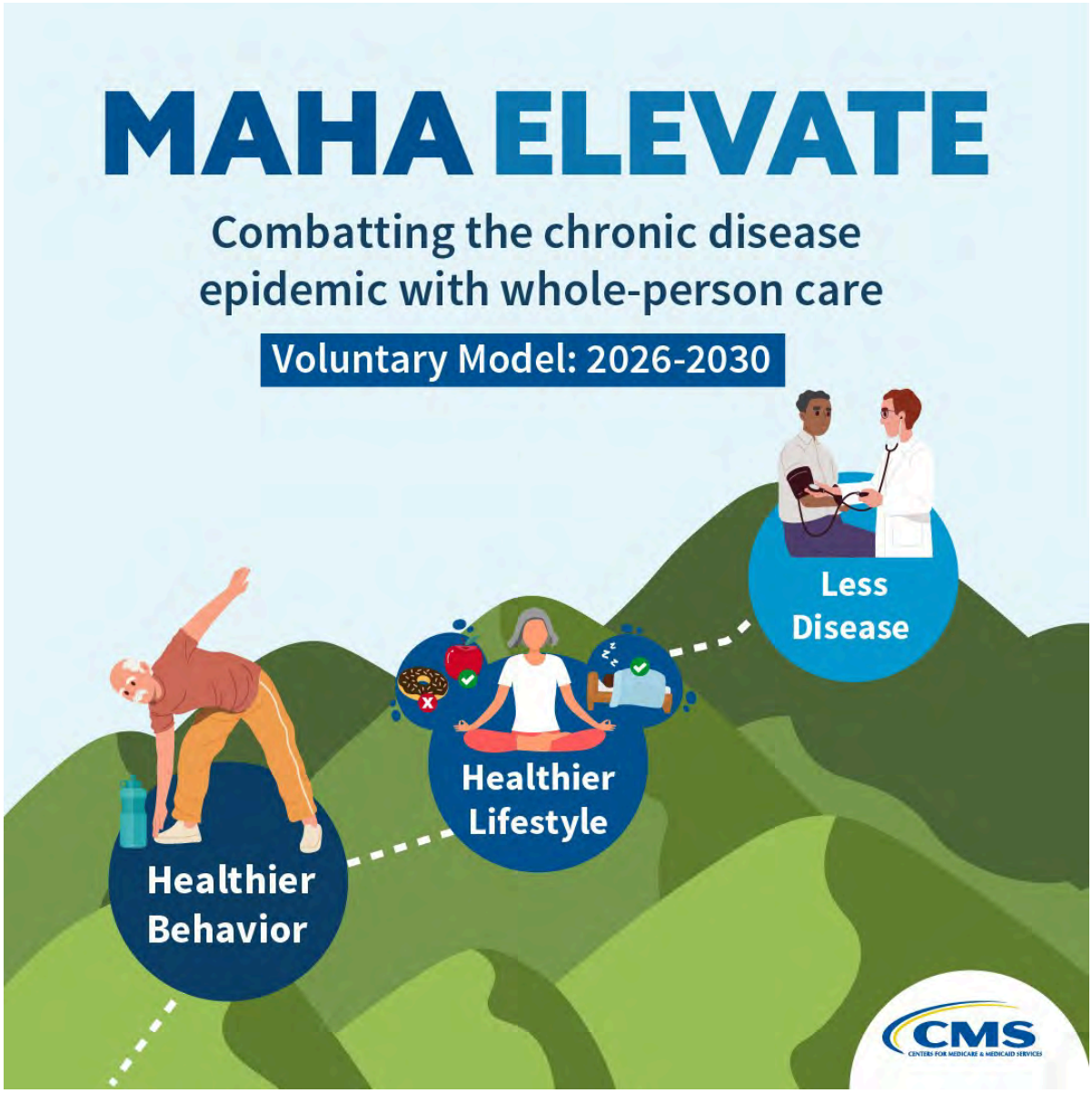
Notice of Funding Opportunity

Application due Friday, May 15, 2026



Make America Healthy Again: Enhancing Lifestyle and Evaluating Value-Based Approaches Through Evidence (MAHA ELEVATE)

Opportunity number: CMS-2W2-27-001

Contents

Before you begin

If you believe you are a good candidate for this funding opportunity, secure your SAM.gov and Grants.gov registrations now. If you are already registered, make sure your registrations are active and up-to-date.

SAM.gov registration (this can take several weeks)

You must have an active account with SAM.gov. This includes having a Unique Entity Identifier (UEI).

See Step 2: Get Ready to Apply

Grants.gov registration (this can take several days)

You must have an active Grants.gov registration. Doing so requires a Login.gov registration as well.

See Step 2: Get Ready to Apply

Apply by the application due date

Applications are due by 11:59 p.m. Eastern Time on Friday, May 15, 2026.

To help you find what you need, this NOFO uses internal links. In Adobe Reader, you can go back to where you were by pressing Alt + Left Arrow (Windows) or Command + Left Arrow (Mac) on your keyboard.

Step 1:
Review the Opportunity

In this step

Basic information

Centers for Medicaid & Medicare Services (CMS)

Center for Medicare and Medicaid Innovation ("CMS Innovation Center")

Patient Care Models Group (PCMG)

Test innovative, evidence-based clinical approaches rooted in whole-person functional and lifestyle medicine that hold strong potential for improving health outcomes and reducing costs.

Summary

The Centers for Medicare & Medicaid Services (CMS), through its Centers for Medicare and Medicaid Innovation (CMMI or Innovation Center), is soliciting applications for the Make America Healthy Again: Enhancing Lifestyle & Evaluating Value-based Approaches Through Evidence (MAHA ELEVATE) Model. This voluntary, three-year service delivery model is designed to test evidence-based, whole-person functional or lifestyle medicine ("whole-person FLM") approaches to care. Rather than treating diseases separately after they develop, MAHA ELEVATE takes a proactive, comprehensive approach that combines psychological, nutritional, and physical interventions with personalized, lifestyle-based strategies for prevention and early treatment.

Throughout this NOFO, we use the term "whole-person FLM" to represent a range of services or approaches often incorporated in lifestyle and functional medicine that are not currently covered under Medicare. It is important to clarify that CMS is not establishing a new industry standard through the use of this terminology. The term "whole-person FLM" as used in this NOFO does not represent an attempt by CMS to create, define, or establish any new industry-wide standard, practice guideline(s), or healthcare delivery model beyond the scope of this specific Innovation Center model and funding opportunity. Similarly, through this funding opportunity, CMS is not creating a new category of covered services for Medicare purposes. This term serves solely as a descriptive reference within this document to facilitate clear communication about the non-covered services being tested in this model and should not be interpreted as having any regulatory, coverage, or policy implications beyond the context of this specific Innovation Center model.

Have questions?
Go to Contacts and Support.

