Centers for Medicare & Medicaid Services  
Center for Medicare and Medicaid Innovation  
Seamless Care Models Group

Beneficiary Engagement and Incentives Models—Shared Decision Making Model  
(SDM Model)

Request for Application (RFA)
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I. Background and Introduction

The Centers for Medicare & Medicaid Services (CMS) identifies strengthening beneficiary engagement as one of the agency’s goals to help achieve better care, smarter spending, and healthier people. Specifically, “CMS Quality Strategy envisions health and care that is person-centered, provides incentives for the right outcomes, is sustainable, emphasizes coordinated care and shared decision making, and relies on transparency of quality and cost information.” The Shared Decision Making (SDM) Model promotes patient-centered care delivery with a focus on improved experience, patient self-management, and structured shared decision making. The SDM Model includes the use of patient decision aids (PDA), tools that present information about common medical choices.

Shared decision making can ensure that treatment decisions better align with beneficiaries’ preferences and values for many preference-sensitive conditions that have no clearly superior course of treatment. The SDM Model seeks to test how to best integrate a specific, structured shared decision making process into routine clinical practice. The model will directly address a number of the barriers identified in research studies in peer-reviewed scientific literature and by experts in the field of shared decision making. CMS is providing participating Accountable Care Organizations (ACOs) with financial support to invest in a structured process that it believes will result in improvements in patient engagement and experience with care, as well as reduced Medicare spending or keeping expenditures neutral.

The SDM Model aims to integrate a specific, structured, Four Step shared decision making process into routine clinical practice of ACOs, resulting in informed and engaged beneficiaries who collaborate with their practitioners to make medical decisions that align with their values and preferences. By testing the model within participating ACOs, CMS anticipates improvements in patient engagement and experience with care, as well as reduced Medicare spending, results which would help CMS make the case to ACOs to integrate this approach to shared decision making process as part of their clinical care processes in their practices.

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II. Statutory Authority

A. General Authority to Test Model

Section 1115A of the Social Security Act (the Act) (42 U.S.C. 1315a) (as added by Section 3021 of the Patient Protection and Affordable Care Act of 2010 (hereinafter “ACA”) authorizes the Center for Medicare & Medicaid Innovation (the Innovation Center) to test innovative health care payment and service delivery models that have the potential to lower Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) spending while maintaining or improving the quality of beneficiaries’ care.

B. Financial and Payment Model Authorities

Section 1115A(b)(2) of the Act requires the Secretary to select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The statute provides a non-exhaustive list of examples of models that the Secretary may select, which includes a model to assist individuals in making informed health care choices using patient decision-support tools, including tools that meet the standards developed and identified under section 936(c)(2)(A) of the Public Health Service Act, that improve applicable individual and caregiver understanding of medical treatment options.

C. Fraud and Abuse Waiver Authority

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), and 1903(m)(2)(A)(iii) 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 this standard, 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 for the SDM Model, if any, would be set forth in separately issued documentation. Notwithstanding any provision of this proposal, individuals and entities 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 SDM Model. Any such waiver issued in connection with the SDM Model would apply solely to that particular model and could differ in scope or design from waivers granted for other programs or models.

Additionally, CMS provides no opinion on the legality of any contractual or financial arrangement that the award recipients, sub-award recipients, practitioners, affiliated entities or any other relevant individuals or entities may pose, implement, or document. The receipt by CMS of any such documents 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, Department of Health and Human Services (HHS), or its 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.

**D. Payment Rule Waiver Authority**

Section 1115A(d)(1) of the Act authorizes the Secretary to waive such requirements of Title XVIII of the Act as may be necessary solely for purposes of carrying out the testing by the Innovation Center of certain innovative payment and service delivery models, including the SDM Model. The design of the SDM Model includes payments made under Medicare Part B that will be provided without beneficiary cost-sharing. A waiver of certain provisions of section 1848 of the Act, including section 1848(a)(1), and certain provisions of section 1833 and 1842 of the Act are necessary in order to make payment from the Part B trust fund to participating ACOs for each SDM Service.

These waivers would apply solely to SDM Model participants (i.e. Participating ACOs) and may differ in scope or design from waivers granted for other programs or models. Any waivers granted would be contingent upon: 1) the ACO participating in SDM Model and entering into a Model Participant Agreement (MPA) with CMS; 2) the ACO continued compliance with the terms and conditions of the MPA, including the terms and conditions of the waivers as specified in the MPA; and 3) CMS not making a determination that continued use of a payment rule waiver puts beneficiaries or program integrity at undue risk. CMS may amend or terminate any payment waiver granted for purposes of the SDM Model at any time and for any reason.

**III. Model Design—Shared Decision Making**

**A. Theory of Action**

The overall aim of the SDM Model is to have informed and engaged Medicare beneficiaries collaborate with their practitioners using a specific, structured Four Step SDM Process (Refer to Table 1) based on beneficiary preferences. The SDM Model proposes an agreement between CMS and the ACO, which will be formalized and detailed in the SDM Model’s MPA.

The SDM Model uses the following terms, as defined below: a participating ACO, a SDM practice, a SDM practitioner.

A participating ACO is an applicable ACO {i.e. Medicare Shared Savings Program} or an applicable Next Generation ACO (i.e. Next Generation ACO Model) that will be participating in the SDM Model.

A SDM practice is the applicable ACO participant {i.e. Medicare Shared Savings Program}, or a Next Generation Participant or Preferred Provider (i.e. Next Generation ACO Model), that is implementing the SDM Model.
A SDM practitioner is an applicable ACO professional (i.e. Medicare Shared Savings Program), or a Next Generation Professional (i.e. Next Generation ACO Model), that will be furnishing the SDM Service to applicable beneficiaries in the SDM Model.

