation Center ACO Models, including the NGACO Model's test of the population based payment (PBP) and all-inclusive population based payment (AIPBP) policies from 2016-2021, and the ACO REACH Model's test of primary care capitation (PCC), total care capitation (TCC), and advanced payment option (APO) policies starting in 2021. These were prospective payments, based on historical spending estimates, made to ACOs that elected to participate. In return, CMS applied corresponding fee reductions to claims-based payments for participating providers and suppliers. While PBP and AIPBP remained directly linked to Medicare fee-for-service payment and utilization through the annual reconciliation process, the ACO REACH Model's capitation payment mechanisms are not reconciled against actual claims expenditures. Similarly, the ACO PC Flex Model PPCP is not reconciled against actual claims expenditures. In contrast to previously tested CMS Innovation Center models, the rate for the PPCP is not based on a PC Flex ACO's historical spending estimates. In the ACO PC Flex Model, the PPCP rate is based on a county's average primary care spending, before adjusting for social and clinical risk factors. Also, in contrast to previous tests, a portion of the PPCP

³⁵ 42 C.F.R. §§ 425.312 and 425.310.

³⁶ 42 C.F.R. Part 425 Subpart G.

³⁷ In the CY 2024 Physician Fee Schedule final rule (<u>88 FR 78818</u>, CMS finalized modifications to certain benchmarking provisions in the Shared Savings Program, applicable to agreement periods beginning on January 1, 2024, and in subsequent years.

(the Enhanced Amount, discussed below) is not recouped by CMS to the extent it exceeds the greater of positive regional adjustment and prior savings adjustment. This means that for many PC Flex ACOs, the ACO PC Flex Model Enhanced Amount will be an increase in primary care revenue.³⁸

i. Advance Shared Savings Payment

CMS will provide a one-time shared savings advance of \$250,000, the "Advance Shared Savings Payment," to each PC Flex ACO after the start of the first performance year (after January 1, 2025). The PC Flex ACO may use the Advance Shared Savings Payment to cover costs associated with forming an ACO (where relevant) and administrative costs of necessary ACO PC Flex Model activities. The Advance Shared Savings Payment may be used to develop the infrastructure necessary to administer prospective payments, including the development and execution of ACO participant agreements with primary care providers, determination of primary care provider PPCP amounts, and processing of PPCP, as well as certified electronic health record technology and administrative costs for Spend Plan and health equity data reporting. The Advance Shared Savings Payment will be deducted from shared savings each performance year until the full \$250,000 is repaid, and any balance owed will be carried over from performance year to performance year. For additional details see section IV.E. Financial Settlement, section V.A. Allowable Uses of PPCP, Reporting, and Monitoring and section XII. Remedial Action and Termination on repayment requirements related to termination.

ii. Prospective Primary Care Payment (PPCP)

The PPCP, a payment for primary care services³⁹ provided by participating primary care providers (see Appendix A) to the ACO's assigned beneficiaries, is comprised of (1) a County Base Rate and (2) an Enhanced Amount. The County Base Rate is the county average primary care spending on the current procedural terminology (CPT⁴⁰)/healthcare common procedure coding system (HCPCS) codes listed in Appendix D for all assignable Medicare beneficiaries in each county, billed by primary care providers in a historical period (see section IV.C.ii.a. Prospective Primary Care Payment County Base Rate for details). The County Base Rate is intended to pay for primary care services furnished to PC Flex ACO assigned beneficiaries. The Enhanced Amount is the collective value of the County Enhancement and the Flex Enhancement, after adjusting for clinical risk, primary care delivered outside the PC Flex ACO, and application of the cap on enhancement (see section IV.C.ii.b. Prospective Primary Care Payment Enhanced Amount and section IV.C.iii. Prospective Primary Care Payment Adjustments for details). To the extent that the Enhanced Amount exceeds the positive regional adjustment and prior savings adjustments, it is not recouped by CMS (See section IV.E. Financial Settlement).

For most PC Flex ACOs, CMS expects that the PPCP will increase primary care funding relative to the PC Flex ACOs' historical expenditures. This is particularly true for ACOs participating in regions for which the average level of primary care spending is higher than the ACO providers' historical primary care spending. PC Flex ACOs that have historical primary care spending above their regional average in the base years may also see higher upside from the County Base Rate when the County Enhancement (described in the County

³⁸ To the extent that an ACO has a positive regional adjustment or a prior savings adjustment to benchmark, the enhanced portion of the PPCP will be recouped in financial settlement. See Section IV.E for more information.

³⁹ See 42 C.F.R. § 425.20 "Primary Care Services"; see also § 425.400(c). Any service billed on an FQHC / RHC claim will be considered a Primary Care Service performed by a Primary Care Physician. 42 C.F.R. § 425.404(b).

⁴⁰ CPT codes, descriptions and other data only are copyright 2022 American Medical Association. All Rights Reserved. Applicable FARS/HHSAR apply. CPT is a registered trademark of the American Medical Association.

Enhancement section below) is applied. The County Enhancement would be especially beneficial for ACOs participating in regions of the country with relatively low primary care spending. CMS expects that model participation decisions will be driven by the final PPCP rate (reflective of all payment adjustments articulated in section IV.C.iii. Prospective Primary Care Payment Adjustments), as well as by the flexibility and predictability in the use of funds for primary care afforded by the prospective payment and the perceived value of the PPCP for care delivery relative to the status quo.

The PPCP consists of several components, each of which is described in further detail below:

- 1. PPCP County Base Rate
- 2. Add-on for beneficiaries with FQHC- or RHC-Focused Care
- 3. PPCP Enhanced Amount
 - a. County Enhancement
 - b. Flex Enhancement
- 4. PPCP Adjustments (with the exception of the adjustment for primary care delivered outside of ACO, the below adjustments are applied to all components of 1, 2, and 3)
 - a. Operational: Payment Precision Withhold
 - b. Payment: Risk Adjustment
 - c. Payment: Adjustment for Primary Care Delivered Outside of ACO (not applied to Flex Enhancement)
- 5. Payment: Health Equity Adjustment (not adjusted for items in 4)
- 6. Primary Care Prospective Administrative Trend (PCPAT) (not applied to component 5)

The eligibility criteria for payment enhancements and adjustments are in Table 2. The following section details the operationalization of each component of the PPCP.

Table 2. Eligibility for Payment Enhancement and Adjustments⁴¹

BASE RATE	COUNTY ENHANCEMENT	FLEX ENHANCEMENT	ADJUSTMENTS	PCPAT
All PC Flex ACOs	Eligible if at or below 2 nd decile of standardized spending	All PC Flex ACOs	All PC Flex ACOs	All PC Flex ACOs

a. Prospective Primary Care Payment County Base Rate

PPCP is based on county-level historical utilization of primary care services billed by primary care providers. This is referred to as the "County Base Rate." Using a County Base Rate as the basis of the PPCP, rather than PC Flex ACOs' historical expenditures (or a blend of both), separates target primary care spending from PC Flex ACOs' historical primary care expenditures, which for many providers is below the levels required for the delivery of patient-centered, coordinated care. Use of a County Base Rate also ensures that any PC Flex ACO serving beneficiaries in a given county would receive the same baseline PBPM payment as any other PC Flex ACO in the county before accounting for specific details of the assigned population profile. The County Base Rate enables the ACO PC Flex Model to increase payment for primary care without

⁴¹ For the County Enhancement: spending standardized at the national level. Adjustments refer to the Payment Precision Withhold, Risk Adjustment, Add-on for beneficiaries with FQHC / RHC Focused Care, Adjustment for Primary Care delivered Outside of ACO, and Health Equity Adjustment.

⁴² Jabbarpour Y. (2023). <u>The Health of US Primary Care: A Baseline Scorecard Tracking Support for High-Quality Primary Care</u>. Milbank Memorial Fund.

entrenching historical patterns of inappropriately low spending for underserved communities and populations.

Rate Book Construction

To calculate a County Base Rate for each county, CMS will construct a county-level ACO PC Flex Model Rate Book ("Rate Book") of performance year primary care spending using a set of CPT/HCPCS codes and their associated spending for all assignment-eligible Medicare beneficiaries in each county billed by primary care physicians (internal medicine, family medicine, general practice, geriatric medicine, and pediatric medicine) and non-physician providers (NPPs: nurse practitioners (NP), physician assistants (PA), clinical nurse specialists (CNS)). The CPT/HCPCS codes used to calculate the County Base Rate are listed in Appendix D and are the same as those used for beneficiary assignment in the Shared Savings Program with three exceptions. Beneficiaries who received the plurality of primary care services based on allowed amounts at FQHCs or RHCs will be excluded from the reference population in Rate Book construction. See section IV.C.iii.c for more information about the add-on payment for these beneficiaries.

- Exception 1: Inclusion of HCPCS Code G0463. In the Shared Savings Program assignment
 methodology, HCPCS code G0463 is only included if it is provided at an electing teaching
 amendment (ETA) hospital. For the Rate Book and fee reductions, G0463 will be included at any
 hospital outpatient department (HOPD) setting if it is billed by a primary care provider. This ensures
 we include all primary care services that may be performed when this HCPCS code is billed.
- Exception 2: Exclusion of CPT Codes 99304–99318. In the Shared Savings Program assignment methodology, professional services furnished in a nursing facility (CPT Codes 99304–99318) are included as primary care services if the date of service does not overlap with a claim for a skilled nursing facility (SNF) inpatient stay. The ACO PC Flex Model will exclude professional services furnished in nursing facilities from the PPCP, and fee-for-service claims for these services will be paid without a fee reduction. Such services will be excluded from all PPCP-related calculations including county base rates, adjustment for primary care delivered outside the ACO (PCOA), add-on for beneficiaries with FQHC / RHC Focused Care, and the PPCAT. For purposes of the ACO PC Flex Model methodology, we will consider professional services furnished in nursing facilities during a SNF stay to be post-acute care rather than primary care.
- Exception 3: Inclusion of CPT Codes 99497 and 99498. In the Shared Savings Program assignment methodology, advance care planning services (CPT Codes 99497 and 99498) are not included as primary care services when furnished in an inpatient care setting. Operationally, this is done during assignment by checking to see if there is an inpatient claim that includes the date of service on which advance care planning is performed. For claim reductions in the ACO PC Flex Model, it is not feasible to do this check as claims are processed. Instead, all claims for these services provided by primary care ACO professionals to ACO assigned beneficiaries will be reduced, including those furnished in an inpatient care setting. The County Base Rates and related adjustments will also include these services including in cases where they are furnished in an inpatient care setting.

The county rates contained in the Rate Book will be risk-standardized (i.e., expenditures calibrated to an average risk adjustment factor (RAF) score of 1.0 such that they represent the cost of an average-risk Medicare beneficiary before being risk adjusted in the performance year) and calculated prior to any subsequent model-wide or ACO-specific adjustments (see below). The Rate Book will be published in advance of each performance year so that PC Flex ACOs may assess their likely ACO PC Flex Model primary

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care County Base Rate.

Each county will have two County Base Rates: an ESRD base rate and a non-ESRD base rate. The non-ESRD base rate will reflect primary care spending for all assignment-eligible Medicare beneficiaries in the following enrollment types: aged non-dual, aged dual, and disabled. The ESRD base rate reflects primary care spending for all assignment-eligible Medicare beneficiaries in the ESRD enrollment type. The ACO PC Flex Model's use of two categories (ESRD vs. non-ESRD) aligns with the methodology to construct the Accountable Care Prospective Trend (ACPT) under the Shared Savings Program.

Calculation of Rates

CMS will use the following data in the calculation of the Rate Book: (1) applicable fee-for-service expenditures at the national level ("national conversion factor") and (2) county-specific indices that account for average spending levels at the county level ("county relative cost indices"). CMS will use three base years, equally weighted, to calculate County Base Rates. The most recent base year will be two years prior from the model's first performance year (i.e., 2021, 2022, and 2023). This approach broadly mirrors CMS's development of the ACO REACH / KCC Rate Book (which in turn reflects the Medicare Advantage rate book approach). ACO PC Flex Model base years (2021–2023) will be fixed for the duration of the model. CMS is still exploring the best approach to use 2021 utilization in the Rate Book construction due to lingering effects of the COVID-19 Public Health Emergency. Other possible approaches include weighting the impact of 2021 less than 2022 and 2023 as well as using a preliminary Rate Book until a final Rate Book based on 2022, 2023, and 2024 may be constructed, likely mid-2025. The final methodology for the Rate Book will be detailed in a methodology paper later summer 2024 and will be published with the actual Rate Book.

Beneficiaries with FQCH/RHC Focused Care will be excluded from the reference population in the Rate Book construction. See section IV.C.iii.c Add-on for beneficiaries with FQHC / RHC Focused Care for more information about the add-on payment for beneficiaries with FQHC / RHC Focused Care.

CMS will establish an adjusted County Base Rate for counties that have too few beneficiaries to generate a credible County Base Rate. This process is similar to the "credibility adjustments" made in the Medicare Advantage and ACO REACH / KCC Rate Book. Specifically, for counties with fewer than 1,000 beneficiaries, county experience may be blended with experience from the applicable Medicare core based statistical area (CBSA). If a county is not associated with a CBSA, the county experience would be blended with statewide experience. Subsequently, such county rates would be scaled down by the average ratio of change created by the credibility adjustments within the corresponding state; this is to maintain budget neutrality relative to the pre-credibility adjusted rates.⁴⁴

b. Prospective Primary Care Payment Enhanced Amount

The ACO PC Flex Model PPCP includes an Enhanced Amount that consists of two types of payment enhancements: (1) the County Enhancement, which is applied at the county level in counties designated as low spending counties relative to standardized spending nationally, and (2) the Flex Enhancement, which is applied at the ACO level to all PC Flex ACOs, regardless of location or utilization.

To encourage true investments in primary care, to the extent that it exceeds the greater of an PC Flex ACO's positive regional adjustment and prior savings adjustment, the Enhanced Amount will not be subject to

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⁴⁴ The secondary adjustment scales the credibility-adjusted rates back by a common state-wide average ratio so the overall sum of adjusted rates across the state stays the same to maintain budget neutrality.

recoupment by CMS based on the PC Flex ACO's performance in achieving shared savings. CMS will at the time of performance year settlement reduce the value of the payment enhancement by no more than the dollar value of the PC Flex ACO's positive regional adjustment or prior savings adjustment. Additional details on enhanced payment dollars and interactions with the broader Shared Savings Program benchmarking methodology are in section IV.E. Financial Settlement, below.

Additionally, the total value of the Enhanced Amount (County Enhancement and Flex Enhancement) - after risk adjustment for clinical risk and PCOA (described in section IV.C.iii. Prospective Primary Care Payment Adjustments) and the PCPAT - will be limited to \$200 per beneficiary per year (PBPY). This is called the cap on enhancement. Additional details on enhanced payment dollars and interactions with the broader Shared Savings Program benchmarking methodology, including an illustrative example, are in Appendix E.

County Enhancement

The County Enhancement is an additional amount that, when combined with the County Base Rate, brings the county-specific amount up to a national threshold of primary care spending. The County Enhancement will enhance payment to PC Flex ACOs in counties with historically low levels of primary care spending (defined below), evidence of underuse of medical services, and socioeconomic disadvantage. Details on the equity-promoting goals of the County Enhancement are described in section III.H. Focus on Health Equity above.

To identify counties where the County Enhancement will apply, CMS will calculate each county's primary care utilization. For the purpose of calculating the County Enhancement amount, primary care utilization is defined as the risk-adjusted mean primary care spending per beneficiary for the reference population and after applying relevant credibility adjustments described in section IV.C.ii.a. Prospective Primary Care Payment Adjustments above. CMS will group counties into deciles from lowest to highest spending and identify counties with low spending relative to a national threshold, defined here as the top of the second decile of risk-standardized primary care spending nationally. For counties with average primary care spending less than the national threshold amount, the County Enhancement will be calculated as the difference between the PBPM national threshold amount and the county's County Base Rate.

Flex Enhancement

The Flex Enhancement will apply at the ACO level to all PC Flex ACOs. It is designed to increase primary care funding to all PC Flex ACOs and encourage investment in primary care. The Flex Enhancement amount is \$125 PBPY. This amount accommodates the budget limitations of the model while maximizing the proportion of PC Flex ACOs that would receive a higher total PPCP rate relative to their historical fee-for-service spending. PC Flex ACOs will not be subject to risk on the Flex Enhancement portion of the PPCP to the extent it exceeds the greater of positive regional adjustment and prior savings adjustment. This is described in further detail below in section IV.E. Financial Settlement.