Key facts

Opportunity name: Make America Healthy Again – Enhancing Lifestyle and Evaluating Value-based Approaches Through Evidence

Opportunity number: CMS-2W2-27-001

Assistance listing: 93.460

NOFO version: Original

Key dates

Application submission deadline:
Friday, May 15, 2026

Required letter of intent deadline:
Friday, April 10, 2026

Informational webcast:
Thursday, April 2, 2026

Additional dates may be posted on the MAHA ELEVATE website.

Expected award date:
October 2026

Expected earliest start date:
October 2026

See other submissions for other time frames that may apply to this NOFO.

CMS will select a total of up to 30 Recipients to participate in MAHA ELEVATE. The model will be split into two cohorts, one year apart (years 2026 and 2027). Approximately $3.3 million in Cooperative Agreement Awards will be available to each selected recipient over a three-year period of performance for a total of up to a $100 million investment.

CMS will select recipients based on five key criteria:

- Whole-person FLM intervention design, including cost savings.
- Beneficiary recruitment and study design.
- Organizational and administrative capacity.
- Data management capabilities.
- Budget.

Highly competitive applicants must demonstrate several important strengths:

- Strong, evidence-based support for your proposed intervention(s) and proof of your own successful history of implementation of the intervention and cost savings.
- Ability to recruit large numbers of participants with a clear randomization plan and advanced data management capabilities.

Given the model's minimum beneficiary targets and extensive data management requirements, applicants who do not directly provide clinical care are strongly encouraged to form partnerships with care entities or organizations that deliver clinical care. This collaboration helps ensure you can meet the full operational requirements of the program.

Funding details

Funding type: Cooperative agreement, which means that both you and CMS will have roles in the project. Throughout the life of your project, we will be there to help and work with you.

Expected total funding for the program: $100 million, subject to the availability of funds.

Expected total awards: Up to 30

Funding range per applicant for the period of performance: Up to $3.3 million over a three-year performance period.

We will provide funding in up to nine disbursements over a three-year period of performance based on completing the milestones for each payment detailed in Table E: Operational Milestones. We will provide funding in two budget periods of 18 months each over a three-year period of performance. The three-year period includes six months at the start to help you get ready.

Cohorts

We will give out awards in two cohorts, with 15 awards in each cohort, for a total of up to 30 awards. If we give out fewer than 15 in the first cohort, we may give out more than 15 in the second cohort. You may apply to both cohorts. If you are selected in 2026, you can apply again in 2027 for a different intervention or chronic condition.

- The first cohort period of performance will start in October 2026.
- The second cohort period of performance will start in October 2027.

Additionally, three out of the 30 total awards are set aside specifically for programs focused on dementia and cognitive decline.

The two separate application deadlines are:

- **Cohort 1:** Friday, May 15, 2026 by 11:59 p.m. ET.

If you apply under the first cohort and are not awarded funds, you may apply again during the second cohort using the same application or an updated application.

Eligibility

Eligible applicants

Eligible applicants include any organization that meets the requirements outlined in this NOFO. Individuals are not eligible to apply.

Examples of eligible applicants may include, but are not limited to:

- Private medical practices.
- Health systems and Accountable Care Organizations (ACOs).
- Academic organizations.
- Functional, lifestyle, preventive, and integrative medicine centers.
- Community-based organizations (CBOs).
- Federally Qualified Health Centers (FQHCs).
- Rural Health Clinics (RHCs).
- Indian Health Service/Tribal Services/Urban Indian Programs (ITUs).
- Local and state governments.

Organizations spanning multiple states are eligible to apply.

Other eligibility requirements

Organizations in all 50 states, District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands are eligible to apply.

Organizations must have experience integrating whole-person FLM into conventional medical care, resulting in demonstrated improvements in health, quality, and costs.

Requirement	Narrative
Organization type	CMS seeks to engage a broad range of organizations to promote diversity in testing whole-person FLM approaches. To be eligible, you must demonstrate clinical oversight capabilities to ensure appropriate care delivery and beneficiary safety. However, as the applicant, you are **not required to be a clinical entity.** If you are not a clinical entity, but partner with one, you will need to submit a partnership document as described in the application template. CMS may require the submission of additional documentation regarding the partnership after application submission.
Valid TIN, NPI, CCN, or EIN	Your organization **must be a legally recognized entity** with a valid Tax Identification Number (TIN), National Provider Identifier (NPI), CMS Certification Number (CCN), and/or Employer Identification Number (EIN).
Original Medicare enrollment	**We strongly recommend that your organization enroll in Original Medicare before you begin your project.** If you will provide covered Medicare services to patients as part of your overall proposed intervention, you must be enrolled in Medicare by model start. If you are not enrolled in Medicare, you will need to verify your ability to enroll Medicare beneficiaries in your program through a partnership with a clinical entity or otherwise, as demonstrated by a memorandum of understanding or other partnership document.
Able to recruit beneficiary minimum and sample size	We will determine the minimum number of beneficiaries who must enroll in and complete your intervention. This is known as the minimum beneficiary target and is based on the intervention you propose and the size of the effect on patients that you expect to see. For more information, including some examples of minimum beneficiary targets, please see Appendix A. Disbursement of some funding under this award will be tied to making progress toward meeting this target.

Requirement	Narrative
CEHRT or other data capabilities	While Certified Electronic Health Record Technology (CEHRT) as defined for certain CMS programs in 42 CFR 414.1305 and 495.4 is not required, you must demonstrate past experience with data collection or the ability to accurately collect and report all required data from patient enrollees in a timely manner. You must demonstrate appropriate data privacy and security protections and an understanding of how to store and analyze data with model goals in mind. In addition, HHS Health IT Alignment requirements for use of health IT standards and certified health IT may apply, depending on health IT activities funded through the cooperative agreement. Please refer to the Grants Policy Statement, Appendix D: Administrative and National Policy Requirements, which describe HHS Health IT Alignment requirements, for further information. You and your care delivery partners are solely responsible for obtaining any Institutional Review Board (IRB) procedures and approvals and any other permissions that may be required by federal or state law. You must comply with regulations for the protection of human subjects in 45 CFR Part 46 and obtain IRB approval as applicable.
Model overlaps	Organizations participating in the Medicare Shared Savings Program are eligible to apply. Organizations accepted to multiple active CMS Innovation Center models will be assessed for participation on a case-by-case basis.
Insured	Your organization must have liability and/or malpractice insurance, as appropriate.

Completeness and responsiveness criteria

We will review your application to make sure it meets the requirements found in Eligibility, Application contents and format, and Application submission and deadlines.

We won't consider an application that:

- Is from an organization that doesn't meet all eligibility criteria.
- Requests funding above the award ceiling shown in the funding range.
- Is submitted after the deadline.
- Is not submitted through Grants.gov.

The Division of Grants Management director or deputy director may choose to continue the review process for an ineligible application if it is in the best interests of the government to meet the objectives of the program.

Application limits

Organizations can submit multiple proposals during the application period and receive multiple awards. However, CMS aims to fund a wide range of applicants for thorough testing. CMS may ask single applicant organizations to combine related proposals into a single, comprehensive proposal.