The SDM Model requires all participating ACOs to enter into a SDM MPA with CMS. Further, the participating ACO’s practices and practitioners that participate in SDM (“SDM practices and practitioners”) will complete key aspects of the Four Step SDM Process and thus, the SDM MPA will require the participating ACO to enter into a contractual relationship (or update their existing contractual relationship) for purposes of the SDM Model with each of its SDM practices and practitioners. The MPA will set forth specific requirements that must be in the contractual agreements between the ACO and each of its SDM practices and practitioners (see the Payment Amount Section).

CMS expects a participating ACO to implement the Shared Decision Making Model in all of its practices and practitioners, unless the ACO demonstrates to CMS that, based on the preference-sensitive conditions being targeted and the nature of the particular practice or practitioner, a particular practice or practitioner is unlikely to provide services to beneficiaries within any of the preference-sensitive conditions. This information will be requested as part of the RFA and will be reviewed by CMS.

The Innovation Center identifies the following components as key drivers associated with a participating ACO’s success in achieving this aim:

- The participating ACO works with its SDM practitioners and practices to develop clinical pathways and processes that incorporate a specific, structured Four Step shared decision making process, including the use of PDAs.
- The SDM practitioners take steps to involve beneficiaries and elicit their values and preferences while beneficiaries engage in their medical decision making as true partners.
- The overall effects of the SDM Process are measured and the participating ACO and its SDM practices and practitioners are provided with feedback on these effects.
- Practice workflow is redesigned to incorporate new processes and structures that facilitate the use of shared decision making, including PDAs.
- CMS pays participating ACOs for SDM Services that are furnished by their SDM practitioners, when these SDM Services are completed in conjunction with SDM Activities coordinated between the participating ACO and its SDM practices and practitioners.
- If the preference-sensitive condition is appropriate (i.e., the practice has beneficiaries with one of the preference-sensitive conditions, meaning one of those for which the clinical evidence does not clearly support one treatment option and the appropriate course of treatment depends on the values or preferences of the beneficiary) for a practice or
practitioner participating in the ACO, that practice or practitioner would be expected to participate\(^5\) in the SDM Model.

### Table 1. Four Steps of the Shared Decision Making Process

<table>
<thead>
<tr>
<th>Four Steps</th>
<th>Required Elements</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1:</strong> Identify Eligible Beneficiaries</td>
<td>The shared decision making process begins with the identification of eligible beneficiaries who have one of the preference-sensitive conditions (refer to Table 2).</td>
<td>SDM practice identifies beneficiaries with a preference-sensitive condition using inclusion/exclusion criteria. SDM practice will flag beneficiaries in the Electronic Medical Record (EMR) that meet criteria. SDM practitioners will see flag in the system and will verify that the beneficiary is a candidate for shared decision making. For a new patient presenting to the practice for the first time, the SDM practitioner will identify whether the beneficiary that has one of the preference-sensitive conditions during the initial visit.</td>
</tr>
<tr>
<td><strong>Step 2:</strong> Distribute PDA</td>
<td>An evidence-based standardized PDA that matches the preference-sensitive conditions will be distributed to the beneficiary for each shared decision making process.</td>
<td>Practice/practitioner will distribute patient decision aid.</td>
</tr>
<tr>
<td><strong>Step 3:</strong> Furnish SDM Service (Shared Decision Making: Discussion, Decision and Documentation)</td>
<td>SDM practitioner will document step 3 in the beneficiary’s clinical record. SDM practitioner offers the patient questionnaire and documents in the beneficiary’s clinical record. SDM practitioner documents Step 2 in the beneficiary’s EMR.</td>
<td>This discussion generally occurs all at once (CMS does not require it to be all at once) and is required to occur through a face to face conversation. The shared decision making should include the following major tenets(^6): <strong>Team Talk</strong> – SDM practitioner and beneficiary consider available options together <strong>Option Talk</strong> – SDM practitioner describes pros and cons of available options in more detail; uses PDAs <strong>Decision Talk</strong> – SDM practitioner helps beneficiaries explore and form their personal preferences <strong>Decision is Made</strong> – Beneficiary makes a decision based on their preferences.</td>
</tr>
</tbody>
</table>

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\(^5\) CMS expects a participating ACO to implement the Shared Decision Making Model in all of its practices and practitioners, unless the ACO demonstrates to CMS that, based on the preference-sensitive conditions being targeted and the nature of a particular practice or practitioner participating in the ACO, that particular practice or practitioner is unlikely to provide services to beneficiaries with one or more preference-sensitive conditions with respect to that condition or conditions.

### Four Steps

<table>
<thead>
<tr>
<th>Four Steps</th>
<th>Required Elements</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>on their personal preferences. Immediately after the beneficiary completes the 4 tenets of shared decision making, the SDM practitioner will offer the beneficiary a questionnaire to capture the beneficiary’s experience. The SDM practitioner will document in the beneficiary’s EMR that a questionnaire was offered. SDM practitioner completes necessary documentation for the SDM Reporting.</td>
<td></td>
</tr>
<tr>
<td>Step 4: Track and Submit SDM Reporting</td>
<td>Submission of SDM reporting (i.e. the claim), operational data and beneficiary questionnaire for each SDM Process.</td>
<td>SDM practices and practitioners report data to participating ACO. Participating ACO submits SDM Reporting (i.e., the claim), operational data and beneficiary questionnaire data on behalf of its SDM practices and practitioners to the Implementation Monitoring Contractor (IMC). The participating ACO will be responsible for working with its SDM practices and practitioners to submit the SDM Reporting to the IMC. The IMC will only accept reports from the ACO, not any of its SDM practices or practitioners.</td>
</tr>
</tbody>
</table>

### B. Intervention

Under the SDM Model, CMS will pay participating ACOs $50 for each SDM Service furnished by their SDM practitioners. CMS considers the SDM Service to be Step 3 of the Four Step SDM Process referenced in Table 1. Step 3 must be completed by a SDM practitioner (defined on the previous page). Steps 1, 2 and 4 are considered SDM Activities and are completed by the ACO, its SDM practices, and its SDM practitioners, in accordance with the MPA (Refer to Figure 1).