Cap on Enhanced Amount

The combined value of the adjusted County Enhancement and the Flex Enhancement for a PC Flex ACO will be limited to \$200 PBPY. This is not applied at a beneficiary level. This cap is applied at the individual ACO level based on the total enhancement dollars divided by the ACO's total average PPCP eligible beneficiary person-years. "Adjusted" here means that the value of the enhancements compared to the limit will be evaluated after risk adjustment, adjustment for PCOA, and the PCPAT.

⁴⁵ Please note that this amount may be updated and final values will be in the Financial Specification papers.

iii. Prospective Primary Care Payment Adjustments

a. Payment precision withhold

CMS will apply a prospective discount to the PPCP of not more than 3% to create a buffer against potential non-reduction of PPCP-eligible claims (claims for CPT/HCPCS codes listed in Appendix D billed by primary care providers for assigned beneficiaries which should be reduced 100% but are not). Non-reduction of PPCP-eligible claims can occur as a result of implementation of payment mechanism and claims processing issues, including but not limited to reprocessing of non-reduced claims after a claims runout period specified by CMS (i.e. March 31 of the calendar year following the performance year), processing errors that remain unresolved after a claims runout period specified by CMS, or claims incurred in the performance year but not submitted prior to the end of a claims runout period specified by CMS. This would allow for up to a 3% non-reduction rate on claims for primary care services without needing to reprocess claims such that they match remitted PPCP amounts. The payment precision withhold would be applied to a PC Flex ACO's entire PPCP.

b. Risk adjustment

CMS will risk adjust primary care expenditures using the CMS hierarchical condition category (HCC) prospective risk adjustment model⁴⁶ which will maintain parity between the overall benchmark and PPCP. In addition, evidence suggests that the CMS-HCC model effectively predicts primary care specific risk and expenditures. The County Base Rate, County Enhancement, and Flex Enhancement will all be risk-adjusted using the CMS-HCC risk adjustment model. The County Base Rate will also be risk-standardized based on the same approach.

For each performance year, the PPCP will be risk-adjusted using the same CMS-HCC prospective risk adjustment model version or version blend that is used to adjust benchmarks in the Shared Savings Program. To support more precise PPCP payments compared to using prior years' final scores and minimize the impacts of retrospective updates to the PPCP due to risk adjustment, interim risk scores will be used throughout the performance year and updated based on the schedule in Appendix E.

c. Add-on for beneficiaries with FQHC / RHC Focused Care

The County Base Rate, described above, was developed by examining variation in risk and geographic standardized historical utilization of primary care services billed under the Physician Fee Schedule. Because FQHCs and RHCs are paid under a different payment system (the FQHC prospective payment system and RHC all-inclusive rates (AIR), respectively) and because these providers receive all-inclusive per-visit payments, the historical claims for FQHCs and RHCs do not lend themselves to standardization and inclusion in the county variance analysis. Additionally, some FQHC and RHC claims include services that are not primary care services as defined in Table 3 (Appendix D). To align with the Shared Savings Program, the ACO PC Flex Model will treat all services reported on an FQHC / RHC claim as primary care services performed by a primary care physician for the purposes of fee reductions (FQHC / RHC claims for services provided to assigned beneficiaries will be zeroed out) provided the beneficiary was assigned to the ACO via "Step 1" or "Step 3." The add-on for beneficiaries with FQHC / RHC Focused Care described in this section corrects for the exclusion of FQHC / RHC claims from the county rates. All In developing the predecessor to the Rate Book to simulate County Base Rates, CMS conducted county variance analysis of primary care spending. Beneficiaries receiving a plurality of primary care services based on allowable charges at FQHCs and / or RHCs were excluded from county variance analysis (and will be excluded from County Base Rates in the Rate

⁴⁶ More information on the CMS-HCC prospective risk adjustment model can be found here.

⁴⁷ 42 C.F.R. § 425.404(b).

Book development). This supported development of the County Base Rate and the County Enhancement (described above) but the County Base Rates and County Enhancements do not incorporate spending for care delivered by FQHCs and RHCs.

As a result, a beneficiary level add-on for FQHC / RHC Focused Care will be required for beneficiaries who receive the plurality of primary care services based on allowable charges at FQHCs or RHCs. Because the payment methodology is different for FQHCs and RHCs, there will be a different PBPM add-on for beneficiaries with FQHC / RHC Focused Care for each of these settings to encourage FQHCs and RHCs to participate in the ACO PC Flex Model (see <u>Appendix E</u>). These add-ons will be a fixed dollar amount added to the PPCP for these beneficiaries based on the average difference in national historical spending for beneficiaries who receive the plurality of primary care services at FQHCs or RHCs and the average County Base Rates that exclude these beneficiaries. These are model-level variables for the PPCP, one for beneficiaries who receive the plurality of primary care services at FQHCs and separately, one for RHCs.

To ensure that ACOs are appropriately funded for assigned beneficiaries with FQHC / RHC Focused Care, CMS will monitor the PPCP compared to actual fee reductions on a quarterly basis. Should PPCP payments for these beneficiaries be less than actual fee reductions on a year-to-date basis, additional payment will be made in the next available monthly PPCP. This will be evaluated on an individual ACO basis for the ACO's total population that received the plurality of their primary care services at an FQHC or RHC. Each quarter, CMS will calculate the year-to-date difference between the relevant PPCP components, including any prior adjustment for the performance year, and the actual fee-for-service claims reductions to determine an additional payment amount. Below is the calculation that will be used at the ACO level for beneficiaries who received the plurality of primary care services at an FQHC or RHC:⁴⁸

(Actual YTD claims reductions for the same set of beneficiaries) – ((County Base Rate + County Enhancement + Add on for beneficiaries with FQHC/RHC Focused Care) \times RAF \times PCOA \times PCPAT) + prior YTD adjustment for underpayment)

If this amount is positive, the amount will be added to the next PPCP payment, allocated to individual beneficiary months in the monthly PPCP payment report.

d. Adjustment for Primary Care Delivered Outside the ACO (PCOA)

The County Base Rate, described above, is calculated using county level historical expenditures for primary care services by primary care providers for assignable beneficiaries. The County Base Rate and subsequent enhancements and adjustments are agnostic to ACO participation by those primary care providers. Assigned beneficiaries will receive some primary care from providers who are not participating in a PC Flex ACO, and therefore the ACO PC Flex Model financial methodology must adjust the County Base Rate to account for this. Examples of primary care delivered outside the ACO, or PCOA, include office-based acute or urgent care at an after-hours or retail clinic, beneficiary transition to a new, non-ACO primary care provider, and care delivered while traveling or while at an alternate residence. To accommodate variability between PC Flex ACOs in the amount of PCOA provided, the ACO PC Flex Model will adjust each PC Flex ACO based on historical experience of (the amount / the rate of) primary care delivered by providers outside the PC Flex ACO. The adjustment will remain fixed for the PC Flex ACO for at least the first two years of the model (2025–2026). Upon assessment of care delivery patterns and the impact of innovative care delivery on this adjustment factor during the first two years of the model, CMS will determine whether to update the

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⁴⁸ In the equation above, RAF refers to risk adjustment factor, PCOA refers to Primary Care Delivered Outside of the ACO, and PCPAT refers to Primary Care Prospective Administrative Trend.

adjustment and whether CMS should update on an ongoing basis (a "rolling" adjustment). Each PC Flex ACO's adjustment factor will be calculated using the PC Flex ACO's historical experience from a period preceding the performance year to allow for sufficient claims data completion. Although the adjustment will be at the ACO level, it will be applied to the PPCP at the beneficiary level as a single multiplier to the monthly beneficiary specific PPCP amount. This ensures that all PPCP payment amounts are at the beneficiary-month level and can be used in settlement calculations and future benchmarking where appropriate. Primary care services performed by NPPs who the PC Flex ACO has designated specialist NPPs will be treated as care outside the PC Flex ACO for the purpose of calculating the PCOA adjustment.

e. In-Year Retrospective Adjustments to the PPCP

In some cases, the PPCP must be updated retroactively for individual beneficiary-months to reflect changes in beneficiary eligibility status, risk scores and normalization factors, beneficiary county of residence, and other changes. This ensures appropriate payment as well as accurate recording of the PPCP at the beneficiary level, which is required for in-year reporting, performance year settlement, and future benchmarking that may include these beneficiaries and these payments. Beneficiary status changes that could result in retrospective adjustments include mortality, enrollment in Medicare Advantage, dual-eligibility or ESRD status, change of residence (impact to county and/or area deprivation index (ADI)), and updates to risk adjustment. Adjustments to past payments for which information is known within the performance year will be retrospectively applied to the earliest possible subsequent monthly payment. Adjustments that require information attainable only after final monthly payments have been made will be accounted for in the ACO PC Flex Model settlement process. Reporting and settlement timelines may require a final cut-off date for adjustments earlier than March 31st following the performance year. While the PPCP is intended to be prospective, the kinds of retrospective adjustments described here are common in capitation arrangements.

f. Health Equity Adjustment to the PPCP

The ACO PC Flex Model will adjust the amount of PPCP payable to a PC Flex ACO using the approach devised for ACO REACH in performance year 2024 to adjust ACO benchmarks to account for relative differences in beneficiary underservedness (the ACO REACH health equity benchmark adjustment). Specifically, a PBPM dollar adjustment (positive and negative adjustments, respectively, see table below) will be made for the assigned beneficiaries in the model with the highest and lowest equity scores (all beneficiaries assigned to a PC Flex ACO will receive an equity score). A beneficiary's equity score will be determined by three factors: national ADI score, state ADI score, and dual-eligibility / low-income subsidy status (partial or full). CMS will compare the equity scores of beneficiaries that are assigned to PC Flex ACOs (ACO-assigned beneficiaries) to the distribution of equity scores in the assignable population. The total health equity adjustment policy in the ACO PC Flex Model will be budget-neutral – i.e., all dollars given to PC Flex ACOs for their care of highly underserved beneficiaries will be offset by reductions for PC Flex ACOs serving the least underserved. In addition, strengthening resources for the care of underserved communities, this beneficiary-level adjustment encourages PC Flex ACOs to attract more underserved beneficiaries.

Table 3. Health Equity Adjustment to the PPCP Amount

EQUITY SCORE RANGE (PERCENTILE)	PBPM ADJUSTMENT
Equity Score _b ≥ P ₉₀	\$3
P ₈₀ ≤ Equity Score _b < P ₉₀	\$2

⁴⁹ See 42 C.F.R. § 425.20 "assignable beneficiary."

P ₇₀ ≤ Equity Score _b < P ₈₀	\$1
P ₃₀ ≤ Equity Score _b < P ₇₀	\$0
P ₂₀ ≤ Equity Score _b < P ₃₀	-\$1
P ₁₀ ≤ Equity Score _b < P ₂₀	-\$2
Equity Score _b < P ₁₀	-\$3

iv. Primary Care Prospective Administrative Trend (PCPAT)

After the adjustments described above have been applied to the County Base Rate and Enhanced Amount (if applicable), the resulting amount will be trended forward to the applicable performance year based on a Primary Care Prospective Administrative Trend (PCPAT). For performance year 2025, the PCPAT will be based on projected growth in reimbursement per fee-for-service enrollee for Physician Fee Schedule services, derived from projected incurred reimbursement amounts per fee-for-service enrollee for Physician Fee Schedule practitioner services published in table IV.B2 of the Medicare Trustees Report. The separate aged and disabled projections will be combined to create a single PCPAT. Application of the PCPAT to the adjusted PBPM rate will result in the final trended adjusted PBPM rate used to set the total PPCP. CMS may modify the methodology for the trend for performance years 2026–2029 to account for substantial changes to primary care reimbursement during the model.

Application of the PCPAT to the adjusted PBPM rate will result in the final trended adjusted PBPM rate used to set the total PPCP.

D. Fee Reductions

i. General

PPCP will be paid to PC Flex ACOs in lieu of reimbursement for claims billed by PC Flex ACO Participants for most primary care services provided to assigned beneficiaries by participating primary care providers. PC Flex ACOs will determine and distribute payments to PC Flex ACO Participants. Primary care providers in participating PC Flex ACOs will be subject to a 100% fee reduction of their claims-based payment for primary care services provided to assigned beneficiaries. PC Flex ACO Participants will continue to submit claims to CMS for services provided to assigned beneficiaries. CMS will reduce claims payment amounts according to the standards detailed below for primary care services furnished to assigned beneficiaries, provided by primary care providers, and billed by the PC Flex ACO Participant. The CPT and HCPCS codes that correspond to primary care services used to calculate the County Base Rate and fee reductions are listed in Appendix D. They are the same as codes used for beneficiary assignment in the Shared Savings Program except as detailed above in section IV.C.ii.a. Prospective Primary Care Payment County Base Rate.

For performance year 2025, primary care services subject to PPCP fee reductions are:

Services billed on a professional claim format: Claims for certain evaluation and management
office services for both new and established patients using the CPT and HCPCS codes listed in

⁵⁰ 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. (2023). Centers for Medicare & Medicaid Services.

<u>Appendix D</u> and billed by a primary care provider. See section the section below for details related to NPPs designated as specialty practice NPPs.

Services billed on an institutional claim format: All services billed by FQHCs (type of bill = 77x) and RHCs (type of bill 71x, respectively). Claims for HOPD (type of bill = 13X), ETA hospital (type of bill = 13x), and critical access hospital (CAH) method II (type of bill = 85x with revenue codes 096x, 097x, or 098X) for certain evaluation and management services for both new and established patients using the CPT and HCPCS codes described in Appendix D and billed by a primary care provider, as described above. 51

ii. Claims Payments Excluded from Prospective Primary Care Payment

Notwithstanding the above, primary care services will not be subject to a 100% fee reduction under certain circumstances. These include:

- Claims payments where Medicare is not the primary payer;
- Claims payments for providers enrolled in the periodic interim payments program or other Medicare programs or initiatives specified by CMS prior to the start of the performance year or relevant subsequent quarter;
- Claims payments that are subject to the Medicare Health Professional Shortage Area (HPSA)
 Physician Bonus Program;
- Claims payments for beneficiaries who elect to decline data sharing or for services related to the diagnosis and treatment of substance use disorder;
- Payment of PPCP for beneficiaries assigned based on primary care services performed by specialists (see below); and
- Payment for primary care services performed by NPPs in a specialty practice (see below).

Payment of PPCP for beneficiaries assigned based on Primary Care Services performed by specialists

The provision of primary care services by specialist physicians are not included in the calculation of PPCP or subject to claims reduction because it is not possible to distinguish between primary and specialty services provided by specialist physicians in claims. It is outside the scope of the model to test the benefits of prospective population-based payment for the provision of specialty care based on county rates.

Assignment of beneficiaries to Shared Savings Program ACOs is based on the plurality of primary care services, qualified by allowed amount, for three categories of providers. Primary care physicians are included first, in "Step 1." Second, certain specialist physicians⁵² are included in "Step 2." Finally, certain non-physician providers are included in "Step 3." The assignment step under which each beneficiary is assigned is indicated in the quarterly and annual assignment list reports.

As noted in Section IV.A above, assignment of beneficiaries to PC Flex ACOs uses the same methodology as the Shared Savings Program. However, in the ACO PC Flex Model, the PPCP will not be paid for beneficiaries assigned via "Step 2" nor will claims be reduced for these beneficiaries. PPCP will also not be paid for

⁵² Physicians with primary specialty designations considered during the second and third step of assignment are: cardiology, osteopathic manipulative medicine, neurology, obstetrics/gynecology, sports medicine, physical medicine and rehabilitation, psychiatry, geriatric psychiatry, pulmonary disease, nephrology, endocrinology, multispecialty clinic or group practice, addiction medicine, hematology, hematology/oncology, preventative medicine, neuropsychiatry, medical oncology, and gynecology/oncology. 42 C.F.R. § 425.402(c).

⁵¹ This list is subject to change for each subsequent performance year.

beneficiaries who through voluntary assignment identified a specialty physician included in the "Step 2" list of specialties (See section IV.D. Fee Reductions).