All applications must independently meet the following criteria:

- **Distinct design:** Each proposed whole-person FLM program or intervention must be substantively different from other submissions by the same organization and from existing Medicare Fee-For-Service (FFS) models and programs.
- **Independent merit:** Each proposal must demonstrate individual merit and scientific value worthy of separate testing and evaluation.

Cost sharing

This program has no cost-sharing requirement, meaning you do not need to contribute to the costs of this project.

If you choose to include cost-sharing funds, it won't change the way we score your application. If you receive an award, we will include your voluntary commitment in the award, and you must report on the funding.

Program description

Purpose

MAHA ELEVATE will enable small scale tests of the feasibility, impact, and scalability of new interventions in an Original Medicare[1] population. It will provide critical data to inform new coverage determinations or a potential future full-scale model that integrates such services into Original Medicare. Given the limited evidence that currently exists for whole-person FLM in the Original Medicare population, MAHA ELEVATE aims to strengthen the evidence base through testing innovative health care approaches developed and implemented by a variety of health care organizations nationwide.

Testing small trials of various whole-person FLM interventions (complementing conventional medical care) will generate evidence that may support a larger, more generalizable test or new coverage determinations. It may also build toward transformation of the current health care system from reactive and symptom-focused, to one that emphasizes proactive strategies for chronic disease prevention and upstream disease management.

Lifestyle medicine focuses on preventing and treating chronic disease through evidence-based behavioral changes such as nutrition, physical activity, sleep, stress management, social connection, and avoidance of harmful substances.

Functional medicine uses a systems-based, individualized approach that aims to identify and address the root causes of illness by examining interactions among genetics, environment, and lifestyle.

Over time, we hypothesize that this approach will lead to a healthier population and lower health-care costs.[2]

Throughout this document, the term “intervention” refers to one or more interventions. “Program” refers to the entire project and all its components, while “intervention” refers to the specific services or activities delivered within that program.

Background

Over the last 15 years, the Center for Medicare and Medicaid Innovation (the Innovation Center) has tested alternative payment models with the goal of improving quality and outcomes and/or reducing Medicare spending. The Innovation Center's new 2025 vision is guided by three interrelated strategic pillars: promoting evidence-based prevention, empowering people to achieve their health goals, and driving choice and competition.

Consistent with the Innovation Center's vision and strategic pillars, MAHA ELEVATE addresses one of the most urgent and costly challenges in American health care: the rising burden of chronic disease. In 2022, about 45% of Medicare beneficiaries had four or more chronic conditions[3], and beneficiaries with chronic conditions accounted for nearly 90% of total health care expenditures[4]. Despite the scale of the problem, care delivery remains largely reactive and focuses on symptom and disease management (secondary and tertiary) rather than identifying and addressing the root causes of illnesses (primary), leading to suboptimal health outcomes and unsustainable spending[5]. Through this model, CMS aims to address the core lifestyle and preventive elements of human behavior that are associated with the development of chronic disease.

Program requirements and expectations

Program design

Your program will test the idea that whole-person[6] FLM interventions — particularly those that incorporate nutrition and physical activity — can improve patient health and chronic condition management when integrated into daily life and care plans. We expect that prevention and management of chronic conditions will lead to a healthier population and lower health-care costs.[7]

You will identify the chronic condition that you wish to address in the Original Medicare population (also known as Medicare and Medicare Fee-For-Service or FFS). Chronic conditions may range from those requiring ongoing treatment and evaluation to complications or conditions that place a person at low or medium complexity or level of need. This could be a specific diagnosis or a set of persistent, troubling symptoms that have not yet been diagnosed. You may choose to address a set of diagnoses, such as metabolic disorders. You may include people who are at risk of developing the chronic condition but haven't

yet, and you may determine other inclusion or exclusion criteria.You will also identify the intervention or set of interventions you will use to address your selected chronic condition. The model's approach is shaped, in part, by insights from the American College of Lifestyle Medicine's (ACLM) six foundational pillars for the effective prevention and management of chronic conditions, adapted to meet the model's specific objectives:

- Nutrition — Evidence-based dietary interventions and nutritional counseling.
- Physical activity — Structured exercise programs and movement-based therapies.
- Restorative sleep — Sleep hygiene education and sleep disorder management.
- Stress management — Mindfulness, meditation, and stress reduction techniques.
- Avoidance of risky substances — Tobacco cessation, alcohol moderation, and substance abuse prevention.
- Positive social connections — Community engagement and social support interventions.

Your intervention must align with this framework, but you do not have to have a certification in functional or lifestyle medicine. You must incorporate nutrition[8] or physical activity as part of the program, and you can include any of the other areas if you choose.

We are looking for programs that incorporate whole-person FLM interventions to support, not replace, conventional medical care for a chronic condition. You may include a combination of whole-person FLM and conventional interventions, such as a nutrition intervention paired with support for medication adherence. (Covered services will be billed to Medicare and are not funded by the cooperative agreement.) Your program must include at least one service not covered by Original Medicare and must provide evidence of the intervention's efficacy for the target population. You must ensure that patients are not harmed by your program, and you must be sure that they maintain choice in their care and treatment plans. You will recruit Original Medicare patients to join your program, and you will measure the impact of your program on those Medicare patients who complete the entire intervention. Although you may be providing services to many types of patients, you may only use the cooperative agreement funds for the portion of the program that serves Original Medicare patients.

We want to see how your intervention changes the patients' clinical measures, health care utilization, and health care costs. Therefore, on at least a quarterly basis, you will submit beneficiary rosters which have key information about patients enrolled in the intervention(s) as detailed in Table B, Identifiers of beneficiaries and providers involved in the intervention, and Table C, Documentation of the interventions.

You will also need to collect data on a separate but similar group of eligible and interested patients. The best way to do this is to use randomized enrollment for your Medicare patients so that some receive your whole-person FLM intervention and some receive the conventional standard of care. This allows for the strongest measurement of your program and is what we prefer. If you can't randomize your patients, an alternative may be practice-, provider-, or site-level randomization. We can help you further design and implement randomization if needed.

After we receive your application, we can determine exactly how many Original Medicare patients you will need in your treatment group and your comparison group to allow us to measure your program's impacts. For more details, see Appendix A. Programs with larger numbers of Original Medicare patients will be easier for us to measure, so you may wish to partner with other organizations to increase your potential. Your partners may help refer patients to you, or you may work with other organizations to deliver the FLM intervention to a larger group.

You will need to demonstrate successful experience delivering this intervention and cost savings by showing us your own data (including outcome data). You may show us data from a past or current program that did or did not include Original Medicare patients, and you may use the cooperative agreement to expand it to include Original Medicare as a new population. Sharing your data allows us to see that you have an existing program and that you are able to collect the data we require.

You will also need to provide published, peer-reviewed evidence demonstrating the safety, efficacy, and cost effectiveness of your proposed intervention. While this evidence is not required to be based on your own work, it should be similar in scope.