Participating ACOs will oversee implementation of this model and the Four Step SDM Process by their SDM practices and practitioners. The MPA will require the ACO to have and maintain a contractual relationship with each of its SDM practices and practitioners.

The SDM Model targets a set of conditions for which the clinical evidence may not clearly support one treatment option, and the appropriate course of treatment depends on the values or preferences of the beneficiary. These conditions are referred to as a “preference-sensitive conditions.”

Prior to the start of the SDM Model, participating ACOs will be responsible for developing the inclusion/exclusion criteria used to identify eligible beneficiaries with one of the preference-sensitive conditions (Refer to Table 2) for the SDM Model. The Innovation Center’s IMC will support participating ACOs in the development of these criteria. This support will occur during the pre-implementation activities, which will begin approximately 6 months prior to the start of
the Model and will focus on ensuring participating ACOs can meet model requirements and successfully implement the Four Step SDM Process prescribed in this RFA. The participating ACO and its SDM practices will also work together during this pre-implementation period to select appropriate PDAs to be used during this model.

Once the SDM Model starts, the participating ACO’s SDM practices/practitioners are responsible for determining which beneficiaries are eligible for the SDM Process based on inclusion/exclusion criteria developed by the IMC and the ACOs. The SDM practices will identify beneficiaries with a preference-sensitive condition using the predetermined inclusion/exclusion criteria. SDM practices will flag the beneficiaries that meet the criteria in their EMR. The SDM practitioners will see the flag in the EMR and will verify that the beneficiary is a candidate for shared decision making based on their clinical history and the judgment of the practitioner. For new patients presenting to the SDM practice for the first time, the SDM practitioner will identify whether the beneficiary has one of the preference-sensitive conditions during the initial visit (Step 1).

The PDAs and the SDM Service will be carefully designed to impartially provide information on medical care options for preference-sensitive conditions so beneficiaries may select the treatment option that best meets their needs and values. The PDAs will be distributed to the beneficiary by the participating ACO’s SDM practice or practitioner (Step 2), in accordance with the MPA, and the SDM practitioner will document such distribution in the beneficiary’s EMR.

After the beneficiary receives a PDA, he or she will discuss treatment options with the SDM practitioner, including the pros and cons of each option, and values and preferences of the beneficiary. The beneficiary and SDM practitioner will then make a treatment decision, followed by the practitioner offering the beneficiary a questionnaire. The SDM practitioner will document the completion of the SDM Service (Step 3), including documentation that the beneficiary questionnaire was offered and that a PDA was distributed to the beneficiary. This documentation will be placed in the beneficiary’s EMR (Step 3).

The participating ACO will be responsible for collecting all documented information from its SDM practices and practitioners, and submitting such information to CMS. The participating ACO and its SDM practices and practitioners shall each certify the truthfulness and accuracy of all submitted information. The participating ACO will be required to submit detailed information to CMS in order to receive payment for each SDM Service, completed in coordination with all of the SDM Activities (Step 4). All information submitted to CMS must be submitted by an individual legally authorized to bind the ACO.

The beneficiary is permitted to opt out of the SDM Process at any point. If the beneficiary opts out before completing the SDM Service, then no payment will be made to the ACO under the SDM Model. If the Four Steps of the SDM process are completed, the participating ACO will still be paid if the beneficiary was offered the beneficiary questionnaire, but refused to respond. The SDM reporting (i.e. the claim) will be processed outside of the traditional billing system and will be further explained in the MPA between CMS and the ACO. Participating ACOs will
submit monthly reporting of shared decision making (referred to from this point forward as *Monthly SDM Reporting*) for its SDM practices/practitioners to the Innovation Center’s IMC.

Additional information and training on the reporting will be provided during the pre-implementation activities.

This model uses the terms, as defined below: Shared Decision Making, Patient Decision Aid, and Preference-Sensitive Condition.

**Shared Decision Making**

Shared decision making is a process of communication, deliberation, and decision making that includes sharing information with the beneficiary that outlines treatment options, including harms, benefits, and alternatives; eliciting and supporting the beneficiary’s values and preferences; maintaining an interactive and meaningful dialogue based on the best medical evidence tailored to the beneficiary’s condition; and making an optimal decision that takes into account the evidence-based information on options, practitioner/care team expertise, and the beneficiary’s values and preferences.7,8

**Patient Decision Aids**

A PDA is an educational tool that helps beneficiaries to communicate their values, beliefs, and preferences related to their treatment options, in order to decide with their health care practitioner what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.9

**Preference-Sensitive Condition**

A preference-sensitive condition is a medical condition for which the clinical evidence may not clearly support one treatment option, and the appropriate course of treatment depends on the values or preferences of the beneficiary regarding the benefits, harms, and scientific evidence for each treatment option.10

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9 42 U.S.C. § 299b–36

C. Preference-Sensitive Conditions

a) This model will require each participating ACO and its SDM practices and practitioners to implement the specific, structured, Four Step shared decision making process for a set of six preference-sensitive conditions, as shown in Table 2. The current set of conditions were selected, with input from a group of clinicians at the Innovation Center, based on the following:

b) The conditions are relatively high prevalence, high cost to the Medicare beneficiary population;
c) Implementation of the six preference-sensitive conditions would not be unduly burdensome to the clinical practice;
d) Viable treatment options that exist for the conditions;
e) The conditions meet the definition of preference-sensitive condition; and
f) Evidence-based, standardized PDAs for each preference-sensitive condition that are already publicly available.