All claims by FQHCs and RHCs are considered primary care claims and are included in "Step 1" of assignment, and all claims for beneficiaries assigned to the ACO in "Step 1" or "Step 3" billed by FQHCs and RHCs will be zero-paid and covered by the PPCP.

Primary Care Services performed by NPPs in a specialty practice

Within the claims processing systems, it is not possible to identify the clinical specialty of NPPs or to distinguish primary care from specialty care provided by an NPP. NPPs designated as specialty practice NPPs by PC Flex ACOs will not have claims reduced for assigned beneficiaries. During the application process PC Flex ACOs will designate each ACO professional by NPI who is an NPP as a "primary care" NPP or a "specialty care" NPP. Once an NPI has been designated by the PC Flex ACO, a change of designation for that provider NPI will not be permitted unless documentation is provided to support a change of clinical practice. Acceptable documentation includes but is not limited to a change in the NPI's National Plan and Provider Enumeration System (NPPES) taxonomy registration. In the event that an NPP ACO professional's designation is successfully changed, it will become effective for the purposes of fee reductions and other PPCP adjustments on January 1st of the next performance year.

Because all claims submitted by FQHCs and RHCs are considered primary care claims, there will be no exclusion of any ACO professionals for these claims for the purposes of claims reductions. For NPPs who exclusively submit claims through an FQHC or RHC, PC Flex ACOs do not need to designate the NPP as "primary care" or "specialty care." If the NPP also submits claims under a TIN or CCN that is not an FQHC or RHC, however, the PC Flex ACO will be required to provide the designation.

E. Financial Settlement

Given PC Flex ACOs will still be participating in the Shared Savings Program, PC Flex ACOs will be subject to the Shared Savings Program financial settlement process codified in federal regulations.⁵³ At a high level, financial settlement for PC Flex ACOs will compare the performance year benchmark to performance year expenditures to calculate gross savings and losses. The performance year benchmark represents the average Medicare beneficiary total cost of care for assigned beneficiaries and refers to the target expenditure amount that will be compared to Medicare expenditures for items and services furnished to ACO PC Flex assigned beneficiaries during a performance year.

The calculation of the benchmark for PC Flex ACOs will be unchanged from the Shared Savings Program's methodology codified in federal regulations.^{54,55} Benchmarks are constructed using nationally and regionally adjusted historical expenditures. Additional information may be found in the Shared Savings Program <u>Guidance and Specifications</u> page.

Below, CMS outlines the high-level steps of these calculations and adds descriptions of sub-steps or modifications related to the ACO PC Flex Model. CMS encourages readers to review the full details provided in the Shared Savings Program technical document but will here focus on modifications for the ACO PC Flex

⁵³ 42 CFR 425 Subpart G.

⁵⁴ 42 CFR Part 425 Subpart G.

⁵⁵ In the CY 2024 Physician Fee Schedule final rule <u>(88 FR 78818)</u>, CMS finalized modifications to certain benchmarking provisions in the Shared Savings Program, applicable to Agreement Periods beginning on January 1, 2024, and in subsequent years.

Model.

• **First Set of Processes:** Update historical benchmark and determine total updated benchmark and total performance year expenditures in aggregate and per capita.

ACO PC Flex modification A: Include PPCP in performance year expenditures

The total value of the paid PPCP before sequestration will be added to per capita expenditures and total expenditures and be included in resulting calculations of total savings and total losses. Later in the settlement calculation, after shared savings and shared losses have been determined, the Total Enhancement Credit (See <u>Appendix A</u>) to settlement will be added to increase shared savings, reduce shared losses, or shift shared losses to shared savings.

An example of beneficiary level and ACO level calculation of the total PPCP before sequestration is provided in the companion workbook, "ACO PC Flex Exhibits and Example Calculations" on the Exhibit 2 – PPCP build tab. This example steps through the various components of the PPCP and application of adjustments. In this example, the amount that will be included in performance year expenditures for the PC Flex ACO is shown in column H ("ACO Weighted Average"), row 50 ("Total PPCP payment before Sequestration and Payment Precision Withhold") on a PBPM basis. Multiplying this value by the number of PPCP eligible beneficiarymonths results in the total dollar amount to be included in the performance year expenditures.

The value of this addition to performance year expenditures, on a year-to-date basis, will be easily derivable in the monthly ACO PC Flex payment detail report and will be included in the standard Shared Savings Program quarterly expense and utilization reports.

 Second Set of Processes: Determine gross savings/losses and perform calculations relative to MSR/MLR, shared savings and losses rates, determine shared savings or losses amounts, apply sequestration for shared savings, and apply performance payment limit or loss recoupment limit.

ACO PC Flex modification B: Apply the Total Enhancement Credit to settlement after sequestration.The Total Enhancement Credit to settlement is calculated in 4 steps:

Step 1: Determine the combined value of the County Enhancement and Flex Enhancement on a PBPM basis after application of adjustments, trend, and the cap on enhancement. This amount is the Total Enhancement subject to offset by the greater of the positive regional adjustment and prior savings adjustment at settlement. An example of this calculation is provided in the companion workbook, "ACO PC Flex Exhibits and Example Calculations" on the Exhibit 2 – PPCP build tab on row 53. This is an ACO level calculation.

Step 2: Determine the offset to Total Enhancement on a PBPM basis. In this step, the regional adjustment and prior savings adjustment (on a PBPY basis), which are provided in the Shared Savings Program benchmark report on Tables 1A and 1B respectively, are evaluated to determine which is greater and then divided by 12 to convert the PBPY value to a PBPM value. An example of this calculation is provided in the companion workbook, "ACO PC Flex Exhibits and Example Calculations" on the Exhibit 3 — enhancement offset tab on rows 8-11. This is an ACO level calculation.

Step 3: Reduce the Total Enhancement Credit by the offset amount determined in Step 2. The resulting value is the Total Enhancement Credit to settlement, after offsetting for the greater of positive regional adjustment and prior savings adjustment on a PBPM basis. The floor for this value is \$0.00 PBPM. An

example of this calculation is provided in the companion workbook, "ACO PC Flex Exhibits and Example Calculations" on the Exhibit 3 – enhancement offset tab on row 13. This is an ACO level calculation.

Step 4: Convert the PBPM value in Step 3 to a total dollar value by multiplying by the total number of PPCP eligible beneficiary months assigned to the PC Flex ACO for the performance year. PPCP eligible beneficiary months are ACO assigned beneficiary months for which the PPCP was paid in the performance year. An example of this calculation is provided in the companion workbook, "ACO PC Flex Exhibits and Example Calculations" on the Exhibit 3 – enhancement offset tab on row 15. This is an ACO level calculation.

Adding a positive Total Enhancement Credit to the settlement will have four possible outcomes:

- **Outcome 1:** When the PC Flex ACO has an earned performance payment before enhancement credit, a positive Total Enhancement Credit will increase the earned performance payment.
- Outcome 2: When the PC Flex ACO has a payment due to CMS before enhancement credit that is greater than the positive Total Enhancement Credit, the payment due to CMS will be reduced by the amount of the positive Total Enhancement Credit.
- Outcome 3: When the PC Flex ACO has a payment due to CMS before enhancement credit that is less than the positive Total Enhancement Credit, the PC Flex ACO will have an earned performance payment equal to the positive Total Enhancement Credit minus the payment due to CMS.
- Outcome 4: When the PC Flex ACO has neither an earned performance payment nor a payment due to CMS, the PC Flex ACO will have an earned performance payment equal to the positive Total Enhancement Credit.

ACO PC Flex modification C: Recoup to pay down Advance Shared Savings Payment.

For PC Flex ACOs that as of the performance year still have a balance owed to CMS for the ACO PC Flex Advance Shared Savings Payment, the earned performance payment after Total Enhancement Credit will be used to paydown the Advance Shared Savings Payment balance. To the extent that the performance year's earned performance payment after enhancement credit is larger than the balance owed to CMS for the Advance Shared Savings Payment, the remaining earned performance payment after enhancement credit will be paid to the PC Flex ACO.

As described in ACO PC Flex modification C above, the Advance Shared Savings Payment will be deducted from shared savings (defined in Shared Savings Program federal regulations),⁵⁶ if applicable, but will not be added to shared losses. The Advance Shared Savings Payment will be deducted from shared savings for each performance year the PC Flex ACO generates savings and the balance owed will be carried over from performance year to performance year, until the full \$250,000 is repaid. If the ACO fails to generate sufficient shared savings during the agreement period for the ACO PC Flex Model and signs a subsequent agreement period for 2030-2034, the Advance Shared Savings Payment balance will carry forward to the subsequent agreement period. Please see section XII. Remedial Action and Termination for the repayment requirements related to termination.

F. Benefit Enhancements

PC Flex ACOs may use the SNF 3-Day waiver available in the Shared Savings Program as well as flexibilities available in the Shared Savings Program for the delivery of services through telehealth consistent with the

⁵⁶ 42 C.F.R. § 42 CFR 425.20.

availability of those flexibilities in the Shared Savings Program. PC Flex ACOs may apply for a SNF 3-day rule waiver during Phase 1 of the Shared Savings Program application submission period. The telehealth waiver is available through the Shared Savings Program to ACOs that are in a two-sided Shared Savings Program risk track (i.e., BASIC track levels C, D, or E, or the ENHANCED track).⁵⁷ Additional information is available in the Shared Savings Program Telehealth Fact Sheet.

G. Quality Monitoring and Performance

PC Flex ACOs must meet Shared Savings Program quality reporting requirements and performance standards,⁵⁸ including the quality performance standards that are necessary to receive shared savings and to remain in the model and the Shared Savings Program.

In addition to reporting the Shared Savings Program's existing quality measure set, the ACO PC Flex Model will include a patient-reported experience measure (PREM), the Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM or PCPCM).⁵⁹ Use of the PCPCM is an important component of the ACO PC Flex Model quality strategy given its focus on person-centeredness and care aspects related to the integrating, prioritizing, and personalizing functions of primary care. The PCPCM will allow CMS to assess whether PC Flex ACOs are improving the patient experience and transforming care by focusing their attention, and associated resources, on high value aspects of primary care. Evaluation of the PCPCM will use the evaluation design described further in section VI. Evaluation.

The PCPCM survey will be fielded (i.e., data collected and reported) for all PC Flex ACO Participants. To reduce the burden of PCPCM reporting, CMS will fund and manage the administration of the PCPCM survey. The PCPCM will not be included as part of the Shared Savings Program quality performance standard used to determine shared savings and shared losses.

PC Flex ACOs must continue to comply with current Shared Savings Program quality performances standards for the duration of the model, to the extent they are not subject to a future waiver. Specifications for the quality strategy will be reviewed annually and may be subject to revision each performance year. Appendix F lists the quality measure set. ACO PC Flex Participants will be assessed on their PCPCM performance beginning in performance year 2.

To facilitate accurate and complete collection of the PCPCM, PC Flex ACO Participants may be asked to submit supportive information, for example, beneficiary roster data, by a date and in a manner specified by CMS. Details will be communicated in the forthcoming ACO PC Flex Model quality reporting guide. To ensure the PCPCM is reported accurately and completely, CMS may conduct data validation audits of ACO quality data. These audits may involve ad hoc or scheduled desk reviews, focused audits, or full audits. These efforts will be in addition to the overall program monitoring and oversight strategy described in section V. Monitoring and Oversight, below.

V. Monitoring and Oversight

⁵⁷ 42 C.F.R. § 425.612(f).

⁵⁸ 42 C.F.R. § 425 Subpart F.

⁵⁹ American Medical Association. (2022). <u>Quality ID #483 (NQF 3568): Person-Centered Primary Care Measure Patient Reported</u> Outcome Performance Measure (PCPCM PRO-PM); measure questions available at https://www.green-center.org/pcpcm.

CMS will conduct monitoring activities to ensure the ACO PC Flex Model is being implemented appropriately by PC Flex ACOs. PC Flex ACOs will be subject to Shared Savings Program monitoring as well as additional monitoring under the model to ensure they are in compliance with the terms and conditions of the ACO PC Flex Participation Agreement. Beneficiaries assigned to a PC Flex ACO will remain in traditional Medicare and thus retain full traditional Medicare benefits and protections. This means that the ACO PC Flex Model guardrails would be in addition to longstanding traditional Medicare protections that allow beneficiaries to see any Medicare provider without prior authorization (or other constraints or limits) and ensure beneficiaries are notified that their provider is part of an ACO and that their Medicare benefits have not changed.

In addition to monitoring activities described in the general monitoring activities section below, the ACO PC Flex Model will monitor how PPCP funds were spent by PC Flex ACOs via PPCP Spend Plan reporting to ensure that funds are used to support primary care services.

A. Allowable Uses of PPCP, Reporting, and Monitoring

A PC Flex ACO must spend PPCP on the provision and support of advanced primary care (Category 1 expenditures) and, subject to certain limitations, the cost of operating the PC Flex ACO (Category 2 expenditures). An PC Flex ACO may not use PPCP for any other purpose (Category 3 expenditures). This section describes the permitted and prohibited uses of the PPCP as well as limits on the use of PPCP for certain categories of expenditures, reporting requirements for the use of the PPCP, and CMS monitoring of PPCP reports and PC Flex ACO use of the PPCP.

i. PPCP Expenditure Categories

Category 1 – Provision and Support of Advanced Primary Care

Category 1 expenditures are expenditures for the provision and support of an advanced level of primary care services. These expenditures reflect important components for improving primary care. The category is informed by experience in AIM, advance investment payments, previous CMS Innovation Center primary care models, and the literature on advanced primary care.

In addition to payment for the direct provision of primary care services payable under the Medicare Physician Fee Schedule, Category 1 expenditures include payments for care management, patient navigation, augmented primary care team services, other care coordination services, and behavioral health integration related to the delivery of primary care services. PC Flex ACOs may use PPCP to hire dedicated staff to support activities, such as identifying and addressing patients' health related social needs (HRSN), and to cover costs associated with establishing relationships with external providers to facilitate information sharing during care transitions. PPCP are meant to support enhanced care management and other primary care services which overlap with covered services under the Physician Fee Schedule.

Category 1 expenditures are directly or indirectly mappable to Physician Fee Schedule coded services in Table 3 (see Appendix D). For example, category 1A (replacement of fee-for-service revenue for PC Flex ACO Participants) corresponds in part to services where payments are zeroed out. Category 1C (HRSN screening and supports) corresponds in part to activities included in the definition of G0136 – SDOH risk assessment and G0019 and G0022 – community health integration services. Category 1E (health care practice infrastructure) may include new functionality in electronic health records (EHRs) to support care management registries and workflows that enable provision of care management services (99424-99427 for example).

We have broadly defined category 1 subcategories and provided illustrative examples. PC Flex ACOs will deploy PPCP funds to be compliant with the ACO PC Flex Participation Agreement and to support the required Spend Plan reporting described below. PC Flex ACOs may also confer with CMS to determine if a use is permissible within the scope of the permitted uses outlined within Category 1. Innovative and compliant uses that are proposed by PC Flex ACOs may be added as a permissible use within an existing subcategory in subsequent years, although use of PPCP funds for an innovative and compliant service is not contingent upon the item being listed as an example where it is otherwise consistent with a permissible spend category.

1.A. Replacement of fee-for-service revenue for PC Flex ACO Participants: This category is expected to be the largest category of expenditure. This includes payments to participating primary care providers who have entered into a payment arrangement with the PC Flex ACO and whose primary care claims are being zero-paid, to cover the set of primary care service billing codes paid under the Physician Fee Schedule, as described in Table 3 (see Appendix D). This category has two types:

- 1. Prospective Population-Based Payment or Capitation
- 2. Payment Based on Fee-for-Service Billings

1.B. Provision of Other Advanced Primary Care: Items in this category include: costs of third-party services for provision of advanced primary care such as care management, referral management, and patient event alert management. Unlike spend category 1A where PPCP is flowed to PC Flex ACO Participants, spending under 1B is by the PC Flex ACO for the benefit of PC Flex ACO Participants' assigned beneficiaries. Under 1B, the PC Flex ACO may spend PPCP for care management services at the ACO level (for all the ACO's assigned beneficiaries, rather than paying each practice for care management services).