Quality measures and data reporting elements

If awarded, you will be required to collect and report patient-level data to CMS for program monitoring and/or evaluation purposes. We will provide technical assistance to help you efficiently collect and report data. You may use part of your funding under this award to collect and submit data to CMS. You are responsible for obtaining any other permissions from patients, your organization, or state/local entities that may be needed to collect, share, or analyze internal data and for complying with any applicable laws and model data policies related to such data collection and sharing. These procedures and approvals must not hinder cooperation with evaluation activities, data collection, or data sharing and submission to CMS or its contractors related to this award.

You must measure either a nutrition **or** physical activity metric, **and** a behavioral health metric for all patients receiving your intervention. You must also identify and track at least two clinical measure metrics that are evidence-based, practical, and directly related to your intervention. For example, if you are proposing a nutrition intervention to address weight loss, you may choose to routinely collect patient's waist circumference and weight.

Table A below shows the required and optional data you will collect. Beyond the required measures, you can select from the optional domains to measure and track additional data to support your theory of change. We will work with you to finalize your chosen measures if we select your application.

Table A: Quality measures

Category	Details
Required measures: **Nutrition or physical activity***	You will choose and track one.
Required measures: **Clinical measures**	You will choose and track at least two clinical measures that are relevant, feasible to collect, and related to your intervention. **For example**: Intervention: Nutrition education for weight loss. Clinical measures: 1. Waist circumference. 2. Weight.
Required measures: **Behavioral health**	You will choose and track one.
Required measures: **Patient satisfaction**	CMS will develop and track.
Optional measures: • Sleep. • Stress management. • Avoidance of risky substances. • Positive social connections.	You will choose and track if desired. *If you choose nutrition or physical activity as a required domain, you may choose the other as optional.

Beginning in the first quarter of Model Year 1, you will be required to participate in **monitoring activities** that include but are not limited to:

- Submitting quarterly progress reports.
- Engaging with appropriate partners as necessary to develop strategies and draft agreements to link and share data.
- Communicating regularly with a CMS project officer.

- Regularly attending and participating in learning system events.
- Participating fully in technical assistance activities.

You must collect the following data elements to monitor your progress:

- **Medicare identifiers.** You must provide Medicare FFS patient and provider identifiers linkable to CMS claims and enrollment data. This is so you can longitudinally track all beneficiaries and providers involved in the intervention and control/comparison groups.
- **Control/comparison group data.** You are expected to provide data to CMS and its contractors on beneficiaries enrolled in the intervention and for a control or comparison group. We can help you identify the most appropriate control or comparison group based on the structure of the proposed intervention. We can also provide technical assistance related to data submission and reporting requirements.
- **Qualitative and additional survey data.** During the award, you and your program partners will be required to assist CMS and its contractors with survey and qualitative (interview, site visit, focus group, documents, observational) data collection. Individual Medicare beneficiaries enrolled in the intervention are not required to participate in any specific qualitative data-gathering activity. Data collection activities that may require your cooperation or participation may include:
  - Arranging and granting interviews.
  - Helping recruit for focus groups and individual interviews with model-associated staff and beneficiaries.
  - Allowing and facilitating observations of any model-funded activities and care delivery settings.
  - Providing documents such as beneficiary education and staff training materials.
  - Facilitating surveys of staff and/or beneficiaries.
- **Other site-level health, utilization, and referral data** that are not captured in sources listed in the previous bullets. This may include information on care that patients receive from other providers that you have referred them to as part of the intervention. Such data may include referrals, patient follow-ups on recommended services, and interactions with related partners, organizations, or other data deemed necessary.
- **Program documentation.** Documents may include training materials, recruitment and educational materials, and other documents that you develop or use during your project.

Tables B through D show the required data elements and reporting frequency.

Table B: Identifiers of beneficiaries and providers involved in the intervention

Data elements	Unit of analysis	Frequency of data reporting (required in bold and marked with asterisk)
Medicare identifiers linkable to CMS claims and enrollment data for **beneficiaries (screened and enrolled** for the intervention, and for the control/comparison group).	Patient level	• Baseline (if available). • Pre-implementation (quarterly). • **Implementation (quarterly).***
Medicare identifiers (like TINs or NPIs) linkable to CMS claims data for **providers participating in the intervention** and **control/comparison group** (if applicable).	Provider level	• Baseline (if available) • Pre-implementation (quarterly). • **Year 1 (quarterly).*** • **After Year 1 (semiannual).***

Table C: Documentation of the intervention

Data elements	Unit of analysis	Frequency of data reporting (required in bold and marked with asterisk)
Duration of beneficiary enrollment in intervention (start and stop dates; frequency of contact).	Patient level	• Baseline (if available). • Pre-implementation (quarterly). • **Implementation (quarterly).***
Nutrition and/or physical activity data and results on **beneficiaries screened** and follow-up data on those **enrolled** in the intervention as well as **beneficiaries assigned to the control or comparison group.**	Patient level	• Baseline (if available). • Pre-implementation (quarterly). • **Year 1 (quarterly).*** • **After Year 1 (semiannual).***
Referrals to partners (such as CBOs, fitness centers, nutritionists) or other providers (primary care, specialists) based on screening and assessment data, if applicable.	Patient level	• Year 1 (quarterly). • After Year 1 (semi-annual).

Table D: Clinical data reporting

Data elements	Unit of analysis	Frequency of data reporting (required in bold and marked with asterisk)
Data on two different clinical measures (such as blood pressure, weight and height, waist circumference, HbA1c levels, cholesterol levels) expected to change due to the intervention for all **beneficiaries enrolled** in the intervention and for **beneficiaries in a control or comparison group**.	Patient level	• Baseline (if available). • Pre-implementation (quarterly). • **Year 1 (quarterly).*** • **After year 1 (semiannual).***

All data collection, storage, and reporting must comply with applicable privacy and security laws and model data policies. Please see Data collection and sharing for further information and additional requirements.

Disbursement timelines for milestones

Your cooperative agreement funding operates on a milestone-based system with two main components. The majority of your award — 60% — depends on meeting operational milestones by specific deadlines outlined in Table E. **You must hit all these targets on time to receive this funding; should an organization miss a milestone, they forego eligibility for all future disbursements.**

The remaining 40% is tied to enrolling the minimum numbers of people described in Table F. We built in these critical milestones for recruitment targets to ensure that you make steady progress toward your enrollment goals. However, this portion offers flexibility since you can earn funding as targets are met.

To count toward your beneficiary targets, participants must meet three requirements:

- They must enroll in your program.
- They must be confirmed by CMS as eligible Medicare Fee-For-Service beneficiaries.
- They must complete the entire program.

Any beneficiaries who drop out before completion or cannot be verified by CMS will not count toward your target numbers.

This structure ensures you're accountable for both operational efficiency and successful patient outcomes. You may use up to six months for pre-implementation activities at the start of the award. For example, you might use this time to build referral networks with partners. After six months, you should start enrolling patients into your program. If you haven't started enrolling patients by 12 months post-award, your award may be terminated.

You may request that we modify this timeline for your award if, for example, your intervention lasts more than 12 months.

The following table is based on a $3 million award.