Table 2. Preference-Sensitive Conditions

<table>
<thead>
<tr>
<th>Topic</th>
<th>Preference-Sensitive Conditions</th>
<th>Treatment/Decision Options</th>
<th>Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Disease</td>
<td>Stable Ischemic Heart Disease</td>
<td>Medical Management vs. Revascularization (e.g., angioplasty +/- stenting/bypass surgery)</td>
<td>Primary care Cardiology Surgery</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>Hip</td>
<td>Non-surgical Management vs. surgery</td>
<td>Primary care Orthopedics</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>Knee</td>
<td>Non-surgical Management vs. surgery</td>
<td>Primary care Orthopedics</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>Back Pain</td>
<td>Non-surgical Treatments, Injection Treatments, Surgical treatment</td>
<td>Primary care Orthopedics Neurosurgery Pain Medicine Neurology Rheumatology Radiology Physiatry</td>
</tr>
<tr>
<td>Cancer</td>
<td>Clinically localized prostate cancer (cancer that is confined to the prostate gland)</td>
<td>Observation vs. treatment options</td>
<td>Urology Radiation Oncology</td>
</tr>
</tbody>
</table>
D. Shared Decision Making Process

Shared decision making is a process requiring the exchange of information, values, and preferences between beneficiary and practitioner to arrive at a treatment decision that is based on the beneficiaries’ values and preferences. To frame and standardize this process for the SDM Model, CMS requires the completion of Four Steps of the SDM Process (Refer to Table 1). Steps 1, 2, and 4 are considered SDM Activities; Step 3 is considered the SDM Service that is provided by a practitioner.

E. Programmatic Components

To facilitate the specific, structured Four Step shared decision making process, participating ACOs shall develop, in conjunction with their SDM practices and practitioners, the following structured programmatic components: practitioners and practices staff training, practice support for workflow and care delivery redesign, and a system for maintaining PDAs.

Practitioners and Participating ACO Training

Enhancing SDM practitioner/practice skills on the specific, structured Four Step shared decision making process will be a critical component and expectation for participating ACOs in the SDM Model. To ensure that this specific, structured, Four Step shared decision making process becomes a routine part of clinical practice, the practitioners/practices must be trained in shared decision making.\textsuperscript{11,12} Various professional Continuing Medical Education (CME) training opportunities and online resources focus on shared decision making training and implementation. These resources cover such areas as addressing challenges, facilitating the shared decision

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|}
\hline
Topic & Preference-Sensitive Conditions & Treatment/Decision Options & Specialty \\
\hline
Urinary & Benign prostate hyperplasia (BPH) & Observation, Non-surgical Treatment, Surgery & Primary care Urology \\
\hline
\end{tabular}
\end{table}

The preference-sensitive conditions will be reviewed annually, in collaboration with the participating ACOs and physician leadership at their SDM practices, to ensure consistency with evidence-based practice and treatment options. CMS may consider modifications to the preference-sensitive conditions, however such changes would be applied to all participating ACOs and would be implemented through modifications or addendum to the MPA.


making conversation, practicing communication skills, understanding the role and value of decision aids, and how to implement shared decision making in both primary and specialty care settings. All SDM practitioners/practices will be required to attend the training and the participating ACO must document that all SDM practitioners/practices received training. The training will be funded as part of The Innovation Center IMC’s scope of work.

Workflow and Care Delivery Redesign

Successful integration of the Four Step shared decision making process into a clinical practice within a participating ACO will require workflow redesign and the participation of SDM practitioners/practices in the redesign process. Some of the key considerations in workflow and care delivery redesign include:

- The actual composition of the practice team will depend on the size, staff capacities, and resources available at each participating ACO’s SDM practices.
- Shifting to a culture that invites active participation of beneficiaries and authorized representatives in health care decisions requires the active support of organizational leaders.

Patient Decision Aid System

Participating ACOs shall establish a system or library of evidence-based PDAs and make them available to its SDM practices and practitioners. It is critical that all PDAs used in the model are evidence-based. Participating ACOs shall provide evidence that they used a process and framework to select or develop PDAs, and they shall ensure the PDAs are maintained and updated routinely.

After award selection, participating ACOs and their SDM practices will be required to propose a standard set of PDAs for use in all of their respective participating ACO practices. The IMC will

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facilitate the selection and review of these PDAs based on the framework described below. The IMC will facilitate the selection and review of these PDAs based on the framework described below.

One framework for demonstrating PDA quality recommended by the Institute of Medicine includes using the guidelines from the International Patient Decision Aids Standards (IPDAS) Collaboration. IPDAS is a global group of researchers, practitioners, and stakeholders that has established a set of internationally approved criteria for determining the quality of PDAs using an evidence-informed framework. The framework calls for evaluating decision aids based on content, presentation, and effectiveness. IPDAS developed a checklist that decision aid developers and evaluators can use to test whether PDAs meet the criteria.

A second option for demonstrating PDA quality is through the Ottawa Hospital Research Institute PDA evaluation, which evaluates and scores sets of PDAs. A third option is that participating ACOs select PDAs that have been certified for the Washington State SDM program by the Medical Director of the Washington Health Care Authority.

**F. Payment Amount**

The SDM Model is designed to pay participating ACOs to incorporate the Four Step shared decision making process into the routine clinical care of their SDM practices. CMS will process, review and make payments, on a quarterly basis, to participating ACOs outside of the standard fee-for-service (FFS) claims system. CMS will pay $50 to the participating ACO for each SDM Service provided by an SDM practitioner, as long as all the SDM Activities are also completed by the participating ACO, and/or SDM practice or practitioner. Figure 1 depicts the SDM Service as a part of the Four Step SDM Process, and differentiates steps that are considered SDM Activities. Step 3 is considered a SDM Service (furnished by the SDM practitioner) and Steps 1, 2, and 4 are considered SDM Activities (completed by the participating ACO, and/or SDM practice or practitioner).

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22 [http://www.hca.wa.gov/hta/Pages/shareddecisionmaking.aspx](http://www.hca.wa.gov/hta/Pages/shareddecisionmaking.aspx)
In order to be eligible to receive payment for a SDM Service, the MPA will require the participating ACO to have a contractual relationship with each of its SDM practitioners whereby the practitioner waives his or her right to bill and receive payment for furnishing the SDM Service, consents to CMS paying the ACO for the SDM Service he or she furnished, agrees to not bill for any services furnished or activities performed in relation to the SDM Model under Medicare FFS, and agrees to joint and several liability to CMS for the SDM Payment. The MPA will require that a participating ACO’s SDM practices and practitioners be participating in that ACO in the Shared Savings Program or Next Generation ACO model for the duration of the ACO’s participation in the SDM Model.