1.C. HRSN Screening and Supports: Items in this category include costs of implementation of HRSN screening and referrals to community-based organizations (CBOs) to address HRSNs. PPCP may be used for screening and referral to CBOs to provide services to address HRSN; PPCP are not intended to fund the delivery of HRSN services. ⁶⁰ The funding for referral and CBO coordination services could be: 1) within the primary care practices that are part of the PC Flex ACO (PC Flex ACO Participants and ACO providers/suppliers as defined under the Shared Savings Program regulations), or 2) at the ACO level, in which the primary care practices have a contractual arrangement with the PC Flex ACO to fund screening and referral activities within the practices.

1.D. Behavioral Health Integration: Expenditures in this category include: hiring behavioral health providers and case managers to integrate behavioral health care into the primary care setting; referrals to behavioral health services; investments to support access to behavioral health services and specialists including those co-located within primary care settings and care teams; investments in primary care behavioral health integration and scope of practice including screening, intervention, referrals, and treatment.

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⁶⁰ CMS expects that the sorts of HRSN services that CBOs might offer to beneficiaries identified via this screening process might include: securing transportation services; housing-related services to address housing insecurity, home or environmental modifications to support a healthy lifestyle, legal aid services to help patients address social needs, employment-related services, food-related services, utilities-related supports, services to support personal safety, services to reduce social isolation, services to help patients cope with or address financial strain or poverty, patient caregiver supports, providing meals; ensuring individuals are able to access culturally and linguistically tailored, accessible health care services and supports that meet their needs. As noted Category 1C is intended to capture the use of the PPCP to implement screening and referral systems to identify beneficiaries who may require such HRSN services, not to fund the actual delivery of such services.

1.E. Expansion and Retention of Primary Care Workforce: Expenditures in this category include:

- Expansion of Primary Care Workforce: Examples include hiring practice nurse case managers, medical assistants, or other relevant support staff; hiring community health workers, certified peer recovery specialists, other health care professionals with training in delivering culturally and linguistically tailored. The increased staffing could be both within the primary care practices that are part of the ACO (PC Flex ACO Participants, ACO providers/suppliers as defined under the Shared Savings Program regulations)⁶¹ or at the ACO level to provide primary care staffing services and supports across PC Flex ACO Participants and primary care practices through contractual arrangements. Staffing support may be through a health professional staffing agency/company. Funds used for staffing must be used to support the provision of primary care services provided under the model.
- Retention of Primary Care Workforce: Examples include higher reimbursement rates or performance-based bonuses (bonuses tied to performance on outcomes or quality; not volumebased). This is intended to support the provision of primary care services and move away from feefor-service care and toward alternative payment arrangements that support time spent with patients.
- 1.F. Health Care Practice Infrastructure: Items in this category include: spending on certified electronic health record technology (CEHRT) (including system enhancements and upgrades), connections to clinical data registries and networks that support health information exchange across disparate providers and systems involved in patient care, integration of ACO participant systems including tools to share and analyze operational and quality data, remote access technologies, telemonitoring, screening tools, case management to improve care coordination operations across the health and social care continuum including coordination with CBOs, physical accessibility improvements, tools to further integrate dental services into primary care settings; systems to provide and track patient referrals, as well as enable coordination and measurement of health; and integration of systems to support coordination between primary care and specialty care including e-consults and data to support referral decisions. The funding could go directly to the primary care practices that are part of the PC Flex ACO (PC Flex ACO Participants, ACO providers/suppliers as defined under the SSP regulations)⁶² or at the ACO level to provide health care practice infrastructure across PC Flex ACO Participants through contractual arrangements.
- 1.G. Implementation of Evidence-based Protocols/Guidelines for Primary Care: Items in this category include: the implementation of standing orders and protocols for uncomplicated acute illnesses and chronic disease management, as well as encouraging non-clinician team members to use standardized workflows for patient care without requiring direct clinician intervention.

Category 2 – Operations of PC Flex ACO

Category 2 expenditures are administrative expenses of the PC Flex ACO that are related to an PC Flex ACO Participant's provision of primary care services but not Category 1 expenditures. Category 2 expenditures are less directly connected to Physician Fee Schedule coded services by virtue of them not being Category 1 expenditures; however, they are still related to an PC Flex ACO Participant's provision of primary care services. A prospective, population-based, or capitation payment is a replacement for the PC Flex ACO Participant's fee-for-service payment for primary care services. This may include non-physician labor costs

^{61 42} C.F.R. § 425.20.

^{62 42} C.F.R. § 425.20.

as well as the PC Flex ACO's administrative expenses. The allowed Category 2 expenditures below include management services that the PC Flex ACO provides to its PC Flex ACO Participants, workforce expenses, capital expenditures, and expenditures for certain professional services.

- Legal, actuarial, financial, analytic, or other professional services necessary to implement and
 maintain payment arrangements between the PC Flex ACO and PC Flex ACO Participants, including
 for the development and execution of agreements necessary for participation in the ACO PC Flex
 Model, determination of payment amounts under the model, processing of payments made under
 the model, and development and operation of reporting to support such payment arrangements.
- Development, maintenance, and operations related to required Spend Plan reporting described below in the Spend Plan reporting section.
- Support to PC Flex ACO Participants to facilitate incorporation of prospective payments into the revenue cycle or other financial systems of the PC Flex ACO Participant.
- Other ACO Administrative Costs.

Category 3 – Prohibited Uses of PPCP and Advance Shared Savings Payment

Category 3 expenditures are any expenditure not otherwise permitted under Category 1 or Category 2. Examples of Category 3 expenditures include:

- Management company, Parent Organization, affiliate, or similar business profit, markup, or fees;
- ACO executive bonuses;
- Items or services that are not reasonably related to one or more purposes of the PC Flex ACO and the Shared Savings Program;
- Expenses incurred prior to the start of the PC Flex ACO or incurred outside of the period they have been submitted for review (funding should be tracked and reported on a cash basis) except as otherwise described as permitted under the RFA;
- Imaging equipment or other revenue generating equipment;
- Interest or fees related to securing the repayment mechanism or payment of the repayment mechanism;
- Financial or gainsharing arrangements in which PPCP are tied to performance-based arrangements with conveners or other third parties;
- Payment of shared losses; and
- Any use not otherwise specified.

With the exception of certain expenses incurred prior to the start of the PC Flex ACO or start-up costs, all other examples listed are prohibited uses of the Advance Shared Savings Payment.

ii. Required Allocation Proportions of PPCP to Expenditure Categories

While we expect a large part of the PPCP will be allocated to Category 1 items and will support delivery of advanced primary care, a portion may be used to support the operation of ACO PC Flex Model features such as distribution of the PPCP to PC Flex ACO Participants and fulfillment of Spend Plan reporting requirements described below (uses covered under Category 2). Because some elements of Category 2 items require one-time implementation or development spend, PC Flex ACOs may use more of the PPCP on Category 2 items in the first year of receiving the PPCP than in subsequent years. The following table describes the required allocation proportions by spend category for first and subsequent years.

Table 4. Allocation Requirements by PPCP Payment Year

EXPENDITURE CATEGORY	FIRST PAYMENT YEAR	SECOND PAYMENT YEAR
1	At least 90%	At least 95%
2	Not more than 10%	Not more than 5%
3	0%	0%

As long as PC Flex ACOs satisfy the minimum spend requirements as described above (e.g. at least 90% of PPCP must be spent on Category 1 during performance years 1, at least 95% spent on Category 1 in subsequent performance years), there are no additional restrictions or limitations on when PPCP need to be spent by PC Flex ACOs. PC Flex ACOs are not required to spend all PPCP each performance year.

iii. Use of Advance Shared Savings Payment

The Advance Shared Savings Payment can be used for items in Expenditure categories 1 and 2, and there is no maximum percent that can be used on Expenditure Category 2. The purpose of the Advance Shared Savings Payment is to provide PC Flex ACOs with cash flow for start-up costs and initial acquisition or development of solutions to administer the PC Flex ACO and fulfill ACO PC Flex Model requirements. The Advance Shared Savings Payment cannot be used for items in Expenditure Category 3, with the exception that the Advance Shared Savings Payment can be used for start-up costs as described in the Spend Plan reporting templates.

iv. Spend Plan Reporting and Monitoring

PC Flex ACOs must submit reports that specify how the PC Flex ACO plans to spend and has spent PPCP and Advance Shared Savings Payment. PC Flex ACOs can only spend the PPCP on items specified in Expenditure Category 1 and 2, following the specified allocation requirements. Items in Expenditure Category 3 are prohibited uses of the PPCP.

Spend Plan Reporting Templates are a set of standardized data-entry tools, developed by CMS for the purpose of reporting on PPCP and Advance Shared Savings Payment use within Expenditure Categories, subcategories, and types. These templates will reduce administrative burden for PC Flex ACOs by establishing standardized categorization of PPCP and Advance Shared Savings Payment spend in a way that may be directly mapped from entries in Accounts Payable or other financial systems. Additionally, the standardization of this data will facilitate CMS use for monitoring and learning (see subsection d below).

- At time of Application and In Advance of Subsequent Performance Years Spend Plan: As part of
 the ACO PC Flex Model application (phase 2, see section <u>D. Application Process</u>) and prior to the start
 of performance year 2 and subsequent performance years, PC Flex ACOs will be required to submit
 a Spend Plan describing their intended use of the PPCP and the Advance Shared Savings Payment
 with percentage allocation to Expenditure Categories, subcategories, and types. CMS will review the
 initial Spend Plan as part of its disposition of the PC Flex ACO's application.
- Quarterly Short Form Spend Report: Quarterly, PC Flex ACOs will be required to submit a short form
 spend report that describes the PC Flex ACO's cash expenditure for the prior quarter with dollar
 amounts at the Expenditure Category, subcategory, and type level. This reporting will not require an
 PC Flex ACO to report the category distribution of funds by PC Flex ACO Participants (e.g., use of
 funds by PC Flex ACO Participants), but only what was flowed by the PC Flex ACO to PC Flex ACO
 Participants. Additionally, for Category 1, subcategory A (replacement of fee-for-service revenue),

- the PC Flex ACO will be required to report the type at the payee level (the PC Flex ACO Participant TINs and/or CCNs).
- Annual Long Form Spend Report: Annually, PC Flex ACOs will be required to gather information from PC Flex ACO Participants to report all uses by both the PC Flex ACO and PC Flex ACO Participants at the Expenditure Category, subcategory, and type level.

PC Flex ACOs may use the Advance Shared Savings Payment to cover start-up related expenses that predate the start of the ACO PC Flex Participation Agreement (that begins on 01/01/25), as long as use of the Advance Shared Savings Payment funds is consistent with the terms of the ACO PC Flex Participation Agreement and does not violate fraud and abuse laws. To the extent that PC Flex ACO Participants or ACO providers/suppliers receive any benefit from the Advance Shared Savings Payment (e.g., information technology infrastructure or other technology) that financial arrangement must be consistent with the terms of their ACO participant agreements and meet the requirements of an applicable ACO Shared Savings Program waiver or otherwise not violate fraud and abuse laws. See section II.C. Waiver and Safe Harbor Authority.

PC Flex ACOs must also be required to publish publicly all Spend Plan reporting, which ensures additional accountability and transparency in how the PC Flex ACOs are spending PPCP and Advance Shared Savings Payment to support the provision of primary care. In addition to ACO public reporting, we will also survey participating primary care providers to ensure that funds are flowing directly to providers.

CMS will monitor Spend Plan reporting to understand:

- Compliance with Spend Plan reporting timelines;
- Completeness of Spend Plan reporting;
- Compliance with required allocation proportions of PPCP to Expenditure Categories;
- Timeliness of spend in Expenditure Category 1, subcategory A (replacement of fee-for-service revenue for PC Flex ACO Participants);
- Annual Spend Plan versus actual spend variance; and
- Actual allocation of PPCP to Expenditure Categories, subcategories, and types.

Failure to meet the Spend Plan requirements will be considered non-compliance, subject to remedial action. Beyond compliance and corrective action, CMS will use the information from Spend Plan reporting to evaluate effectiveness of Expenditure Categories, subcategories, and types towards the goals of the ACO PC Flex Model as well as facilitate cross-ACO learnings via the national ACO PC Flex Model learning community.

A PC Flex ACO must maintain a bank account solely for the purpose of storing and disbursing Advance Shared Savings Payment and PPCP consistent with the use and reporting obligations described above.

B. General Monitoring Activities

In addition to the Spend Plan monitoring described above, CMS will also conduct general monitoring activities which will include the review of the following:

1. **Vetting Data:** Prior to the start of the model, applicant ACOs will be subject to a program integrity screening by the Center for Program Integrity to determine if they are eligible to participate in the model. This screen will occur annually thereafter for all PC Flex ACOs and at the time of any change in ACO's organizational structure (e.g., merger, acquisition).

- 2. **Roster Data:** ACOs will submit a roster that includes each ACO professional by NPI who is an NPP, designating each as "primary care" or "specialty care." NPPs designated on the roster as specialty practice NPPs by PC Flex ACOs will not have claims reduced for beneficiaries assigned to the ACO. See section IV.D. Fee Reductions for more information.
- 3. Cost, Utilization, Patient Survey, Care Delivery, Financial, and Quality Data: CMS will review cost, utilization, patient survey (e.g. PCPCM), care delivery, financial and quality data at least annually to identify PC Flex ACOs that are performing well, those that have low performance, and to monitor for compliance and potential violations of the model requirements. Electronic clinical quality measure submissions will also be monitored to help ensure PC Flex ACOs report quality data for all ACO professionals and claims data will be reviewed for potential stinting or increases in medically unnecessary care.

Regular program monitoring will also result in audits of select PC Flex ACOs. The audits will target high-risk areas and focus resources where the greatest exposure exists and return on investment can be maximized (e.g., crucial elements of the ACO PC Flex Model, potential harm to beneficiaries, possible adverse impact to program integrity, degree of misuse/improper payment, complaints from providers, care stinting). Primarily, audits will focus on, but not be limited to, the prevention, detection, and/or mitigation of improper payments and care deprivation to beneficiaries.

Analyses will be conducted using the data received from the PC Flex ACOs, environmental scans, and beneficiary and provider interactions, including but not limited to complaints. PC Flex ACOs with anomalies will be selected for audit. Audits will help determine if patient complexity levels, quality, and utilization scores can be substantiated.

The ACO PC Flex Participation Agreement will include CMS' rights to audit and the PC Flex ACOs will be informed of their selection for audit based on several factors such as continued noncompliance, complaints, or selection due to random sampling. PC Flex ACOs will be required to maintain copies of all documentation related to their use of ACO PC Flex Model funds and their work on ACO PC Flex Model requirements. CMS may conduct random audits or select a PC Flex ACO for audit based on data the ACO has submitted to CMS, the ACO's performance on utilization and quality measures, and other ACO information.

C. Remedial Actions

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

- Notify the PC Flex ACO and, if appropriate, the PC Flex ACO Participant of the violation;
- Require the PC Flex ACO to provide additional information to CMS or its designees;
- Conduct on-site visits, interview beneficiaries, or take other actions to gather information;
- Place the PC Flex ACO on a monitoring and/or auditing plan developed by CMS;
- Require the PC Flex ACO to remove an PC Flex ACO Participant from the ACO participant list and to terminate its arrangement, immediately or within a timeframe specified by CMS, with such PC Flex ACO Participant with respect to this model;
- Require the PC Flex ACO to terminate its relationship with any individual or entity performing functions or services related to ACO activities or marketing activities;
- Prohibit the PC Flex ACO from distributing shared savings to a PC Flex ACO Participant;

- Request a corrective action plan (CAP) from the PC Flex ACO that is acceptable to CMS, by a deadline established by CMS;
- Amend the ACO PC Flex Participation Agreement without the consent of the PC Flex ACO to deny, terminate, or amend the use of PPCP by the PC Flex ACO or PC Flex ACO Participants;
- Prohibit the PC Flex ACO from accessing any or all waivers of existing law made pursuant to section 1115A(d)(1) of the Act;
- Amend the ACO PC Flex Participation Agreement without the consent of the PC Flex ACO to deny
 the use of one or more benefit enhancements and to require that the PC Flex ACO terminate any
 agreements effectuating such benefit enhancements by a date determined by CMS;
- Prohibit the PC Flex ACO or an PC Flex ACO Participant from furnishing any in-kind remuneration or from implementing one or more beneficiary incentive payments;
- Discontinue the provision of data sharing and reports to the PC Flex ACO;
- Prohibit the PC Flex ACO from distributing marketing materials, or conducting marketing activities, including voluntary assignment activities;
- Retroactively reverse the assignment of beneficiaries to the PC Flex ACO that is based solely on voluntary assignment; and
- Terminate the PC Flex ACO from the model for continued non-compliance and failing to remediate issues as set forth in the ACO PC Flex Participation Agreement.