Table E: Operational milestones

Disbursement	Percent	Milestones
Initial ($1. 2 million)	40%	Receipt of Notice of Award
14 months post-award ($150,000)	5%	• Submitted 90% or more of beneficiary rosters on time. • Participated in technical assistance (when applicable). • Secured CMS IT systems access within six months post-award. • Submitted TIN/NPI information in recipient portal within 6 months post-award • Submitted cooperative agreement progress and financial reports. ◦ Enrolled at least 10% of beneficiary target. (Program completion is not required for this milestone.)
20 months post-award ($150,000)	5%	• Submitted clinical data on time. • Submitted 90% or more of beneficiary rosters on time. • Completed at least 20% of your minimum beneficiary target, meaning they have **enrolled and completed** the program.* • Submitted cooperative agreement progress and financial reports.
26 months post-award ($150,000)	5%	• Submitted clinical data on time. ◦ Submitted 90% or more of beneficiary rosters on time. • Submitted information to the evaluation contractor. • Submitted cooperative agreement progress and financial reports.
32 months post-award ($150,000)	5%	• Submitted clinical data on time. ◦ Submitted at least 90% of beneficiary rosters on time. • Submitted information to the evaluation contractor.

Disbursement	Percent	Milestones
		• Submitted cooperative agreement progress and financial reports. • Completed at least 65% of the minimum beneficiary target.**
Total ($1,800,000)	**60%**	• $1.2 million pre-implementation funding • $600,000 milestone funding

*At 20 months, if you have not reached 20% of your minimum beneficiary target, your award may be terminated.

**At 32 months, if you have not reached 65% of your minimum beneficiary target, your award may be terminated.

Table F: Minimum beneficiary target quartiles

Percent of beneficiary target	Percent of funding disbursed
25%	7.5% ($225,000)
50%	12.5% ($375,000)
75%	7.5% ($225,000)
100%	12.5% ($375,000)
Total	**40% ($1,200,000)**

We will disburse this target quartile funding after you meet each target during the award period. However, you cannot receive a disbursement if you fail to meet the previous operational milestone. For example, if you reach 50% of your beneficiary target at 29 months but you did not submit clinical data for your 26-month operational milestone, you will not receive the operational milestone disbursement nor the beneficiary target disbursement.

Evaluation

CMS, with its evaluation contractor, will conduct a formal and concurrent evaluation of your intervention to assess whether it:

- Improved experience, clinical indicators, and outcomes for Medicare FFS beneficiaries.
- Decreased utilization of emergency department visits, acute care hospitalizations, and unplanned readmissions.
- Optimized spending.

We will investigate the effects of the intervention on patient-level outcomes and changes across the model by analyzing data across similar interventions in your cohort. The evaluation will use multiple sources (such as claims, clinical data you submit, and survey data collected by the evaluation contractor) to cross-verify and ensure that findings are reliable.

This evaluation is expected to cover the entirety of the project period. CMS acknowledges that individual beneficiaries cannot be compelled to participate in the evaluation.

We will evaluate you using the most rigorous evaluation design feasible. We will apply appropriate quantitative and qualitative mixed methods to examine program outcomes and the implementation processes that lead to successes or challenges.

Cooperative agreement terms

Cooperative agreements require substantial CMS project involvement after an award is made. There are specific roles for both you and CMS. We may be in contact at least once a month, and more frequently when appropriate.

Your responsibilities

- Comply fully with CMS and any CMS contractors' efforts to monitor and evaluate your project.
- Comply with the terms and conditions of the award.
- Work closely with CMS project staff to implement and monitor the project, and track its progress.
- Submit the performance measures requested.
- Submit all required performance assessments, evaluations, and financial reports included in the terms and conditions.

- Attend monthly calls with the CMS project or grants management specialist to discuss your project's progress and challenges. The meetings will include key personnel and the project officer.
- Participate in any virtual meetings.

Our responsibilities

- Monitor the project's performance and progress through data collection and reporting.
- Collaborate with you and provide substantial project planning and implementation input.
- Provide substantial input in evaluation activities.
- Provide feedback on your implementation to comply with the award terms and conditions.
- Monitor your performance based on the disbursement milestones and terms and conditions.
- Make recommendations for continuing the project.
- Review and approve marketing and website content before launch and updates.
- Review and approve all key personnel.
- Maintain regular communication with you through at least monthly conference calls along with technical assistance and consultation.
- Review and provide feedback on all required performance assessment reports.
- Review and approve all required submitted data.
- Provide a structured approach to sharing, integrating, and actively applying improvement concepts, tactics, and lessons learned.

Substantial involvement relates to programmatic involvement, not administrative oversight.

Statutory authority

General authority to test model:

Section 1115A of the Social Security Act (the Act) (added by Section 3021 of the Affordable Care Act) (42 U.S.C. § 1315a) authorizes the Secretary of the Department of Health and Human Services to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, or CHIP expenditures while preserving or enhancing the quality of care.

Authority to waive Medicare program requirements:

Section 1115A(d)(1) of the Act authorizes the Secretary to waive such requirements of Titles XI and XVIII of the Act 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 the testing by the CMS Innovation Center of an innovative payment and service delivery model.

Fraud and abuse waivers and Safe Harbor authority:

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 NOFO; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Any such waiver would apply solely to the individual MAHA ELEVATE recipient and could differ in scope or design from waivers granted for other recipients, programs, or models. MAHA ELEVATE recipients 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 MAHA ELEVATE recipient.

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 incentives (42 C.F.R. § 1001.952(ii)) is available to protect remuneration exchanged pursuant to certain financial arrangements or patient incentives ultimately permitted under MAHA-ELEVATE cooperative agreements. Any such patient incentives may include limitations on allowable costs. Again, no such determination is being issued in this NOFO. Such determination, if any, would be set forth in documentation separately issued by CMS.

Data collection and sharing:

Under 42 CFR § 403.1110(b), any entity participating in the testing of an Innovation Center model is required to collect and report such information, including “protected health information” as defined at 45 CFR § 160.103, determined necessary to monitor and evaluate the model. The MAHA ELEVATE model will require recipients to collect certain beneficiary-level information on beneficiaries who enroll in the recipient’s program as well as data for a control or comparison group, including identifying information, enrollment start and end dates, and clinical outcomes. Recipients will also be required to submit this data to CMS. The data will be used to monitor and evaluate the model. The recipient will be responsible for securing all appropriate authorizations necessary to collect, store, record, and share

beneficiary information in accordance with applicable federal, state, and local laws and regulations.

To submit this information to CMS, recipients will use the Health Data Reporting (HDR) tool or other tools developed by the Innovation Center for data collection. CMS is cautious of additional clinician reporting burden and will aim to utilize Innovation Center tools such as automated data pulls from electronic health records as feasible.

The recipient must establish and maintain appropriate administrative, technical, and physical safeguards to protect sensitive patient information, including Protected Health Information (PHI), consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, 45 CFR Part 160 and Part 164, Subparts A, C, and E, even if the recipient is not a HIPAA covered entity or business associate, as well as comply with other applicable privacy and security requirements. These safeguards must ensure the confidentiality, integrity, and availability of all data collected under this cooperative agreement.