In order to receive payment for a SDM Service, the MPA will require the participating ACO to have a contractual relationship with each of its SDM practices and practitioners whereby the SDM practices and practitioners agree to comply with all applicable conditions of payment and other relevant terms set forth in the MPA and to complete all Four Steps of the SDM Process as applicable and in accordance with the MPA.

At the end of each month, CMS will pay for all SDM Services in one lump-sum payment to the participating ACO. ACOs will report the SDM Service (i.e. the claim) as part of the Monthly SDM Reporting. Figure 2 illustrates how SDM Activities and Services fit into the Monthly SDM Reporting. The ACO is responsible for certifying and reporting all SDM Activities and SDM Services to the IMC performed by its SDM practices and practitioners (who have already certified and reported to their ACO) or directly by the ACO. Likewise, it will be the participating ACO who will request and receive payment from CMS.
Medicare Shared Savings Program ACOs include practices that are participating in the Comprehensive Primary Care Plus (CPC+), Oncology Care, and Million Hearts Cardiovascular Disease Risk Reduction Models. These practices will not be allowed to participate in the SDM Model, and likewise ACOs may not submit bills for SDM services provided by practices participating in these models. CMS specifically asks in this RFA for a list of practices participating in any of these three models identified by TIN and NPI(s). Participating ACOs will be required to update their listing of practices that are participating in one of the three models (that are prohibited from billing of SDM) initially in the in the SDM RFA and then as their participation list changes during the course of the SDM Model. CMS will include SDM Model payments paid to the participating ACO for SDM Services provided to assigned beneficiaries in its calculation of the participating ACO’s total costs of care for financial calculations under the Shared Savings Program or Next Generation ACO Model, as applicable. CMS will not include SDM Model payments for unassigned beneficiaries in calculations of a participating ACO’s total cost of care.
IV. Quality, Cost, and Utilization Measures

CMS will utilize measures and administrative data currently captured for participating ACOs to track quality, cost of care, and utilization. In addition, CMS will use other measures specific to the shared decision making interventions. These measures will include self-reported data from the participating ACO and the beneficiary questionnaire that is collected after each shared decision making session. These data will be reported to CMS monthly. The emphasis is not to add reporting burden for the participating ACOs. Topics measured may include beneficiary knowledge, satisfaction with the SDM Process, and concordance of the beneficiary’s decision with the treatment choice. The data requirements of the SDM Model will not affect the clinical quality measures already reported using the Group Practice Reporting Options (GPRO). Additional information on the measures will be included in the MPA.

V. Monitoring and Oversight

CMS will contract with an IMC to assist with all aspects of the planning, implementation, operation, monitoring/audits, preventing fraud and abuse, and ensure compliance with the terms of the MPA of the SDM Model.

The following will guide the SDM Model monitoring and oversight strategy to ensure compliance within the model, prevention of fraud and abuse, ensuring the integrity of the Medicare program and the safety of the beneficiaries.

Monitoring/Auditing/Compliance

Adherence to the SDM Model

CMS will utilize an IMC to monitor each of the participating ACOs and their SDM practices and practitioners to ensure their adherence to all applicable requirements of the SDM model, including the MPA and the obligations imposed on SDM practices and practitioners through their contractual relationship with a participating ACO. Comprehensive annual reviews will be conducted by the IMC to ensure ACO, practice and practitioner-level compliance with the model. In addition, more targeted (or ad-hoc) audits may be undertaken as necessary.

Requirements will be described in the MPA.

Model Operations Monitoring

CMS plans to monitor aspects of model operations using data collected from various sources. Operations monitoring will consider data submitted in response to the initial request for award (RFA) by the participating ACOs, in addition to information gathered from other sources (e.g., ACOs’ operational reports, patient questionnaire data, on-site visits, etc.). Data submitted by the participating ACO to CMS must be certified for truthfulness and accuracy by its SDM practices and practitioners who submitted data to the ACO. In addition, the data submitted to the IMC must be submitted by a legally authorized individual at the participating ACO. This data will be collected and transferred in accordance with all applicable laws, including the HIPAA Privacy and Security Rules.
Fraud and Abuse: CMS will use a range of methods for preventing health care fraud and model abuse, including but not limited to: verifying SDM payments, implementing specific queries or algorithms that can be run against the payment file (in conjunction with claims data and other administrative data) to alert CMS to suspicious or potentially fraudulent activities, sample audits, and more complex reviews when necessary.

Corrective Action: CMS may, in its sole discretion, terminate the SDM MPA at any time and without prior notice if there are any fraud and abuse concerns with the ACO or any of its practices or practitioners. If any problems are found with a participating ACO and/or its practices and/or practitioners, CMS will first attempt to resolve the issue through remedial action, including discussions with the site, through training and through technical assistance. This remedial action may include requiring the submission and implementation of a corrective action plan (CAP) by the ACO, or the termination of a participating ACO’s SDM Model contractual agreement with an SDM practice or practitioner. Details of this remediation process and related monitoring enforcement will be set forth in the MPA. In cases where a participating ACO is unable or unwilling to make corrections, has poor performance metrics and/or is not meeting other terms and conditions of the MPA, CMS may consider terminating the MPA or consider non-renewal of the participating ACO.

VI. Data Sharing and Reports

Participating ACOs will be required to submit data to the IMC through secure methods. The participating ACOs will adhere to all applicable laws, including, but not limited to HIPAA Privacy and Security rules.

ACO will be required to submit the patient questionnaire and SDM Reporting (i.e. the claim for the SDM Service) on a monthly basis. In addition, on a quarterly basis, the ACO will be required to submit operational data to include: ACO name, ACO TIN, Practice Name(s), Practice TIN(s), # of beneficiaries per month eligible for the inclusion criteria, # decision aids administered, etc. This information will be reported to CMS for monitoring and evaluation purposes.