D. Data Sharing and Reports

i. Data Sharing Strategy

CMS will provide historical and monthly claim and claim line feeds to PC Flex ACOs using tools already developed for the Shared Savings Program and CMS Innovation Center Models such as the ACO REACH Model. All information will be provided consistent with all applicable laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and the Part 2 regulations governing the use of information regarding diagnosis and treatment for substance use disorder.

Specifically, and upon a PC Flex ACO's request, pursuant to a HIPAA-covered data disclosure request and attestation (DRA) form, CMS will make available several types of Medicare beneficiary-identifiable data for the sole purposes of developing and implementing activities related to coordinating care and improving the quality and efficiency of care for ACO PC Flex Model assigned beneficiaries (as described in the first and second paragraphs of the definition of "health care operations" under the HIPAA Privacy Rule at 45 C.F.R. 164.501). Additionally, CMS will provide Medicare data to PC Flex ACOs for calculating payments to PC Flex ACO Participants and ACO providers/suppliers.

Upon request from the PC Flex ACO and execution of a DRA, CMS will provide (1) data on assigned beneficiaries that will include individually identifiable demographic and Medicare eligibility status information and various summary reports with data relevant to ACO PC Flex Model operations and performance in the Model; and (2) detailed claims data files that will include individually identifiable claim and claim line data for services furnished by Medicare-enrolled providers and suppliers to assigned beneficiaries. Historical data files for assigned beneficiaries will be limited to the baseline years (i.e., three years prior to the performance year), consistent with other CMS Innovation Center models and ACO initiatives. Additionally, CMS will provide data to PC Flex ACOs, such as chronic condition-focused episode-based cost measures (EBCMs) and shadow bundles to enable PC Flex ACOs to better assess specialist performance.

In accordance with the HIPAA regulations,⁶³ CMS may make available de-identified beneficiary data to PC Flex ACOs for the express purpose of submitting such data to approved local multi-purchaser databases in order to support comprehensive performance assessment by the PC Flex ACO or its PC Flex ACO Participants. CMS will use the exceptions under HIPAA's permissible use to share data with its covered entities (CE) and business associates (BA) of CE. As specified above, CMS intends to share data for health care operations and payments purposes with PC Flex ACOs.

The data and reports provided to the PC Flex ACOs shall not include individually identifiable data for assigned beneficiaries who have opted out of data sharing with the PC Flex ACO. Moreover, CMS will honor the data sharing opt-out decisions by beneficiaries who made that decision while an assigned beneficiary in another Medicare ACO initiative. The ACO PC Flex Model will follow the Shared Savings Program's beneficiary notification process. PC Flex ACOs will be required to notify newly assigned beneficiaries at the beginning of the performance year regarding the organization's intent to request their claims data from CMS or to provide information or forms regarding the opportunity to decline data sharing. Data sharing will be offered to PC Flex ACOs in accordance with HIPAA for all assigned beneficiaries who were either: (1) not previously assigned to any Shared Savings Program ACO; (2) previously assigned to a PC Flex ACO but did not opt out of data sharing; or (3) de-assigned during the performance year and also assigned at some point during the year (i.e., only for the period in which they were assigned).

In addition to the data mentioned above and the reports listed below, PC Flex ACOs will receive claims and payment information from CMS for the services furnished to assigned beneficiaries by their PC Flex ACO Participants. This information will be sent from CMS to the organization on a periodic basis, at a minimum of once per month.

CMS will provide PC Flex ACOs with reports on a regular basis. PC Flex ACOs will continue to receive reports generated by the Shared Savings Program,⁶⁵ and receive additional ACO PC Flex Model-specific reports. Data reports will provide program performance and program payment data to PC Flex ACOs for performance management and for program cost and savings analyses. The reports may include quarterly and annual utilization; monthly expenditures; and beneficiary assignment. We may be enhancing this functionality, possibly through more frequent feedback, or by leveraging an online data feedback tool developed for the Shared Savings Program, the ACO REACH Model or other CMS Innovation Center models.

ii. Reports

Under Shared Savings Program regulations,⁶⁶ any entity participating in the testing of a CMS Innovation Center model is required to collect and report such information, including "protected health information,"⁶⁷ determined necessary to monitor and evaluate the model. In alignment with the CMS Innovation Center's 2022 Strategic Refresh, PC Flex ACOs must collect beneficiary-level or aggregate level information on race, ethnicity, geography, disability, and certain other demographics as well as HRSN data for all assigned beneficiaries. PC Flex ACOs will also be required to submit this data to CMS. The data will be used to understand and monitor the model impacts on health disparities and to stratify patient outcomes on demographic and HRSN measures.

⁶³ 45 C.F.R. § 164.514(b).

^{64 45} C.F.R. § 425.312.

^{65 42} C.F.R. § 425 Subpart H.

^{66 42} C.F.R. § 403.1110(b).

⁶⁷ 45 C.F.R. § 160.103.

VI. Evaluation

A PC Flex ACO must cooperate with efforts to conduct an independent, federally funded evaluation of the model by CMS and/or its designees, which may include: participation in surveys; interviews; site visits; and other activities (e.g. data collection) that CMS determines necessary to conduct a comprehensive, formative and summative evaluation. The evaluation will assess the impact of the ACO PC Flex Model on the goals of better health care outcomes, better health care delivery, and lower per-beneficiary expenditures. The evaluation will be used to inform policymakers about the effect of the ACO PC Flex Model concepts. To do so, the evaluation will seek to understand the behaviors of providers, suppliers, and beneficiaries, as well as the impacts of PPCP on Medicare expenditures, beneficiary experience, and key health care outcomes for Medicare fee-for-service beneficiaries, including among underserved communities. The evaluation will use beneficiary-level demographic data and data on SDOH submitted to CMS by ACOs to compare how ACOs perform on cost and quality metrics across specific subpopulations of beneficiaries, distinguished by demographic factors and presence of SDOH. Each PC Flex ACO must require its PC Flex ACO Participants to participate and cooperate in any such independent evaluation activities conducted by CMS and/or its designees. If a PC Flex ACO does not provide the data necessary for CMS and/or its designees to complete the evaluation, upon request, CMS may terminate its ACO PC Flex Participation Agreement.

VII. Information Resources for Beneficiaries and Providers

The primary resource for beneficiaries with questions about the ACO PC Flex Model will be 1-800-MEDICARE. CMS has developed scripts for customer service representatives (CSRs) that will answer anticipated questions related to the model. Questions that CSRs cannot answer will be triaged to CMS Regional Offices. PC Flex ACOs will also be required to establish processes to answer beneficiary queries. Finally, CMS will maintain an email inbox for inquiries related to the ACO PC Flex Model at ACOPCFLEX@cms.hhs.gov.

VIII. Application Review, Scoring and Selection

A panel of experts will form a technical evaluation panel (TEP) to review and score complete applications from eligible applicant ACOs. The TEP may include individuals from the Department of Health and Human Services (HHS) and HHS contractors with expertise in primary care payment policy, care improvement and care coordination. Final selection for participation in the model will be based on an assessment of the four domains listed below, as well as applicant ACO screening, eligibility and assessments of program integrity risks outlined below. CMS may choose to interview applicant ACOs and/or conduct pre-selection reviews of applicant ACOs during the application process to better understand ACO participants and the individuals and entities the applicant ACO expects will be participating primary care providers.

Eligibility Screening and Completeness Review

Applications will be screened to determine if the applicant ACO has met the minimum model eligibility requirements, as outlined in section III.C. Applicant Eligibility. Applications deemed eligible will be reviewed

⁶⁸ In accordance with 42 C.F.R. § 403.1110(b), "Any State or other entity participating in the testing of a model under section 1115A of the Act must collect and report such information, including 'protected health information' as that term is defined at 45 C.F.R. 160.103, as the Secretary determines is necessary to monitor and evaluate such model. Such data must be produced to the Secretary at the time and in the form and manner specified by the Secretary."

for completeness to determine if an applicant ACO provided answers for all required questions and to check for the presence of required attachments. Applications will also be reviewed for inconsistencies among an applicant ACO's applications response, such as, a mismatch in the applicant ACO's name between narrative answers and entity information. Reviewers will consider the degree to which instances of incompleteness or inconsistencies materially impact their ability to score a question against the scoring criteria. Applications that cannot be sufficiently scored will be considered ineligible and removed from consideration.

Program Integrity Screening

CMS will conduct a multi-step process to assess an applicant ACO or ACO participant, at both organizational and provider levels, on their eligibility and appropriateness for participation in the model. Beyond the screening of applicant ACOs, ACO participants, and ACO providers/suppliers performed during the Shared Savings Program application process⁶⁹, CMS will include supplemental program integrity screening and reviews related to the applicant's Parent Organization (if applicable), ownership structure, executive leadership team, and governing board membership.

- Organizational Screening: CMS will review the program integrity history of the applicant ACO including relevant owners, executive leaders, and governing body members. The purpose of organizational screening is to establish an informed, non-arbitrary assessment of an applicant ACO's suitability for the model and identify risks related to business practices, solvency, and program integrity.
- 2. **Environmental Screening:** CMS will perform environmental scans by searching public and private sources to identify potential issues and risks associated with an applicant ACO. This information will augment CMS' assessment of an applicant ACO's appropriateness for model participation.

CMS may deny selection to an applicant ACO on the basis of information found during a program integrity (PI) review of the applicant ACO or any other relevant individuals or entities associated with the applicant ACO. The PI review may include the following, without limitation, with respect to the applicant ACO, Persons or Entities With An Ownership Or Control Interest (as that term is defined in <u>Appendix A</u>) in the applicant ACO, Key Executives (as that term is defined in <u>Appendix A</u>), equity partners (e.g., private equity or venture capital), and individuals and entities that the applicant ACO expects will be primary care providers:

- Identification of delinquent Federal debt;
- Review of performance in, and compliance with the terms of, other CMS Innovation Center models, demonstration programs, and initiatives; and
- Confirmation that the applicant ACO has not engaged in anti-competitive practices.

Application Scoring Criteria

CMS will assess and score ACO PC Flex Model applications in accordance with specific criteria in four key domains: (1) organizational readiness; (2) revenue sources and payment arrangements; (3) patient centeredness and beneficiary engagement; and (4) data and health information. Each application will be assessed on a score out of 100 points. Reviewers will assign points based on scoring criteria developed by CMS and provided to the TEP.

As part of the ACO PC Flex Model application process, applicant ACOs will be asked questions specific to their proposed use of the Advance Shared Savings Payment and implementation of the PPCP. Acceptance

⁶⁹ 42 C.F.R. § 425.305.

into the ACO PC Flex Model is not contingent upon an applicant ACO implementing any particular payment arrangement. Responses to questions regarding proposed implementation of the PPCP will assess interest in model design elements, the degree to which an applicant ACO promotes the goals of the model and will assist with CMS planning and model implementation. For example, an applicant ACO might demonstrate promotion of the model goals to enhance the predictability, amount of funding and flexibility for primary care providers by moving away from fee-for-service, visit-based payment approaches in their downstream payment arrangements with providers towards more population-based mechanisms, such as capitation.

Recommendation and Selection

CMS will limit the total number of applicant ACOs accepted to participate in the ACO PC Flex Model to 130. If there are no more than 130 suitable applicant ACOs, CMS will accept those applicant ACOs that, based on the assessment of the TEP, meet the required criteria for eligibility, scoring, and appropriateness for participation in the model. If there are more than 130 suitable applicant ACOs, CMS Innovation Center will prioritize acceptance into the model of those applicant ACOs who, in addition to the above, score highest on the application rubric. Depending on the volume of suitable applicant ACOs, CMS may consider additional methods for selecting PC Flex ACOs. For example, if, after review by the TEP and prioritization based on score, the number of suitable applicant ACOs still exceeds the number of ACOs that can be allowed to participate, CMS may consider randomly selecting applicant ACOs for participation in the model.

IX. Duration of ACO PC Flex Model

The ACO PC Flex Model consists of five performance years (performance year 2025-performance year 2029). Performance years each last 12 months and align with calendar years. CMS may modify or terminate the model at any time if it is determined that it is not achieving the aims of the initiative or as required under section 1115A of the Social Security Act.

X. Learning and Diffusion Resources

CMS will support PC Flex ACOs and their primary care practices (PC Flex ACO Participants, ACO providers/suppliers as defined under the Shared Savings Program regulations)⁷⁰ in accelerating their progress by providing them with opportunities to both learn about achieving performance improvements and share experiences with one another and with participants in other CMS initiatives. This will be accomplished through a "learning system" for PC Flex ACOs. The learning system will use various group-learning approaches to help PC Flex ACOs effectively share experiences, track progress, and rapidly adopt new methods for improving quality, efficiency, and population health. PC Flex ACOs are required to participate in the learning system by attending periodic conference calls and meetings and actively sharing tools and ideas.

XI. Public Reporting

The ACO PC Flex Model emphasizes transparency and public accountability. PC Flex ACOs will be subject to Shared Savings Program public reporting requirements.⁷¹ PC Flex ACOs will also be required to publicly report information regarding their (1) organizational structure, including identification of the members of

⁷⁰ 42 C.F.R. § 425.20.

⁷¹ 42 C.F.R. § 425.308.

the ACO's governing body and PC Flex ACO Participants, as well as equity holders; (2) shared savings and shared losses information; (3) performance on the quality measures; and (4) Spend Plans. Specific public reporting requirements will be described in the ACO PC Flex Participation Agreement.

XII. Remedial Action & Termination

CMS may take remedial action against a PC Flex ACO at any time, such as through a notice of remedial action (NRA). An NRA may be imposed when a PC Flex ACO fails to comply with the terms of the ACO PC Flex Participation Agreement. An NRA may either notify the PC FLEX ACO of the noncompliance or may require an ACO to remedy the situation within a reasonable time frame established by CMS, so that the PC Flex ACO may come into compliance with the terms, conditions and requirements of the ACO PC Flex Participation Agreement. In addition to remedial action, CMS may terminate a PC Flex ACO from the model if the PC Flex ACO fails to correct the issue or displays continued non-compliance with the terms, requirements, and conditions as set forth in the ACO PC Flex Participation Agreement.

Notwithstanding the NRA process described above, CMS reserves the right to terminate ACOs at any time from the model for any failure to comply with the requirements in the ACO PC Flex Participation Agreement. The ACO PC Flex Model will implement the following termination policy similar to that established under the Track 1+ model: if PC Flex ACOs are terminated from the ACO PC Flex Model, the PC Flex ACOs are terminated from the Shared Savings Program as well (PC Flex ACOs will not automatically transition back to the Shared Savings Program and would need to follow the Shared Savings Program's processes to reapply). If a PC Flex ACO or CMS terminates the ACO PC Flex Participation Agreement during the agreement period in which the PC Flex ACO received PPCP, the ACO must repay the enhanced portion of the PPCP. The ACO PC Flex Model will follow the Shared Savings Program's policies for early termination by the ACO.⁷²

An PC Flex ACO must provide at least 30 days advance written notice to CMS and its PC Flex ACO Participants of its decision to terminate the ACO PC Flex Participation Agreement and the effective date of its termination. If the PC Flex ACO participated under a two-sided model, and if the effective date of termination is June 30th or prior, the ACO will not be liable for shared losses for that performance year. If the PC Flex ACO participated under a two-sided model, and if the effective date of termination falls after June 30th of a 12-month performance year, the PC Flex ACO will be liable for a pro-rated share of any shared losses during that performance year. Regardless of whether the effective date of termination is prior to or after June 30th, the PC Flex ACO must repay the enhanced portion of the PPCP. CMS will provide written notification to the PC Flex ACO of the amount due and the PC Flex ACO must pay such amount no later than 90 days after the receipt of such notification.

If CMS terminates an ACO PC Flex Participation Agreement for any compliance related reason at any point during participation in the model, the PC Flex ACO must repay all of the Advance Shared Savings Payment. CMS will provide written notification to the PC Flex ACO of the amount due and the PC Flex ACO must pay such amount no later than 90 days after the receipt of such notification.