CMS intends to share certain limited individual beneficiary enrollment data with recipients to the extent permitted by law for purposes such as identifying which individuals are eligible to receive services from the recipient's program. CMS also intends to share de-identified cost and utilization data with recipients, as applicable. All recipients will receive de-identified total cost of care information and will work with CMS to identify other cost and utilization metrics that are relevant to their programs.

Please note: Any organization that is not a covered entity or business associate of a covered entity under HIPAA must obtain a valid patient authorization that meets the HIPAA authorization requirements set forth in 45 C.F.R. § 164.508 to enable CMS to share any PHI with the applicable organization. The organization will need to receive a completed HIPAA compliant authorization from each prospective patient and submit it to CMS for approval **before** enrolling the patient in the cooperative agreement program. Failure to do so may result in termination of the cooperative agreement. An organization that is a HIPAA covered entity or business associate may use the same approach involving authorizations or may follow an alternative process to request the CMS enrollment data for their health care operations as set forth in 45 C.F.R. § 164.506(c)(4).

Funding policies and limitations

Changes in HHS regulations

As of October 1, 2025, HHS adopted 2 CFR Part 200, with some exceptions included in 2 CFR Part 300. These regulations replace those in 45 CFR Part 75.

Limitations

We do not allow the following costs:

- Pre-award costs.
- Meeting matching requirements for any other federal funds or local entities.
- Services, equipment, or supports that are the legal responsibility of another party under federal, state, or tribal law, such as vocational rehabilitation or education services.
- Services, equipment, or supports that are the legal responsibility of another party under any civil rights law, such as modifying a workplace or providing accommodations that are obligations under law.
- Goods or services not allocable to the project.
- Supplanting existing state, local, tribal, or private funding of infrastructure or services, such as staff salaries.
- Construction.
- Capital expenditures for improvements to land, buildings, or equipment that materially increase their value or useful life as a direct cost, except with our prior written approval.
- The cost of independent research and development, including their proportionate share of indirect costs. See 2 CFR 300.477.
- Funds related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or executive order.
- Certain telecommunications and video surveillance equipment. See 2 CFR 200.216.
- Other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government, funding awarded under this NOFO may not be used for:

- Paying the salary or expenses of any grant recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or executive order proposed or pending before the Congress or any state government, state legislature, or local legislature or legislative body.
- Lobbying, but recipients can lobby at their own expense if they can segregate federal funds from other financial resources used for lobbying.

For guidance on some types of costs that we restrict or do not allow, see 2 CFR Part 200 Subpart E — General Provisions for Selected Items of Cost.

Program-specific limitations

- Meals, food, or vouchers for meals or food. **Please note:** You may use other funding sources to provide food, meals, or vouchers as part of your program. Meals as part of a per diem allowance provided in conjunction with allowable travel are allowable.
- Controlled substances for substance abuse prevention.
- Any Schedule I controlled substances.
- Any substances that cannot legally be marketed as a dietary supplement, including but not limited to kratom and cannabidiol.
- Prescription drugs not approved by the FDA for use in the United States.
- Laboratory tests conducted in laboratories that do not have CMS Clinical Laboratory Improvement Amendments (CLIA) certification.
- Services that are covered by Medicare FFS and can be billed as a claim. **Note:** A service that is offered in excess of current Medicare FFS limits or outside the dparameters of a current Medicare coverage determination is considered a non-covered service and may be funded by the cooperative agreement. Services covered by current Medicare coverage may not be funded from the cooperative agreement.
- Services provided to a person who is not enrolled in Original Medicare.

General policies

- Support beyond the first budget year will depend on:
  - Appropriation of funds.
  - Satisfactory progress in meeting your project's objectives.
  - A decision that continued funding is in the government's best interest.

- If we receive more funding for this program, we will consider:
  - Funding more applicants.
  - Extending the period of performance.
  - Awarding supplemental funding.

Indirect costs

Indirect costs are those shared across multiple projects and not easily separated. Costs included in the indirect cost pool must not be charged as direct costs.

To charge indirect costs you can select one of two methods:

Method 1 — Approved rate. If you currently have an indirect cost rate approved by your cognizant federal agency, you may use that rate.

Method 2 — *De minimis* rate. If you do not have a negotiated indirect cost rate, you may elect to charge a *de minimis* rate (see 2 CFR 200.414(f)). This rate is 15% of modified total direct costs (MTDC). See the definition of MTDC (2 CFR 200.1). You can use this rate indefinitely.

Salary rate limitation

The salary rate limitation in the current appropriations act applies to this program. As of January 2026, the salary rate limitation is $228,000.

Program income

If you earn any money from your award-supported project activities (known as program income), you must use it for the purposes and under the conditions of the award. Find more about program income at 2 CFR 200.307.

Post-award requirements

Before you apply, make sure you understand the requirements that come with an award.

See Step 6: Learn What Happens After Award for information on regulations that apply, reporting, and more.

Step 2:
Get Ready to Apply

In this step

Get registered

SAM.gov

You must have an active account with SAM.gov to apply. SAM.gov registration can take several weeks. Begin that process today.

To register:

- Go to SAM.gov Entity Registration and select Get Started. From the same page, you can also select the Entity Registration Checklist for the information you will need to register.
- You must agree to the financial assistance general certifications and representations [PDF] specifically. Those for contracts are different.

When you register, you will also receive your required Unique Entity Identifier (UEI).

Once you register:

- You will have to maintain your registration throughout the life of any award.
- If your organization has multiple UEIs, use the one associated with your physical location.

Grants.gov

You must also have an active account with Grants.gov. You can see step-by-step instructions at the Grants.gov Quick Start Guide for Applicants.

Need help? See Contacts and Support.

Find the application package

The application package has all the forms you need to apply. You can find it at this NOFO's Grants.gov opportunity page.

We recommend that you select the Subscribe button from the View Grant Opportunity page for this NOFO to get updates.

If you can't use Grants.gov to download application materials or have other technical difficulties, including issues with application submission, contact Grants.gov for assistance.

Step 3:
Build Your Application

In this step

Application checklist

Make sure that you have everything you need to apply:

Narratives

Component	How to upload	Page limit
☐ Project summary	Use the Project Abstract Summary form.	1 page
☐ Project narrative	Use the Project Narrative templates.	15 pages
☐ Budget narrative	Use the Budget Narrative Attachment form.	10 pages

Attachments

Insert each in a single Attachments form.

Component	Page limit
☐ Indirect cost rate agreement	None
☐ Proof of nonprofit status	None
☐ Table G: Outcome measures	None
☐ Table H: Logic model	None
☐ Organizational chart	None
☐ Resumes and job descriptions	None
☐ Table I: Partnerships and roles	None
☐ Partnership documents	None
☐ Table J: Program-level data	None
☐ Business assessment of applicant organization	12 pages
☐ Peer-reviewed evidence — articles	None

Other required forms

Complete each required form in Grants.gov.