VII. Evaluation

CMS, under contract with an independent evaluator, will conduct an independent evaluation of the SDM Model. The goal of the evaluation is to determine whether the model improves the quality of care without increasing spending; reduces spending without reducing quality of care; or improves the quality of care and reduces spending. The evaluation should address what aspects of the model contribute most to success, how contextual factors influence this success, and what considerations should influence decision making on whether to modify, terminate, or expand the models. The evaluation results will be used to inform programmatic policy decisions. All participating ACOs in the SDM Model will be required to cooperate with evaluation, which may include participation in surveys, interviews, site visits, and other activities that CMS determines to be necessary to conduct a comprehensive formative and summative evaluation. The MPA will provide that participating ACOs’ contracts with their SDM practices and practitioners must require the SDM practices and practitioners to cooperate with the evaluation.
VIII. Duration of Agreement, Remedial Action, and Termination

The initial term for the MPA will be two years, after a six month pre-implementation phase. For participating ACOs that are not in compliance with the terms and conditions of the MPA, CMS will consider remedial action, termination, or non-renewal, depending on the severity and the urgency of the problem. If remedial action is selected but is ineffective, CMS may choose not to renew the ACO’s MPA at the end of the agreement period or, in severe cases, may terminate the participating ACO from the model. ACO performance on core performance metrics and adherence to terms and conditions of the agreement will inform whether a participating ACO will have their participation in the SDM Model renewed. Examples of problems that may lead to non-renewal or termination include not implementing the model, very low engagement rates, and/or negative feedback from beneficiaries as determined from the beneficiary questionnaire, participating ACOs failure to meet the requirement of the Four Step Process. Participating ACOs that are in compliance with the requirements of the SDM Model will be considered for renewal in the SDM Model on an annual basis after the initial two year agreement, up to five years total. The participating ACOs in the SDM Model must continue to be ACOs in the Medicare Shared Savings Program (Shared Savings Program) or Next Generation ACO Model in order to continue in the SDM Model. Detailed information about the duration of agreement and termination will be available in the MPA.

IX. Learning and Diffusion Resources

Learning and diffusion strategies will be integrated with the operational elements of the model to support participating ACOs in meeting the model aims. This integrated approach to operational learning may include use of a collaboration site to promote communication between participating ACOs; webinars as a medium for delivering content virtually; affinity groups to share best practices, shared learning, and other aspects of model goals; monthly technical assistance calls; and regular office hours as needed for assistance. To accomplish this, CMS will employ an IMC to develop shared decision making learning systems. Each participating ACO will be required to fully participate in these learning activities and to participate in an annual training meeting on the model.

X. Applicant Eligibility and Participation Requirement

A. Model Participating ACOs

An ACO is a healthcare organization that agrees to be accountable for the overall cost and quality of care provided for an assigned population of Medicare FFS beneficiaries. ACOs are groups of doctors, hospitals, and other health care practitioners that come together voluntarily to give coordinated, high-quality care to their Medicare beneficiaries.

The ACOs that may participate in the SDM Model are limited to the ACOs participating in the Shared Savings Program or Next Generation ACO model. The Shared Savings Program is authorized under Section 1899 of the Social Security Act (42 U.S.C. 1395jjj) (as added by the
ACA), which incentivizes participating ACOs to provide greater care coordination while reducing unnecessary costs. The Next Generation ACO Model, authorized under 1115A of the Social Security Act, tests whether strong financial incentives for ACOs, coupled with tools to support better patient engagement and care management, can improve health outcomes for beneficiaries and lower expenditures for original Medicare FFS beneficiaries. Non-Medicare ACOs are not eligible to apply.

ACOs are well positioned for efficient implementation of the SDM Model because they are already required under Medicare Shared Savings Program rules to implement SDM as part of their beneficiary engagement activities. While they have care coordination infrastructure and analytic capacity to mine their data, they are not necessarily implementing the most effective, or structured shared decision making process available, which presents an opportunity for the SDM Model to improve ACO performance. Testing this model in ACOs can help identify a specific approach to SDM that if successful in improving health and spending outcomes and patient experience with care, can be disseminated more broadly to ACOs and other health systems.

CMS plans to operate the SDM Model in an intervention group of 50 participating ACOs nationwide with an equal number of ACOs in a comparison group. The pool of accepted ACO applicants for the SDM Model will be randomly assigned either to the intervention or comparison group, with only the intervention group participating in the SDM Model; the comparison group will not be subject to monitoring, data submissions, etc., nor will they receive any payment under the SDM Model. Only CMS or its contractors will have knowledge of ACOs in the comparison group.

B. Participating ACOs Eligibility Requirements

A participating ACO shall:

- Be an ACO in the Shared Savings Program or Next Generation ACO Model.
- Have experience in operating and implementing significant projects across practice groups, as well as experience in rapid cycle learning (continuous data collection, rapid feedback and process improvement is disseminated through a learning and diffusion team).
- Use an EHR that meets the requirements of the 2014 Edition Health Information Technology (Health IT) certification criteria.23

Responsibilities of participating ACOs after selection include:

- Engage and collaborate with other participating ACOs, CMS support contractors (i.e. IMC, IPC, etc.), and other CMS components.
- Participate in SDM Model shared decision making training.

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• Implement the specific, structured, Four Steps of the SDM Process and utilize PDAs.
• Provide ongoing practice redesign support. Demonstrate that they will make the changes necessary to implement the Four Step SDM Process into their SDM practices’ and practitioners’ patient workflows.
• Select a standard set of PDAs for each preference-sensitive condition for use across all its SDM practices within the participating ACO. The PDAs used by participating ACOs must meet IPDAS guidelines.
• Establish a venue to house and maintain the repository of PDAs. Establish a process and framework to maintain and update PDAs.
• Establish model-wide inclusion/exclusion criteria for identifying beneficiaries for each preference-sensitive condition.
• Have in place data-sharing capabilities for data collection, and a reporting and tracking system, including the ability to collect, hold, and evaluate personally identifiable information (PII) and protected health information (PHI). The participating ACOs will adhere to applicable laws, including, but not limited to the HIPAA Privacy and Security rules.
• Participate in ongoing data collection and reporting of quality measures and other data specific to the model, which includes the submission of the beneficiary questionnaire and ensure such participation by their SDM practices and practitioners.
• Participate in the various reporting requirements of the SDM Model as outlined in Table 1 and the Payment Amount Section, and ensure such compliance and participation in their SDM practices.
• Implement safeguards to ensure oversight of and accountability by the SDM practices and practitioners completing SDM Activities and furnishing the SDM Service.
• Ensure its SDM practices and practitioners do not withhold or reduce care or otherwise discriminate against beneficiaries that choose not to participate in the SDM Model.