If a PC Flex ACO voluntarily terminates its ACO PC Flex Participation Agreement during the agreement period, CMS will recoup the Advance Shared Savings Payment on a prorated basis. Upon completion of each year of participation, the PC Flex ACO may keep one fifth of the total amount of the Advance Shared Savings

^{72 42} C.F.R. § 425.220 ; 42 C.F.R. § 425.221.

⁷³ 42 C.F.R. § 425.221(b)(2)(iii)(A).

Payment. CMS will provide written notification to the PC Flex ACO of the amount due and the PC Flex ACO must pay such amount no later than 90 days after the receipt of such notification. If the PC Flex ACO terminates prior to completing the first performance year, the entire Advance Shared Savings Payment will be owed to CMS.

Appendix A. Key Terminology

ACCOUNTABLE CARE ORGANIZATION (ACO): Has the meaning given at § 425.20 and refers to a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law, is identified by a TIN and is formed by one or more ACO participants(s).

ACO ADMINISTRATIVE COSTS: Costs necessary for the maintenance of the ACO's participation in the ACO PC Flex Model.

ACO-MS: The ACO Management System (ACO-MS) is the online system in which ACOs complete all Shared Savings Program application related activities.

ACO PARTICIPANT: Has the meaning given at § 425.20 and refers to an entity identified by a Medicare-enrolled billing TIN through which one or more ACO providers/suppliers bill Medicare, that alone or together with one or more other ACO participants compose an ACO, and that is included on the list of ACO participants.

ACO PARTICIPANT AGREEMENT: Has the meaning given at § 425.20 and refers to the written agreement (as required at § 425.116) between the ACO and ACO participant in which the ACO participant agrees to participate in, and comply with, the requirements of the Shared Savings Program.

ACO PC FLEX PARTICIPATION AGREEMENT: Refers to the written agreement between the ACO and CMS that governs the ACO's participation in the ACO PC Flex Model.

ACO PROVIDER/SUPPLIER: Has the meaning given at § 425.20 and refers to an individual or entity that meets all of the following: is a provider (as defined at § 400.202); or supplier (as defined at § 400.202), is enrolled in Medicare, bills for items and services furnished to Medicare fee-for-service beneficiaries during the Shared Saving Program agreement period under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations, and is included on the list of ACO providers/suppliers.

ACO PROFESSIONAL: Has the meaning given at § 425.20 and refers to an individual who is Medicare-enrolled and bills for items and services furnished to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations and who is either (1) a physician legally authorized to practice medicine and surgery by the State in which he or she performs such function or action or (2) a practitioner who is a physician assistant, nurse practitioner, or clinical nurse specialist.

ADVANCE INVESTMENT PAYMENTS: Has the meaning given at § 425.20 and refers to a Shared Savings Program prepayment of shared savings of \$250,000 and two years of quarterly payments. Advance Investment Payments are intended to encourage low revenue ACOs that are inexperienced with risk to participate in the Shared Savings Program and to provide additional resources to such ACOs to support care improvement for underserved beneficiaries.

ADVANCE SHARED SAVINGS PAYMENT: One-time, \$250,000, payment to help cover costs associated with forming an ACO (where relevant) and administrative costs for model activities. Advance Shared Savings Payment will be deducted from shared savings each performance year until the full \$250,000 is repaid, and any balance owed will be carried over from performance year to performance year.

APPLICANT ACO: An ACO that is applying to participate in the ACO PC Flex model.

ASSIGNMENT: Has the meaning given at § 425.20 and refers to the operational process by which CMS determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from ACO professionals so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care during a given benchmark or performance year.

ASSIGNMENT STEP: The particular step of the stepwise assignment methodology that assigned a beneficiary into the ACO.

- "Step 1" means that a beneficiary is assigned based on primary care services with primary care physicians during the assignment window.
- "Step 2" means that a beneficiary was not assigned based on "Step 1" and was assigned based on primary care services with specialist physicians during the assignment window.
- "Step 3" means that a beneficiary was not assigned based on "Step 1" or "Step 2" and was assigned based on primary care services with a physician during the extended assignment window and primary care services with an NPP during the assignment window.

Detailed description of the stepwise assignment methodology is found at § 42 CFR 425.402(b).

APPLICATION DISPOSITION: The status of an applicant ACO as they move through the screening, scoring, and selection process.

COUNTY BASE RATE: One of two components of the PPCP. The County Base Rate is the county average primary care spending on the CPT/HCPCs codes for all assignable Medicare beneficiaries in each county, billed by primary care clinicians in a historical period.

COUNTY ENHANCEMENT: Used to increase the PPCP base rate and is applied at the county level in counties designated as low spending relative to standardized spending nationally. The County Enhancement will reduce geographic variation in primary care utilization nationally by increasing county-level funding for primary care in underserved counties.

EARLY RENEWAL APPLICANT ACO: Has the meaning given at § 425.20 and refers to an ACO currently participating in the Shared Savings Program that elects to voluntarily terminate its ACO participation agreement with an effective date of termination of December 31st of the current performance year and is applying to participate in a new agreement period starting on January 1st of the upcoming calendar year without a break in participation.

ENHANCED AMOUNT: To increase investment in ACO PC Flex primary care professionals, there are two payment enhancements: (1) the County Enhancement applied in counties designated as low spending relative to standardized national spending and (2) the Flex Enhancement, applied to all PC Flex ACOs.

ENHANCEMENT CREDIT (TOTAL): The total value of the adjusted County Enhancement and Flex Enhancement offset by the greater of positive regional adjustment to benchmark and prior savings adjustment to benchmark. This positive credit is applied at settlement to compensate for the inclusion of these enhancements in total expenditure.

EXPENDITURE CATEGORIES: A PC Flex ACO must spend PPCP on the provision and support of advanced primary care (Category 1 expenditures) and, subject to certain limitations, the cost of operating the ACO

(Category 2 expenditures). A PC Flex ACO may not use PPCP for any other purpose (Category 3 expenditures).

FINANCIAL BENCHMARK: Has the meaning given at § 425.20 and refers to the cost target used to assess an ACO's financial performance, and eligibility for an earned shared savings payment.

FLEX ENHANCEMENT: One of two components of the PPCP. The Flex Enhancement is applied at the ACO level to all PC Flex ACOs and will not be subject to recoupment based on the PC Flex ACO's performance in achieving shared savings.

FQHC FOCUSED CARE (BENEFICIARIES WITH): Beneficiaries assigned to the PC Flex ACO who during the first assignment run of the performance year received the plurality of primary care services, based on Medicare allowed amounts, at FQHCs.

HIGH REVENUE ACO: Has the meaning given at § 425.20 and refers to an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is at least 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

INITIAL APPLICANT ACO: Has the meaning given at § 425.20 and refers to an ACO that is applying to participate in the Shared Savings Program that is not considered to have previously participated in the Shared Savings Program.

KEY EXECUTIVES: Individuals who manage or have oversight responsibility for the organization, its finances, personnel, quality improvement, and compliance, including without limitation, a Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Operations Officer (COO), Chief Informational Officer (CIO), medical director, compliance officer, or an individual responsible for maintenance and stewardship of clinical data.

LOW REVENUE ACO: Has the meaning given at § 425.20 and refers to an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is less than 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

OTHER MONIES OWED: Any monetary amount owed to CMS by the ACO or vice versa that is neither shared savings nor shared losses.

ONE-SIDED MODEL: Has the meaning given at § 425.20. and refers to a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, but is not liable for sharing any losses incurred.

OWNERSHIP INTEREST: Possession of equity in the capital, the stock, or the profits of the subject entity.

PARTICIPATION AGREEMENT: Has the meaning given at § 425.20 and refers to the written agreement between required under § 425.208(a) between the ACO and CMS that, along with the regulations in § 425 govern the ACO's participation in the Shared Savings Program.

PARTICIPANT LIST: Has the meaning given at § 425.20 and refers to a list that identifies all of an ACO's participants. An ACO must certify its ACO participant list as accurate prior to the start of its participation agreement with CMS and annually thereafter before the start of the next performance year.

PARENT ORGANIZATION: Parent Organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in an organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

PC FLEX ACO: An ACO that is participating in the ACO PC Flex Model.

PC FLEX ACO PARTICIPANT: An entity identified by a Medicare-enrolled billing TIN through which one or more ACO providers/suppliers bill Medicare, that alone or together with one or more other ACO participants compose an ACO that is participating in the ACO PC Flex Model, and that is included on the list of ACO participants.

PERFORMANCE-BASED RISK: An initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period.

PERFORMANCE YEAR: Has the meaning given at § 425.20 and refers to the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise noted in the participation agreement.

PERSON OR ENTITY WITH AN OWNERSHIP OR CONTROL INTEREST: A person or entity that (1) has an Ownership Interest equal to 5 percent or more in the subject entity; (2) has an indirect Ownership Interest equal to 5 percent or more in the subject entity; (3) has a combination of direct and indirect Ownership Interests equal to 5 percent or more in the subject entity; or (4) has an Ownership Interest equal to 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by a subject entity if that interest equals at least 5 percent of the value of the property or assets of the subject entity.

PPCP ELIGIBLE BENEFICIARY: A beneficiary assigned to the PC Flex ACO for whom the ACO is eligible to receive the PPCP. In both prospective assignment and preliminary prospective assignment with retrospective reconciliation, beneficiaries assigned to the PC Flex ACO via "Step 2"⁷⁴ are not PPCP eligible beneficiaries. Additionally, for PC Flex ACOs who select preliminary prospective assignment with retrospective reconciliation, only beneficiaries who are assigned at the beginning of the performance year and are not subsequently assigned out of the PC Flex ACO later in the performance year are PPCP eligible beneficiaries. Beneficiaries who are assigned to the PC Flex ACO after the first assignment run are not PPCP eligible beneficiaries for that performance year.

PRIMARY CARE DELIVERED OUTSIDE OF THE ACO (PCOA): Includes any services a beneficiary receives from a provider who is not an ACO professional. To accommodate ACO variability along this dynamic, the ACO PC Flex Model financial methodology will include an adjustment based on each PC Flex ACO's historical

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⁷⁴ 42 C.F.R. Part 425.

experience of primary care delivered by providers that are not a part of that specific PC Flex ACO.

PRIMARY CARE PROSPECTIVE ADMINISTRATIVE TREND (PCPAT): Trend reflecting growth in reimbursement per fee-for-service enrollee for Physician Fee Schedule services, which is applied to the adjusted PBPM rate to calculate the final trended adjusted PBPM rate.

PRIMARY CARE SERVICES: Has the meaning given at § 425.20, where it is defined as the set of services identified by the HCPCS and revenue center codes designated under § 425.400I. The current list of codes for the ACO PC Flex Model are reproduced for convenience in <u>Appendix D</u>.

PRIMARY CARE PROVIDER: Refers to an ACO professional (with the meaning given at § 425.20, defined above), where the professional is designated by the ACO as working in a primary care capacity and is either:

- 1. A physician who has a primary care specialty designation of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine; or
- 2. A practitioner who is a physician assistant, nurse practitioner, or clinical nurse specialist.

RE-ENTERING APPLICANT ACO: Has the meaning given at § 425.20 and refers to an ACO that either previously participated in the Shared Savings Program and is applying to participate in the Shared Savings Program after a break in participation, or that CMS determines to be re-entering because greater than 50 percent of their ACO participants have prior participation in the same Shared Savings Program ACO in any of the five most recent past performance years.

RENEWAL APPLICANT ACO: Has the meaning given at § 425.20 and refers to an ACO currently participating in the Shared Savings Program that is in the final performance year of its most recent ACO participation agreement and is applying to renew its participation for a new agreement period starting on January 1st of the upcoming calendar year without a break in participation.

REQUEST FOR INFORMATION (RFI): The process through which CMS gives ACOs the opportunity to correct deficiencies and/or make updates or modifications to the ACO Shared Savings Program application or change request(s). Shared Savings Program RFIs are issued in ACO-MS, and ACOs must respond to RFIs in ACO-MS.

RHC FOCUSED CARE (BENEFICIARIES WITH): Beneficiaries assigned to the PC Flex ACO who during the first assignment run of the performance year received the plurality of primary care services, based on Medicare allowed amounts, at RHCs.

SHARED SAVINGS PROGRAM AGREEMENT PERIOD: The term of the Shared Savings Program participation agreement.

SNF 3-DAY RULE WAIVER: Has the meaning given at § 425.20. and refers to a waiver of the requirement for a 3-day inpatient hospital stay prior to a Medicare-covered, post-hospital, extended-care service for eligible beneficiaries if certain conditions are met.

SPEND PLAN: Specifies how the PC Flex ACO intends to spend the PPCP and Advance Shared Savings Payment.

TAXPAYER INDENTIFICATION NUMBER (TIN): Has the meaning given at § 425.20 and refers to a Federal taxpayer identification number or employer identification number.

TOTAL ENHANCEMENT: Combined value of the County Enhancement and Flex Enhancement on a PCPM basis after application of adjustments, trend, and the cap on enhancement. This amount is the Total Enhancement subject to offset by the greater of the positive regional adjustment and prior savings adjustment at settlement.

TOTAL ENHANCEMENT CREDIT: Is an ACO PC Flex modification applied to settlement after sequestration added to increase shared savings, reduce shared losses, or shift shared losses to shared savings.

TWO-SIDED MODEL: Has the meaning given at § 425.20 and refers to a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred.

UNDERSERVED COMMUNITY: Populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life. We derive this definition from the definition of "underserved communities" provided in <u>Executive Order</u> 13895. Executive Order 13895 provides a list of communities who exemplify its definition of "underserved communities" by referencing, within such definition, the definition it provides for "equity."

Appendix B. ACO PC Flex Model Application Questionnaire

The ACO Primary Care Flex Model (ACO PC Flex Model) is a voluntary model for low revenue Accountable Care Organizations (ACOs) (as defined under 42 CFR § 425.20) that will focus on primary care delivery in the Medicare Shared Savings Program (Shared Savings Program). It will test whether prospective payments and increased funding for primary care in ACOs will positively impact health outcomes, quality and costs of care. The flexible payment design aims to empower participating ACOs and their primary care providers to utilize more innovative, team-based, person-centered and proactive approaches to care.

CMS provides no opinion on the legality of any contractual or financial arrangement that the applicant may disclose, propose, or document in this application. The receipt by CMS of any such information in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules, or regulations, and will not preclude CMS, HHS, the HHS Office of Inspector General, a law enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules, and regulations.

Questions about the application for the PC Flex Model should be directed to ACOPCFlex@cms.hhs.gov.

ACO LEGAL ENTITY INFORMATION	

Confirm ACO Legal Entity Information

- 1. Confirm the following information from your Shared Savings Program:
 - a. Relationship to Medicare Shared Savings Program (Shared Savings Program)
 - Initial (new & re-entering ACO that has break in participation)
 - Renewal (both regular and early renewal)
 - b. Applicant Organization Information:

Note: If your organization is not listed in the "Legal Entity Name" search, choose "+ New Organization" to add a record. Contact the CMMI Help Desk at CMMIForceSupport@cms.hhs.gov to make changes to the existing organizational information.