Component	Page limit
☐ Application for Federal Assistance (SF-424)	None
☐ Budget Information for Non-Construction Programs (SF-424A)	None
☐ Project/Performance Site Location	None
☐ Disclosure of Lobbying Activities (SF-LLL)	None

Application contents and format

We will provide instructions on how to build your application, including document formats in the following sections. See completeness and responsiveness criteria to understand what may disqualify your application from consideration.

Your organization's authorized organizational representative (AOR) must certify and submit your application.

See requirements for Intergovernmental review, if any.

Project summary

Limit to one page. May be single spaced. Follow other formatting requirements for the project narrative.

Write a one-page summary of your proposed project including its purpose and outcomes. Do not include any proprietary or confidential information. We will use this document for information sharing and public information requests if you get an award. Include:

- The name of your organization.
- The names of any subrecipients or sub-awardee organizations, if applicable.
- Project goals.
- Total budget amount.
- A description of how you will use funds.

Project narrative

The project narrative is the most important part of your application and should clearly describe your proposed project. You must address the proposed goals, measurable objectives, and milestones in accordance with the instructions in the following sections.

See the scoring criteria under each section to understand how reviewers will assess and score your project narrative.

Required format for project narrative

Page limit: 15 pages
Endnotes are not included in the page limit.

File name: Project narrative

File format: PDF

Font size: 12-point font
Footnotes and text in graphics may be 10-point.

Font color: Black

Spacing for project abstract, tables, and footnotes: Single-spaced

Spacing for main content: Double-spaced

Margins: 1-inch

Page size: 8.5 x 11

Include consecutive page numbers throughout.

We recommend you use the four narrative templates attached in Appendix B or available for download on our website. Do not use the example responses in your own application. We will not score applications that use the wording in our examples.

Your project narrative should include the following.

Template 1:
Whole-person FLM intervention design

Questions	Example responses
What is your hypothesis statement?	We believe that offering 8 group nutrition counseling sessions along with a five-tiered fitness program to Medicare FFS patients with a BMI greater than 26 will lead to an average reduction of 1-unit HbA1c and 15 lbs in weight, resulting in long-term Medicare FFS savings of [X] dollars.
What chronic condition(s) will you target?	We are targeting a range of metabolic disorders, including pre-diabetes, insulin resistance, and diabetes.
What is your proposed intervention (e.g. what are the services provided)?	The intervention is a weight-loss program that uses healthy eating and lifestyle counseling. It includes 22 sessions (some in person and some virtual) over 6 months. Participants can also join cooking classes and weight-loss support groups during the program and for 6 months after the counseling ends.
How frequently will patients receive the services, and over what time period?	The intervention includes 6 meetings over 6 months with a registered dietitian who works with primary care providers in a group practice focused on lifestyle medicine. The dietitian will create a meal plan for each participant based on their health needs and may recommend other helpful services, such as weight-loss support groups, cooking classes, or supplements.
What existing evidence supports the assumption that your intervention can create measurable improvements for your patients? Include citations and discuss both: • **Safety**: There is no harm to the health or quality of life of Medicare beneficiaries or their communities. The intervention must be safe for the target population. • **Effectiveness:** Your intervention directly improves health outcomes, such as fewer emergency department visits, reduced	Previous studies show that group nutrition counseling provides both information and accountability to patients, resulting in better adherence to a healthy diet and greater change in [outcome]. Note regarding citations: These publications may be your own published research or the published research of others. You will need to submit cited articles in PDFs as attachments. The reviewers will not be able to consider links in reviewing your application. For each cited PDF submitted as an attachment, you must make it easy for reviewers to locate your supporting evidence either by A) highlighting the relevant text directly in the document OR B) including a written narrative that explains exactly where

Questions	Example responses
hospitalizations, or chronic disease management improvements like weight loss, lower HbA1c, or lower blood pressure). This should support the clinical measures you propose.	to find the supporting information (specific page numbers, sections, paragraphs, tables, or figures).
What outcomes do you expect to change because of your intervention? Attach a completed copy of Table G: Outcome measures. Attach a completed copy of Table H: Logic model.	Example 1: We expect HbA1c and total cholesterol levels to drop by ___% within 6 months of starting the program. This estimate is based on pilot data from a similar study using a quasi-experimental design [citation]. Example 2: Within one year, we expect total Medicare FFS costs to fall by ___% for all beneficiaries and by ___% for those with complex chronic conditions. The average spending for all Medicare FFS beneficiaries is about $900–$1,000 per month (standard deviation $1,000–$1,700). For the complex care subgroup, average monthly costs are about $4,000 (standard deviation $4,800), based on 2024 practice data.
As part of your Cost Savings Plan, explain how your intervention has the strong potential to show Medicare FFS savings that exceed the program costs based on at least one of the following: • Financial modeling. • Return on investment analysis. • Budget impact analysis.	Cost savings plans will be highly individual and dependent on your available data, so no example is provided. Note: You don't need to prove cost savings during the three-year cooperative agreement, but you must show a time period when you expect your intervention will reduce health care spending in Original Medicare if it were covered. You must include: • **Your baseline assumptions** (how many Medicare patients have your selected chronic condition, how many you think will participate and complete the intervention, and the baseline costs for these patients). • **Your savings assumptions and evidence:** the percentage reduction in costs per patient and the aggregate savings, and peer-reviewed evidence that supports your assumptions and calculations, including evidence from your existing program (attach PDFs following citation guidelines). • **Your calculated cost** of delivering the intervention to show net savings.

Questions	Example responses
	Note regarding citations: These publications may be your own published research or the published research of others. You will need to submit cited articles in PDFs as attachments. The reviewers will not be able to consider links in reviewing your application. For each cited PDF submitted as an attachment, you must make it easy for reviewers to locate your supporting evidence either by: • Highlighting the relevant text directly in the document, or • Including a written narrative that explains exactly where to find the supporting information (specific page numbers, sections, paragraphs, tables, or figures).

Scoring criteria (Template 1)

Criteria	Points (Maximum = 45)
Interventions and outcomes: Clear link between the intervention, population/condition, and expected outcomes.	10
Approach: The intervention takes a whole-person FLM approach and includes nutrition and/or physical activity.	10
Cost savings plan: Savings plan demonstrates reasonable expectation of generating savings in Original Medicare over time.	10
Description of evidence base: The attached publications provide rigorous evidence demonstrating the intervention's patient safety and effectiveness scored by the following. **Strength and quality of study design (6 out 15 total points)** • Randomized designs are the strongest designs and will receive the highest scores. If cohort research studies are submitted, they must: ◦ Robustly account for confounding variables. ◦ Control for and limit selection bias. ◦ Have clear rules for who was included in the program and avoid specially selecting patients who are more likely to succeed. **Sample size (5 out of 15 total points)** • Preference will be given to studies of over 1,000 individuals with demographics similar to Medicare beneficiaries (see Appendix A for more details). **Direction and magnitude of effect (4 out of 15 total points)** • Study results should demonstrate improved clinical outcomes, quality of care, and cost savings among individuals with characteristics of Medicare beneficiaries. Larger, clinically meaningful effects are preferred over statistically significant effects (see Appendix A for more details).	15