All of the above responsibilities will be defined and enforced per the MPA.

C. Target Population

The target population for the SDM Model is Medicare FFS beneficiaries, including dually eligible FFS beneficiaries. An “eligible beneficiary” for this model must meet all of the following criteria:

• The beneficiary must be enrolled in Medicare Part A and B.
• Medicare must be the beneficiary’s primary payer.
• The beneficiary must not be enrolled in any managed care plan (for example, Medicare Advantage).
• The beneficiary must meet the eligibility requirements and inclusion/exclusion criteria of the preference-sensitive conditions (see Table 2). The IMC along with the ACO will develop these criteria.
• The beneficiary must be treated by a practitioner who is part of a participating ACO in the SDM Model. The beneficiary does not need to be assigned to the ACO to be an eligible beneficiary under the model.

XI. Screening

Applications will be screened to determine eligibility for further review using criteria detailed in this solicitation and in applicable law and regulations. In addition, CMS may deny selection to an otherwise qualified applicant on the basis of information found during a program integrity review of the applicant, its providers/suppliers, its affiliates or any relevant individuals or entities.

XII. Application Process

Each organization must submit a letter of intent (LOI) and an application to be considered.

A. Letter of Intent (LOI)

Interested organizations must submit an LOI no later than 5:00 PM Eastern Standard Time on 3/5/17. A LOI template is provided in Appendix A and is for reference only.

A LOI is mandatory in order to submit an application. The LOI will not bind an interested organization to moving forward under the model.

To submit a LOI, interested organizations may access an electronic portal at https://app1.innovation.cms.gov/beisdm/. The LOI must be submitted online to be considered.

B. Application

Interested organizations must submit an application no later than 11:59 PM Eastern Standard Time on 3/5/17. An application template is provided in Appendix B so that applicants can begin preparing their responses. The applications must be completed online in order to be considered.

Applicants may access the application portal at https://app1.innovation.cms.gov/beisdm/.

CMS reserves the right to request interviews, site visit, or additional information related to application responses from applicants in order to assess their application.

To submit an application, the applicant must first submit a LOI.

Applicants that do not submit a LOI will not be able to access the application page.
Any questions that arise during the application process may be directed to the Beneficiary Engagement and Incentives – Shared Decision Making mailbox {SDMmodel@cms.hhs.gov}

For information please visit the website at:

C. Withdrawal of Application

Applicants seeking to withdraw a completed application must submit an electronic withdrawal request to CMS via the Beneficiary Engagement and Incentives – Shared Decision Making mailbox (SDMmodel@cms.hhs.gov). The request must be submitted as a PDF on the organization’s letterhead and signed by an authorized corporate official. It should include the applicant organization’s legal name, the organization’s primary point of contact, the full and correct address of the organization.
Appendix A: Letter of Intent Template

Draft Template for Letter of Intent (LOI)

Interested organizations must submit an LOI no later than 5:00 PM Eastern Standard Time on 3/5/17. A Letter of Intent is mandatory in order to submit an application. The LOI will not bind an interested organization to moving forward under the model.

To file a LOI, interested organizations may access an electronic portal at https://app1.innovation.cms.gov/beisdm/. The LOI must be submitted online to be considered. Template of the LOI is available for reference only.

CMS will safeguard the information provided in accordance with the Privacy Act of 1974, as amended (5 U.S.C. § 552a). For more information, please see the CMS Privacy Policy at https://www.cms.gov/AboutWebsite/02_Privacy-Policy.asp.

Please note: You must be a Medicare ACO to apply.

Medicare ACO Name
What is your Medicare ACO ID number?
Doing Business As (if applicable):
Organization Type (medical group practice, network of individual practices, integrated delivery system, partnership of medical practice, other):
Organization TIN/EIN:
Street Address 1:
Street Address 2:
City:
State:
ZIP Code:
Website (if applicable):

Applicant Primary Contact
First Name:
Last Name:
Title/Position:
Business Phone Number:
Business Phone Number Extension:
Alternative Phone Number (e.g., cell phone):
E-mail Address:
Street Address 1:
Street Address 2:
City:
State:
ZIP Code:
Is your primary contact here, the same as your primary contact for your Medicare ACO participation?
Secondary Contact
First Name:
Last Name:
Title/Position:
Business Phone Number:
Business Phone Number Extension:
Alternative Phone Number (e.g., cell phone):
E-mail Address:
Street Address 1:
Street Address 2:
City:
State and ZIP code:

ACO Information
1. Tell us how many of the practitioners participating in your ACO are primary care practitioners? How many are specialists?

2. Please provide the number of practices, total number of practitioners and total number of Medicare FFS visits in primary adult care, oncology, radiology, urology, orthopedics and other for the last full calendar year (use CY 2015 data). These are the practices and specialties that we will be working with that will constitute the applicant ACO.
Appendix B: Application Template

General Information
Welcome to the Beneficiary Engagement and Incentives – Shared Decision Making (SDM) Model application.

Applications must be received by 11:59 PM Eastern Standard Time on 3/5/17

An application template is provided in Appendix B so that applicants can begin preparing their responses. **The applications must be completed online to be considered.** The application can be found and completed at: [https://app1.innovation.cms.gov/beisdm/](https://app1.innovation.cms.gov/beisdm/). Please follow the directions listed on the online application screen to complete the application.