- ACO ID:
- Legal entity name:
- Trade name/doing business as (DBA) name:
- Street Address:
- City:
- State:
- Zip Code:
- Taxpayer identification number (TIN):

ACO Organization Profile

- 2. Identify what type of entity best describes the applicant ACO. (Note: describe the applicant ACO itself, not the individuals and entities the applicant ACO expects will provide Primary Care Services). Check only one:
 - Medical group practice
 - Network or group of physician practices (e.g. an Independent Practice Association, or IPA, with a contractual agreement to provide health care for patients in a health plan network or integrated system)
 - Hospital system(s)
 - Integrated delivery system
 - Partnership of hospital system(s) and medical practices
 - Management services organization / 'convener' (i.e., an organization that provides administrative and supportive services to facilitate the participation of Medicare-enrolled providers or suppliers in value-based care).
 - Insurer
 - Other (please describe):
- 3. Provide an executive summary describing the applicant ACO including: a narrative description of entities and individuals that comprise the ACO, the history / context surrounding the formation of the ACO, the ACO's strategy and goals, the ACO's planned focus (geographic, beneficiary populations, planned care coordination, etc.), and the historical and expected role of the applicant ACO relative to the individuals and entities the applicant ACO expects will be primary care providers (e.g., the ACO's experience providing direct patient care vs providing supportive services to Medicare healthcare providers). (6000 characters)
- 4. Fill in the appropriate applicant ACO details in the table if the applicant ACO:
 - Has applied but not participated in any of the listed models, either on its own behalf or on behalf of any other organization.
 - Currently is (or was formerly) operated, managed, or led by an entity that is participating (or formerly participated) in any of the listed models.
 - Select the checkbox below the table if the applicant ACO has never applied for or participated in any of the models listed.
 - Accountable Health Communities Model
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn
 - ACO Investment Model (AIM)
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
 - Advance Payment ACO Model
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
 - Bundled Payment for Care Improvements (BPCI) Model
 - Contract ID number (if applicable):
 - Application or Participation date(s):

- Application Response: Accept, Deny, Withdrawn:
- Bundled Payment for Care Improvements (BPCI) Advanced Model
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Care Management for High-Cost Beneficiaries Demonstration
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Comprehensive ESRD Care (CEC) Model
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Comprehensive Kidney Care Contracting (CKCC) Options of the Kidney Care Choices (KCC) Model
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Comprehensive Primary Care (CPC) Initiative
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Comprehensive Primary Care Plus (CPC+) Model
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Independence at Home Medical Practice Demonstration (IAH)
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Kidney Care First (KCF) Option of the KCC Model
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Maryland Total Cost of Care Model, Maryland Primary Care Program
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Medicare Health Care Quality Demonstration Programs (including Indiana Health Information Exchange and North Carolina Community Care Network)
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Medicare Shared Savings Program (Shared Savings Program)
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:

- Multi-payer Advanced Primary Care Practice Demonstration with a Shared Savings arrangement (MAPCP)
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Next Generation ACO (NGACO) Model
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Nursing Home Value-Based Purchasing Demonstration
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Program of All-Inclusive Care for the Elderly (PACE)
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Pioneer ACO Model
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Physician Group Practice Transition Demonstrations
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Primary Care First (PCF) Model Options
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- Vermont Medicare ACO Initiative
 - Contract ID number (if applicable):
 - Application or Participation date(s):
 - Application Response: Accept, Deny, Withdrawn:
- 5. Describe the applicant ACO's relationship (e.g., geographic, years of experience, relative dominance in major areas of service delivery, ownership interest) to other health care entities in its market. Please include information on the applicant ACO's market share in its primary service area for professional and hospital services and on organizations that are considered main competitors in the applicant ACO's primary service area. (3000 Characters)
- 6. To assist the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ) in their activities to protect competition in the regions in which the PC Flex Model will be tested, CMS may provide certain information, including aggregate claims data regarding allowed charges and fee-for-services payments for your organization, to FTC and the Antitrust Division of DOJ to assist in their monitoring of the competitive effects of potential ACOs in these regions. Please confirm that the applicant ACO understands and agrees that CMS may also share a copy of your application (including

all information and documents submitted with the application) with the FTC and the Antitrust Division of the DOJ.

- Yes
- No

Repayment Mechanism

An ACO that participates in the ACO PC Flex Model must secure a repayment mechanism to ensure CMS is able to recoup amounts owed to CMS under the model. This repayment mechanism is separate from and in addition to repayment requirements under the Shared Savings Program regulations. If an applicant ACO is selected to participate in the model, the ACO must submit draft and final repayment mechanism documentation for CMS review and approval.

CMS will estimate an applicant ACO's repayment mechanism amount using Shared Savings Program beneficiary assignment estimates and other relevant data. CMS anticipates this information will be provided to ACOs as a report prior to phase 1 final dispositions on October 17, 2024.

- Draft Repayment Mechanism Documentation: Due November 18, 2024 (the end of the Phase 2 request for information period).
- Final Repayment Mechanism Documentation: Due December 12, 2024 (the end of the final submission period).

I acknowledge that, if selected to participate in the ACO PC Flex Model, an ACO PC Flex Model repayment mechanism is a requirement of participation, and that draft documentation of compliance with this requirement is due to CMS by November 18, 2024.

[] I agree to the above statement

Select the repayment mechanism(s) that your ACO intends to use to repay CMMI for any losses owed and upload a draft for each selection.

- a. Funds placed in escrow
- b. Surety bond
- c. A line of credit that the Medicare program can draw upon, as evidenced by a letter of credit
- d. Uknown

Organization Contacts

This section asks for organization contact information needed for PC Flex. Please use the explanations provided to identify the most appropriate person for each contact field and enter their most current contact information.

Note: Ensure that you have assigned a designated contact for each of the three contact types listed below. You may select multiple contact types for each individual.

- a. Application Contact
- b. Financial Contact
- c. Authorized to Sign

Incorporation, Licensure, and Structure

- 1. Please attach a proposed organizational chart for the applicant ACO. The proposed organizational chart should depict the legal structure and the proposed operational composition of the ACO itself, including the proposed governing body; the leadership team; any relevant operating bodies or committees (e.g., compliance team, data team); persons with an ownership or control interest (as that term is defined in Appendix A) in the ACO; and any individuals or entities that the applicant ACO expects will perform functions or services related to the applicant ACO's participation in the PC Flex Model (e.g., third party vendors, partners). *Note:* Inclusion of the individuals and entities the applicant ACO expects will be primary care providers in the proposed organizational chart for the applicant ACO is optional.
- 2. Complete and upload the Ownership Interest Template to provide CMS with a full and complete understanding of the ownership interests in the applicant ACO, as well as the ownership interests in the entities with an ownership interest in the applicant ACO. Each party with at least 5% ownership interest in the applicant ACO should be listed.

Table 1. Ownership and Control Interests

		Type; select from:	
		-Private individual	If privately held company,
		-Publicly traded	investment firm, or other, please
		company	provide a complete description of all
Name of	Percent ownership	-Privately held	ownership interests in the privately
	interest in the	company	held company, investment firm, or
person	Applicant ACO	-Investment firm	other, including their name, percent
		(private equity,	ownership and description (private
		venture capital, etc.)	individual, public company, private
		-Other (please	company, investment firm, other)*
		describe)	

Note: If a privately held company with an ownership or control interest in the applicant ACO is a subsidiary of another privately held company, please also list the parent company(ies) and ownership interests in that privately held (parent) company.

Leadership Team

3.	Indicate whether the applicant ACO has or will have a leadership team exclusive to the ACO.
	[] Yes [] No

4. Complete the table below with information specific to the applicant ACO's proposed leadership

team. The leadership team may include, but is not limited to: Key Executives (as that term is defined in Appendix A of the RFA); finance officers; clinical improvement officers; compliance officers; information systems leadership; and the individual responsible for maintenance and stewardship of clinical data. For each identified leadership team member, please attach a resume or curriculum vitae (CV). If specific individuals have not yet been identified, please provide the anticipated date by which the individual will be identified and indicate the "Position/Role" intended for the TBD individuals to serve.

Indicate whether the individual has an ownership or control interest in the applicant ACO or is a person with an ownership or control interest in an entity that the applicant ACO expects will be a ACO participant that includes a primary care provider. If so, please indicate the entity in which the individual has an ownership or control interest and identify the nature and amount of the ownership or control interest.

Table 2. Applicant ACO's Proposed Leadership Team

Leadership Team Member	Position/Role	CV or resume attached	Ownership or control interest	Action

Select an option that best describes the individual:

- The individual has ownership or control interest in the applicant ACO
- The individual has ownership or control in an entity that the applicant ACO expects will be an ACO participant that includes a primary care provider
- Not applicable

If the individual has ownership or control interest, indicate the entity and identify the nature and amount of the ownership or control interest. (1000 characters)

Summarize the background and experience of the individual selected for the applicant ACO's proposed leadership team, specifically explaining why the applicant ACO believes each individual possesses the experience and skills to realize the goals of the ACO PC Flex Model, as described in the RFA, and otherwise lead the applicant ACO to success in the Model by improving care quality and reducing program expenditures. (3000 characters)

Position/Role	Anticipated Date	Action

Governing Body

5. Complete the table below with information specific to the applicant ACO's proposed governing body. If the applicant ACO expects an individual to be a primary care provider or a representative thereof,

please also provide the Legal Name of the entity under which the individual is expected to participate in the ACO. If specific individuals have not yet been identified, please provide the anticipated date by which the individual will be identified and indicate the "Position/Role" you intend for the TBD individuals to serve.

Table 3. Applicant ACO's Proposed Governing Body

Name	Legal Business Name (if applicable)	Title of Role	CV or resume attached	Percent of Board Control	*Other Board commitment(s)	**Ownership or control interests

- Is the individual currently serving or will be concurrently serving on another governing body?
 - Yes
 - No
 - Not applicable
- Select an option that best describes the individual:
 - The individual has ownership or control interest in the applicant ACO
 - The individual has ownership or control in an entity that the applicant ACO expects will be an ACO participant that includes a primary care provider
 - Not applicable
- If the individual has ownership or control interest, indicate the entity and identify the nature and amount of the ownership or control interest. (1000 characters)

5a. Summarize the background and experience of the individual explaining why the applicant ACO believes each individual possesses the experience and skills to realize the goals of the ACO PC Flex Model, as described in the RFA, and is otherwise appropriate for providing leadership on oversight and strategic direction of the applicant ACO and for holding ACO management accountable for the ACO's activities. (3000 Characters)

Oversight and Representation

- 6. Upload the compliance plan intended for use by the applicant ACO and specify whether the proposed compliance officer reports directly to the proposed governing body. *Note*: A tip sheet for creating an ACO PC Flex Model compliance plan is available on the ACO PC Flex Model website.
- 7. Please describe how responsibilities and accountability will be shared across the leadership team and governing body structures in the applicant ACO. Please also describe how the leadership team and/or governing body structures will inform the owners of the applicant ACO regarding the applicant ACO's performance in the ACO PC Flex Model and the activities the applicant ACO is undertaking for the purpose of its participation in the ACO PC Flex Model. (3000 Characters)

- 8. Please describe how the governing body will ensure that the interests of beneficiaries and providers and suppliers will be represented adequately. Specifically, explain the following:
 - The role of the independent Medicare beneficiary(ies) who will participate in the governing body;
 - The role of the independent consumer advocate(s) who will participate in the governing body;
 - Any means by which the applicant ACO will ensure beneficiary representation and/or consumer representation (e.g., through a committee, meeting and/or communication infrastructure); and
 - The rationale for the proposed or existing composition of the governing body and voting power distribution. (6000 characters)

Primary Care Providers

- 9. Describe the planned or actual contractual and/or employment relationships, and ownership interests, between and among the applicant ACO and any individuals or entities that the applicant ACO expects will provide Primary Care Services. (3000 Characters)
- 10. Describe how the applicant ACO plans to coordinate care, improve care quality, reduce program expenditures, and otherwise succeed under the ACO PC Flex Model with its primary care providers. In particular, please describe how the expected mix of providers and suppliers will allow the applicant ACO to ensure that it will serve a diverse population of Medicare patients, achieve the goals of the ACO PC Flex Model as described in the RFA and otherwise reduce health care costs and improve beneficiary quality of care and address health disparities. (3000 Characters)

Disclosures

11. Disclose the following with respect to the applicant ACO, persons with an ownership or control interest (as that term is defined in Appendix A of the RFA) in the applicant ACO, Key Executives (as that term is defined in Appendix A of the RFA), equity partners (e.g., private equity or venture capital), and individuals and entities that the applicant ACO expects will be an ACO participant that includes a primary care provider: (i) any sanctions or corrective action plans imposed under Medicare, Medicaid, or state licensure authorities within the last three years (including corporate integrity agreements); (ii) any fraud investigations initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to the Medicare program, including any debts owed under an Innovation Center model, or any agency of the federal government; (iv) any awards of a CMS contract in the past 5 years, and, if applicable, the contract number and period of performance for such award; (v) whether any such individuals or entities are on a government suspension, debarment, or exclusion list relating to procurement and non-procurements; (vi) any instances of criminal conduct; and (vii) any instances of bankruptcy.

Table 5. Program Integrity Information

Individual or entity	Federal or State Agency or Accrediting Body	Description of Infraction (including date)	Resolution Status (including date)

Information on ACO partners / vendors

12. In the table below, please list separately any core ACO functions, including but not limited to beneficiary engagement and communication, care coordination, marketing, data and analytics, provider contracting, financial analysis and management, payment processing, and legal and compliance, that the applicant ACO expects will be contracted out and performed by a third party partner or vendor. For each expected function that will be contracted out please complete the additional fields.

Table 6. Functions Performed by Third Party Partners or Vendors

Core Function	, , ,	Expected contract size (\$/year) and duration	i vengor	If a vendor is identified, has the vendor been involved in either (1) any fraud investigations initiated, conducted, or resolved within the last five years, or (2) any instances of criminal conduct?

REVENUE SOURCES AND PAYMENT ARRANGEMENTS

Revenue Sources

1. What percentage of the applicant ACO's total clinical revenues in the last fiscal year was derived from the following sources?

Note: The applicant ACO may approximate this through summation of revenue received by all individuals and entities the applicant ACO expects will be ACO Participants providing clinical services:

- Medicare fee-for-service
- Medicare Advantage
- Other Medicare health plan (e.g., PACE, Medicare cost plans)

- Medicaid
- TRICARE
- Indian Health Service
- Commercial health plans
- Self-pay patients
- Other
- Describe your other source:
- 2. Please describe any other sources of revenue from non-clinical services that the applicant ACO a received in the last fiscal year. Please identify the product or service sold, the percentage of the applicant ACO's total revenues (including revenues from clinical services) in the last fiscal year that such revenue comprises, and whether the applicant ACO expects to receive revenues from such products or services while participating in the ACO PC Flex Model. (3000 Characters)

Implementation Plan

- 3. Describe, in detail, how the applicant ACO intends to fund and structure its arrangements with ACO Participants that include primary care providers for the ACO PC Flex Model. In providing a response, please address the following:
 - How the applicant ACO will implement the Prospective Primary Care Payments made by CMS in compensating primary care providers? (3000 Characters)
 - How will the applicant ACO fund its administrative activities? How will the one-time Advanced Shared Savings Payment made by CMS be used? (3000 Characters)
 - How will the applicant ACO use any revenue from Prospective Primary Care Payments not distributed to ACO Participants that include primary care providers? (3000 Characters)
 - Will the applicant ACO's arrangements with ACO Participants that include primary care
 providers address processes or outcomes related to promoting health equity? If so, please
 provide details. (3000 characters)

PATIENT CENTEREDNESS AND BENEFICIARY ENGAGMENT

- Describe the Applicant ACO's historical and planned approach for using interdisciplinary care teams to
 coordinate care. Please describe the roles the applicant ACO plans to establish within a care team,
 examples of specific care improvement interventions they could undertake, and the process by which
 the care team will communicate internally and with the appropriate providers/suppliers. (3000
 characters)
- 2. Describe the applicant ACO's historical and planned population health management and/or population health tools, including previous or planned approaches for furnishing care to Underserved Communities. If applicable, please describe the metrics the applicant ACO has historically used or plans to use to identify health inequities in its patients served, deploy clinicians and invest resources. Where relevant, describe other processes the applicant ACO has used (or plans to use) to make improvements to address and mitigate health disparities in the prioritized Underserved Community. (3000 characters)

- 3. Describe the applicant ACO's current or historical and planned approaches for coordinating care throughout an episode of care and during care transitions, such as a discharge from a hospital or a transfer of care between providers (both inside and outside the ACO). (3000 characters)
- 4. Describe the applicant ACO's historical and planned approaches to integrate behavioral health into primary care settings, for example, access to services, screening, treatment via referrals or colocation, types and roles of care team members located in primary care. (3000 characters)
- 5. Describe the applicant ACO's historical and planned approaches to improving beneficiary access to care. (3000 characters)
- 6. Describe the applicant ACO's historical and planned approaches to conducting beneficiary outreach. Please describe the goals of the applicant ACO's beneficiary outreach strategy, the modes of communication to conduct outreach and how success will be measured as it relates to outreach efforts. (3000 characters)
- 7. Describe the applicant ACO's historical and planned approaches for evaluating patient, caregiver, and/or family experience of care and satisfaction, the frequency and method(s) through which the applicant ACO requests such feedback and how the applicant ACO has and/or intends to use such feedback to improve its care delivery approach. (3000 characters)
- 8. Describe the applicant ACO's historical and planned approaches to ensure that the applicant ACO furnishes individualized care, such as through the use of personalized care plans, processes for shared decision-making between providers/suppliers and patients and culturally-competent care. (3000 characters)
- 9. Describe the history of community engagement, such as collaboration among major stakeholders in the community(ies) being served and the applicant ACO's historical and planned approaches to address the social determinants of health (e.g., access to transportation, housing stability, food security, income) of assigned beneficiaries. If applicable, include specific examples of community stakeholders with whom the applicant ACO has a relationship and the nature of each relationship. (3000 characters)

DATA AND HEALTH INFOR	MATION	

Technical Capability

1. Describe the applicant ACO's current capabilities to utilize tools to ingest bulk Medicare claims data related to the applicant ACO's assigned population for purposes of clinical treatment, care management and coordination, quality improvement activities, population-based activities relating to improving health or reducing health care costs, and provider incentive design and implementation. In providing a response, please address whether the applicant ACO's current software can ingest, process, and transmit data in a Fast Healthcare Interoperability Resources (FHIR)-compliant format. Describe the applicant ACO's experience developing and/or using application programming interfaces (APIs) to ingest, transmit, or otherwise use data. (3000 characters)

- 2. Describe the applicant ACO's capabilities and ability to securely transfer patient data and care plans between health care settings both inside and outside the applicant ACO for purposes of care management and care coordination. (3000 characters)
- 3. Describe the applicant ACO's data security controls that support identifying, detecting, preventing, responding to, and recovering from security incidents. (3000 characters)

Data and Health Information Technology to Inform Clinical Care

- 4. Describe the applicant ACO's and expected ACO Participants' current ability to use electronic health record (EHR) data and digital tools to understand patient risk, risk stratify patients, and use this information for decision-making. (3000 characters)
- 5. Describe the applicant ACO's historical and planned use of health information technology ("health IT") tools, including internally and to support ACO providers/suppliers and patients. (3000 characters)
- 6. Describe the applicant ACO's historical and planned collection and use of demographic (including race, ethnicity, and language preference) data, social determinants of health data, and/or other data to address health disparities. (3000 characters)

Attestation and Signature

I have read the contents of this application. By my signature, I certify to the best of my knowledge, information, and belief that the information contained herein is true, correct, and complete, that I am authorized to sign this application on behalf of the ACO. I authorize the Centers for Medicare & Medicaid Services (CMS) to verify this information. If I become aware that any information in this application is not true, correct, or complete, I agree to notify CMS of this fact immediately and to provide the correct and/or complete information.