Any questions that arise during the application process may be directed to the Beneficiary Engagement and Incentives-Shared Decision Making mailbox at [SDMmodel@cms.hhs.gov](mailto:SDMmodel@cms.hhs.gov)

Letter of Intent #__________________
Please note; you must have a letter of intent # to continue

Background Information
ACO Organization Information
1. Organization Name
2. Doing Business As
3. Organization TIN/EIN
3. Street Address
4. City
5. State
6. Zip Code
8. Website, if applicable
9. List catchment areas by state and county

Applicant Primary Contact
First Name:
Last Name:
Title/Position:
Business Phone Number:
Business Phone Number Extension:
Alternative Phone Number (e.g., cell phone):
E-mail Address:
Street Address 1:
Street Address 2:
City:
State:
ZIP Code:
Applicant Secondary Contact
First Name:
Last Name:
Title/Position:
Business Phone Number:
Business Phone Number Extension:
Alternative Phone Number (e.g., cell phone):
E-mail Address:
Street Address 1:
Street Address 2:
City:
State:
ZIP Code:

ACO Organization Profile

1. Type of Applicant organization. Check only one:
   - Medical group practice:
   - Network of individual practices (e.g., IPA):
   - Integrated delivery system:
   - Partnership of medical practices:
   - Other, please describe:

2. What type of ACO are you?
   - Medicare Shared Savings Program (SSP):
   - Next Generation ACO Model:

3. What is your Medicare ACO #

4. Tell us about the composition of the ACO, including all of the TINs and organizations composing the ACO. Please includes the TIN of the ACO, the TINs of all of your practices and the NPIs of your practitioners.

5. Are any of your primary care practices in the Comprehensive Primary Care Plus (CPC+) Initiative? If so, provide us with the TIN of each practice and the NPI of the provider associated with that TIN.

6. Are any of your practices in the Million Heart Cardiovascular Disease Risk Reduction Model (MH CVD)? If so, provide us with the TIN of each practice and the NPI of the provider associated with that TIN.

7. Are any of your practices in the Oncology Care Model (OCM)? If so, provide us with the TIN of each practice and the NPI of the provider associated with that TIN.
8. Provide the following information:
   o Total number of all visits to practitioners in CY 2015.
   o Number of Medicare assigned and non-assigned FFS patients and visits in CY 2015.

<table>
<thead>
<tr>
<th></th>
<th>Patients</th>
<th>Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assigned</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-assigned</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. To the best of your knowledge, has the ACO applicant, its owners/managers, or any of your ACO practices or any practitioners employed in your ACO practices had a final adverse legal action or been the subject of an investigation by, prosecution by, or settlement with the Health and Human Services Office of the Inspector General, U.S. Department of Justice, or any other Federal or State enforcement agency in the last seven years relating to allegations of failure to comply with applicable Medicare or Medicaid billing rules, the Anti-Kickback Statute, the physician self-referral prohibition, or any other applicable fraud and abuse laws? Failure to disclose could be grounds for application denial or immediate termination from the SDM Model.
   a. Yes
   b. No
   If yes, please explain the legal actions, investigations, prosecutions, and/or settlements; the agency involved; and the resolution, if any.

10. CMS expects a participating ACO to implement the SDM Model in all of its practices and practitioners, unless the ACO demonstrates to CMS that, based on the preference-sensitive conditions being targeted and the nature of a particular practice or practitioner participating in the ACO, that particular practice or practitioner is unlikely to provide services to beneficiaries with one or more preference-sensitive conditions with respect to that condition or conditions. If there is a practice that fits this criteria, please provide the practice name, practice TIN, type of practice and rationale for exclusion. CMS reserves the right to ask for additional information from the ACO and approve the exclusion.

11. Please update the following information based on CY 2015 data.

   Note: The first three columns seen below will be pre-populated from your submission in the LOI. You may change any applicable fields and provide additional details in the box below. In addition, you will need to populate the last column.
Practice Type | # Practices | # Practitioners | # Medicare FFS Visits | # Medicare FFS visits with a preference sensitive condition as defined in Table 2.
--- | --- | --- | --- | ---
Primary Adult Care | | | | |
Oncology | | | | |
Radiology | | | | |
Urology | | | | |
Orthopedics | | | | |
Other | | | | |

Evaluation criteria

The following questions and scores will be used to determine the application selection process. There are a total of 100 points. To earn the full amount of points for each section, the applicant must answer each question. Applications that have a score at or below an evaluator score of 70 points may not result in selection for participation.

Goals Section {scoring for this section will be a total of 20 points}
1. Describe why you want to join the model.
2. What are you currently doing to improve beneficiary engagement? How will this project help you improve?
3. Have you implemented shared decision making in any of the clinical practices that are associated with your ACO? If so, describe your experience and any lessons learned. Provide your list of preference-sensitive conditions (PSCs).

Organization and Leadership Capacity {scoring for this section will be a total of 30 points}
1. Describe your experience in operating and implementing significant projects across large practice groups.
2. Tell us who the leadership team will include, and include information about the project lead.
3. Describe your experience in rapid-cycle learning and improvement.
4. Describe your experience of providing ongoing practice redesign support and training.

Implementation {scoring for this section will be a total of 50 points}
1. Describe your Implementation Plan for this project. Present evidence that the organization is capable of implementing and managing the model. Explain how the ACO will work with individual practices and practitioners to implement the model.
2. Describe your process for selecting a standard set of patient decision aids (PDA) for each PSC to be used across all practices. What framework will you use to determine quality of the decision aids [e.g., International Patient Decision Aid Standards (IPDAS), Ottawa Hospital
Research Institute, Washington State SDM program, etc.? Note that applicants are not required to select the PDAs until selected for the model.

3. Describe the process you will use to identify beneficiaries for inclusion in the shared decision making process and how you will introduce them to the model.

4. Identify major challenges and strategies to mitigate these challenges in implementing shared decision making in your ACO practices.