[signature block]

Appendix C. Program Overlaps

MODEL	PROVIDER OVERLAP PERMITTED WITH THE SHARED SAVINGS PROGRAM?	PROVIDER OVERLAP PERMITTED WITH THE ACO PC FLEX MODEL?
ACO REACH	No	No
Making Care Primary (MCP)	No	No
Kidney Care Choice (KCC)	No	No
Vermont All-Payer Model	No	No
Independence at Home Demonstration (IAH)	No	No
States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model	Yes	No
Primary Care First (PCF)	Yes	No
Maryland Primary Care Program	No	No
Guiding an Improved Dementia Experience (GUIDE)	Yes	Yes
Bundled Payments for Care Improvement (BPCI) Advanced Model	Yes	Yes
End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model	Yes	Yes
Enhancing Oncology Model (EOM)	Yes	Yes
Financial Alignment Initiative for Medicare- Medicaid Enrollees	Yes	Yes

Appendix D. Codes Used to Calculate Prospective Primary Care Payments (PPCP) County Base Rate⁷⁵

SERVICE	CODE(S)
Administration of health risk assessment	96160 and 96161
Caregiver Behavior Management Training	96202 and 96203
Caregiver Training Services	97550, 97551, and 97552
Office or other outpatient visit for the evaluation and management of a patient	99201 through 99215
Patient domiciliary, rest home, or custodial care visit	99319 through 99340
Evaluation and management services furnished in a patient's home	99341 through 99350
Add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code in this list	99354 and 99355
Smoking and Tobacco-use Cessation Counseling Services	99406 and 99047
Online digital evaluation and management	99421, 99422, and 99423
Principal care management services	99424, 99425, 99426, and 99427
Telephone evaluation and management services	99441, 99442, and 99443
Chronic care management	99437, 99487, 99489, 99490 and 99491
Non-complex chronic care management	99439
Assessment of and care planning for patients with cognitive impairment	99483
Behavioral health integration services	99484, 99492, 99493 and 99494
Transitional care management services	99495 and 99496
Advance care planning; services identified by these codes furnished in an inpatient setting are excluded	99497 and 99498
Community Health Integration (CHI) services	G0019 and G0022
Principal Illness Navigation (PIN) services	G0023 and G0024
SDOH Risk Assessment	G0136
The Welcome to Medicare visit	G0402
The annual wellness visits	G0438 and G0439
Alcohol misuse screening service	G0442
Alcohol misuse counseling service	G0443
Annual depression screening service	G0444
Services furnished in ETA hospitals	G0463
Services furnished in HOPD setting*	G0463
Chronic care management	G0506
Cervical or Vaginal Cancer Screening	G0101

⁷⁵ This list will be updated annually to remain consistent with updates to the Shared Savings Program.

The remote evaluation of patient video/images	G2010
Virtual check-in	G2012 and G2252
Non-complex chronic care management	G2058
Principal care management services	G2064 and G2065
Office-Based Opioid Use Disorder Services	G2086, G2087, and G2088
Complex Evaluation and Management services Add-on	G2211
Prolonged office or other outpatient visit for the evaluation and management of a patient	G0317, G0318, and G2212
Psychiatric collaborative care model	G2214
Chronic pain management	G3002 and G3003

^{*}G0463 – Services furnished in HOPD setting (non-ETA HOPD setting) are included in the PPCP but not used for assignment in the Shared Savings Program.

Appendix E. Financial Methodology Technical Details

The final ACO PC Flex Model Rate Book county rate for a county is the product of the national conversion factor and the county's county relative cost index, each of which is calculated as follows:

National conversion factor

- 1. Sum all fee-for-service expenditures, including sequestration amounts and payments for CMMI demonstrations, for beneficiaries who are assignment-eligible to the ACO PC Flex Model in the most recent Rate Book base year (2023).⁷⁶
- 2. Subtract all expenditures that do not pertain to primary care services applicable to the ACO PC Flex Model i.e., only maintain expenditures that correspond to the primary care codes in Table 3 (any primary care expenditures that are for codes not in Table 3 are removed).
- 3. Divide the resulting primary care expenditures by the number of eligible beneficiary-months included in the expenditures.
- 4. Trend the resulting PBPM figure forward to the performance year using the relevant trend factor (e.g., adjusted fee-for-service United States per capita cost (USPCC) growth rate).

County Relative Cost Indices

- Sum all fee-for-service expenditures, including sequestration amounts and payments for CMS Innovation Center demonstrations, for beneficiaries who are assignment-eligible to the ACO PC Flex Model, at the county level, for each county in the United States, for each of the three base years.
- 2. For each county's summed fee-for-service expenditures in each of the three base years, subtract all expenditures that do not pertain to primary care services applicable to the ACO PC Flex Model (as in #2 above).
- 3. Calculate geographic adjustment factors (GAF; which reflect price differentials in Medicare payment systems) for each of the three base years.
- 4. Calculate national conversion factor (see above) for each of the three base years (2021-2023).
- 5. Multiply #2 and #3, and divide result by #4, to calculate county index for each of the base years.
- 6. Take average of each base year county index calculated in #5.
- 7. Divide #6 by three-year weighted average normalized risk score of each county to arrive at risk-standardized, GAF-adjusted county relative index.
- Beneficiaries with FQHC / RHC Focused Care will be excluded from the reference population in Rate Book construction. See section IV.C.iii.c Add-on for beneficiaries with FQHC / RHC Focused Care for more information about the add-on payment for beneficiaries with FQHC / RHC Focused Care.

Risk Adjustment Calendar

To support more precise PPCP payments compared to using prior years' final scores and minimize the impacts of retrospective updates to the PPCP due to risk adjustment, interim risk scores will be used throughout the performance year and updated based on the schedule below (performance year 2025). Preliminary risk scores are calculated with diagnoses from a lagged reporting or diagnosis measurement

⁷⁶ Consistent with the Shared Savings Program, inpatient episodes for COVID-19 will be excluded (3 days prior to admission and 30 days post). See 42 C.F.R. § 425.611. Consistent with the Shared Savings Program, beneficiaries are assignment-eligible if they meet the criteria specified in § 425.401(a) and are not excluded under the criteria specified in § 425.401(b).

period, which is updated during the performance year. Risk scores are then incrementally updated with new diagnoses identified on claims in the reporting period submitted through the claims runout deadlines.

Table 1. Performance Year 2025 Risk Score Measurement Calendar

RISK SCORE	CMS-HCC RISK ADJUSTMENT MODEL DIAGNOSTIC MEASUREMENT PERIOD (DATES OF SERVICE)	CLAIMS RUNOUT THROUGH	
Preliminary	July 2023-June 2024	September 2024	
Mid-Year Q1	January 2024-December 2024	March 2025	
Mid-Year Q2	January 2024-December 2024	June 2025	
Mid-Year Q3	January 2024-December 2024	September 2025	
Mid-Year Q4	January 2024-December 2024	December 2025	
Final	January 2024-December 2024	January 2026	

Please note that all amounts may be updated, and the final values will be in the financial specification papers.

Table 2. Current Estimates of Value of each PPCP Element

ELEMENT	ESTIMATED	NOTES
	VALUE	
County Enhancement	\$10-15 PBPM	Only for beneficiaries residing in those counties
Flex Enhancement	\$10-11 PBPM	\$125 PBPY
Add-on for beneficiaries with	\$249 PBPY	
FQHC Focused Care*		
Add-on for beneficiaries with	\$256 PBPY	
RHC Focused Care*		
Health Equity Adjustment	-\$3-\$3 PBPM	Budget neutral design
Cap on Enhancement	\$16.67 PBPM	Maximum enhancement for ACO, \$200 PBPY

^{*}The add-ons for beneficiaries with FQHC / RHC Focused Care are informed by two principles, that: (1) PF Flex ACOs are sufficiently funded such that FQHCs and RHCs are made whole under the ACO PC Flex Model, and (2) PC Flex ACOs are sufficiently funded such that FQHC and RHC providers receive increased payment above fee-for-service rates under the ACO PC Flex Model. For performance year 2025, the add-ons for beneficiaries with FQHC / RHC Focused Care will be a fixed dollar amount.

An illustrative example of applying the ACO PC Flex financial settlement adjustments is available in the in the RFA companion workbook, "ACO PC Flex Exhibits and Example Calculations".

Assignment Options and PPCP Eligible Beneficiaries

Under **Prospective Assignment** a beneficiary is a PPCP Eligible Beneficiary if they are assigned to the PC Flex ACO via "Step 1" or "Step 3" based on the performance year's prospective assignment run. The beneficiary will remain a PPCP Eligible Beneficiary for the performance year until they are no longer assigned to the PC Flex ACO, for example, if the beneficiary elects to enroll in a Medicare Advantage plan. When retroactive termination happens, any PPCP paid for months after beneficiary termination date will be recouped in the next payment cycle. Beneficiaries assigned to the ACO via "Step 2" are not PPCP eligible beneficiaries for

that performance year. If, in a future performance year, the beneficiary is assigned via "Step 1" or "Step 3", then the beneficiary would become a PPCP Eligible Beneficiary for that performance year.

Under **Preliminary Prospective Assignment with Retrospective Reconciliation**, the following rules apply for each performance year to determine if a beneficiary is a PPCP Eligible Beneficiary.

As of first assignment run of the performance year:

- Beneficiaries are PPCP Eligible Beneficiaries if they are assigned to the PC Flex ACO via "Step 1" or "Step 3."
- Beneficiaries are not PPCP Eligible Beneficiaries if they are assigned to the PC Flex ACO via "Step 2."

At subsequent assignment runs in the performance year. Beneficiaries who are still assigned to PC Flex ACO via "Step 1" or "Step 3" are PPCP Eligible Beneficiaries unless the beneficiary is no longer assigned to PC Flex ACO or if the beneficiary becomes assigned via "Step 2" in which case the beneficiary is no longer a PPCP Eligible Beneficiary and recoupment procedure is applied. If assigned via "Step 2" or newly assigned to the PC Flex ACO the beneficiary is not a PPCP Eligible Beneficiary. Specifically:

- Beneficiaries who are still assigned to PC Flex ACO via "Step 1" or "Step 3" are PPCP Eligible Beneficiaries.
- Beneficiaries who are still assigned to PC Flex ACO via "Step 2" are not PPCP Eligible Beneficiaries.
- Beneficiaries whose assignment moves from "Step 1" or "Step 3" to "Step 2" are not PPCP Eligible Beneficiaries and recoupment procedure applied.
- Beneficiaries whose assignment moves from "Step 2" to "Step 1" or "Step 3" do not become PPCP
 Eligible Beneficiaries. These beneficiaries may be PPCP Eligible Beneficiaries for the next
 performance year if they are still assigned via "Step 1" or "Step 3" in the first assignment run of the
 next performance year.
- Beneficiaries who are no longer assigned to the PC Flex ACO are not PPCP eligible Beneficiaries for the entire performance year, even if assigned back to the PC Flex ACO in subsequent assignment runs for the performance year. Recoupment procedure applied.
- Beneficiaries who are newly assigned are not PPCP eligible Beneficiaries for the entire performance year. These beneficiaries may become PPCP Eligible Beneficiaries for the next performance year if they are assigned in the first assignment run for that next performance year via "Step 1" or "Step 3."

When the **recoupment procedure** is triggered for a beneficiary, in the next available monthly PPCP payment and reporting cycle following the assignment run in which a beneficiary ceased to be a PPCP Eligible Beneficiary:

- All PPCP will be recouped for any payments made year-to-date for the beneficiary by reducing the PC Flex ACO's total PPCP payment for the month in which the recoupment is made.
- Claim reductions for the beneficiary will stop.
- Claims already reduced for the year will be reprocessed and paid to the billing provider normally.
 Note that it is mathematically possible that PPCP recoupment resulting from a quarterly assignment run could exceed the next month's total PPCP payment amount.

Appendix F. ACO PC Flex Model Quality Measure Set⁷⁷

MEASURE	MIPS QUALITY ID	COLLECTION TYPE	NQF	MEASURE STEWARD (ID, if applicable)	MEASURES TYPE	MEANINGFUL MEASURES 2.0 AREA
Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	001	eCQM/MIPS CQM/ Medicare CQMs	0059	NCQA (CMS122)	Intermediate Outcome Measure	Chronic Conditions
Controlling High Blood Pressure	236	eCQM/MIPS CQM/Medicare CQMs	N/A	NCQA (CMS165)	Intermediate Outcome Measure	Chronic Conditions
Preventive Care and Screening: Screening for Depression and Follow-Up Plan	134	eCQM/MIPS CQM/Medicare CQMs	N/A	CMS (CMS2)	Process Measure	Behavioral Health
CAHPS for MIPS	321	CAHPS for MIPS survey	0005	AHRQ	Patient Reported Experience Measure (PREM)	Person- Centered Care
Hospital-Wide, 30- Day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Group	479	Administrative Claims	N/A	CMS	Outcome Measure	Affordability and Efficiency
Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	484	Administrative Claims	N/A	CMS	Outcome Measure	Affordability and Efficiency
Person-Centered Primary Care Measure (PCPCM)	483	CQM, survey vendor, or CMS-fielded ⁷⁸	3568	American Board of Family Medicine	Patient Reported Experience Measure (PREM)	N/A

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CMS reserves the right to amend the ACO PC Flex Measure Set if such amendments facilitate alignment with future CMS-wide quality measure alignment initiatives, such as the Universal Measure Set. Similarly, as measures evolve and new measures become available, CMS reserves the right to incorporate those measures over the course of the model, if appropriate. Any Shared Savings Program quality measure changes that occur through rulemaking in the future will be applicable to PC Flex ACOs.
 CMS proposes to pay for the administration of the Person-Centered Primary Care Measure (PCPCM). The survey costs would be part of the model's annual budget. The PCPCM is only administered at the practice level so we will need to adapt it for the ACO level. Per the measure steward, administration of the PCPCM is between \$100-1k per clinician.