Template 2:
Beneficiary recruitment and study design

Questions	Example responses
Who is your target population? Describe the criteria for determining whether a patient is eligible for the intervention, including tools, clinical indicators, and other factors you will use to screen patients.	Example 1: Medicare FFS beneficiaries with diet-sensitive conditions (such as heart failure or chronic kidney disease) who were recently hospitalized. We will identify Medicare FFS patients with diagnosis codes [list of ICD-10 codes] who were hospitalized within the last 12 months. Example 2: Medicare Fee-for-Service (FFS) beneficiaries with uncontrolled diabetes who want to lose 10 pounds and have struggled to lose weight in the past. We will use our electronic health record to identify Medicare FFS patients with a most recent HbA1c greater than 8% whose BMI is greater than 26. We will then administer a 5-question survey to those patients to assess their desire to lose weight, their previous strategies to lose weight, and their willingness to join our program.
How many beneficiaries do you expect to screen, find eligible, and enroll? Please include: • What these estimates are based on. • How many patients are currently served by your providers or organization. Note: CMS will use your responses to determine a minimum beneficiary target for your program. See Appendix A for more information.	Example 1: In a previous program, we screened 1,000 commercial patients; 500 (50%) were eligible, and 250 (25%) enrolled. We expect similar results among Medicare beneficiaries through our primary care practice, which serves about 10,000 patients. Of these, 4,800 are age 65 or older and have Medicare FFS. Example 2: Last year, 100 people joined yoga classes each month at the local YMCA, and we believe about half were over 65. Although we don't know how many have Medicare FFS, most were overweight or obese and had chronic pain or other health conditions. We plan to partner with 25 additional YMCAs to expand participation. We aim to enroll about 15,000 older adults each year, expecting 9,000 of them to have Medicare FFS. We will use rolling enrollment, marketing, and provider referrals to increase participation over time.
Provide the following information about your plan to recruit for the program: • Service area (counties, cities, regions).	• Our recruitment area is within a 50 mile radius of Baltimore City including three counties: Anne Arundel, Baltimore, and Calvert counties. Referrals will come from our network of 50 PCPs, 15 endocrinologists, and 10 nephrologists within our health system. Patients must have at least one qualifying health condition and

Questions	Example responses
• Health care providers who will refer patients and limit on referrals or services. • How you will assess patient needs. • Your specific dates for reaching enrollment goals and backup plan if enrollment is slower than expected. • How will you reach patients who haven't used your program or similar services before. • Strategies to keep people engaged and prevent dropouts. • Anything you will offer to patients to encourage participation (rewards, health tools, etc.). • Based on your own past experience, why would you say your enrollment goals are realistic? • How does the population you deliver(ed) your intervention to reflect or represent the broader Medicare FFS population?	demonstrate willingness to participate in our program. We will use HbA1c and FPG clinical tests and a program interest survey to identify patients and assess their needs. • We plan to enroll 750 patients by September 1, 2027. If enrollment is slow, we will expand our recruitment area to include 3 more counties (Harford, Howard, and Cecil) and increase our network within the health system. We will provide education about our program and training for our screening survey to all practices included. • Patients will receive a health system branded diet tracker notebook and a T-shirt. We will maintain engagement through virtual and in-person check-in and peer support groups. • Our program served a mixed population (Medicare FFS, Medicaid, and Commercial) of 4,000 over the past 4 years and closely mirrors the Medicare FFS population. Around 50% of our patients are over 65 and live in the urban and surrounding communities. Our patients have similar rates of diabetes (XY%) and obesity (XY%) as the national Medicare population. This similarity implies that our intervention results could be expanded to other Medicare FFS beneficiaries across the country.
Please describe whether you will use randomization and, if so, how. If using randomization: • What type of randomization will you use? E.g., patient-level, provider-level, site-level? • How will you assign patients to the intervention or control groups? Will you use Medicare FFS enrollment and claims data to create these	• We plan to use a randomized design. Eligible patients will be assigned to either the treatment or control group for 12 months. Both groups will be discharged after 12 months. We will use rolling enrollment to increase sample size, meaning patients may start at different times during the study period. • Beneficiaries with diet-sensitive conditions (such as heart failure or chronic kidney disease) will be offered the intervention and enrolled for 6 months. A similar provider practice within the same network will serve as the comparison group. Both practices will screen patients using the same criteria to ensure the groups are similar. Patients in the comparison group will receive standard care but not the intervention. This will help create a strong comparison between groups of similar patients.

Questions	Example responses
groups? If yes, how? If no, describe the challenges to using these data. • Will the control group receive any part of the intervention, and if so, when? If randomization is not possible: • How will you create a valid comparison group? • Can you use Medicare FFS enrollment and claims data to build that group? • What comparison data will you report to CMS? • Will the comparison group be exposed to any part of the intervention? Also describe whether all participants will start the intervention at the same time or if enrollment will happen on a rolling basis.	

Scoring criteria (Template 2)

Criteria	Points (Maximum = 20)
Beneficiary recruitment plan: You have a feasible plan to enroll and retain enough patients: • 200% or more of the minimum beneficiary target: 10 points. • 150 to 199% of the minimum beneficiary target: 9 points. • 125 to 149% of the minimum beneficiary target: 8 points. • 100 to 124% of the minimum beneficiary target: 7 points. • 90 to 99% of the minimum beneficiary target: 6 points. • 80 to 89% of the minimum beneficiary target: 5 points. • Less than 80%: 0 points.	10
Study Design: Your study design meets one of the following: • Achievable randomization plan: 10 of 10 points. • Randomized delayed enrollment for some patients to create a control group: 8 of 10 points. • Other plans to create a comparison group: 4 to 7 of 10 points. • No randomization or comparison group: 0 of 10 points. As part of its implementation contract, CMS or its contractor may support study design improvements for otherwise promising applications. **NOTE: Any applicant that does not ultimately put forward a plan to randomize or construct a comparison group will not be selected for an award.**	10

Template 3: Organization, administration, and capacity

Questions	Example responses
Please describe your organization, including any relevant background information. Attach an organizational chart that names the Authorized Organizational Representative and identifies lines of authority. Attach CVs or resumes of key personnel.	Health Organization Inc, started as a private primary care practice in Baltimore, MD and joined The Hospital System in 2015. We serve more than 10,000 patients across 6 Maryland Counties and Baltimore City. Our leadership consists of: • Chief Executive Officer: [Name, Credentials] • Chief Medical Officer: [Name, Credentials] • Chief Financial Officer: [Name, Credentials] • Chief Compliance Officer: [Name, Credentials] We maintain full compliance with HIPAA privacy and security requirements as well as CMS enrollment, participation, and quality reporting standards. Our formal organizational charts, resumes, CVs, and professional credentials are provided as attachments to demonstrate our team's qualifications.
List the name(s) and title(s) of individual(s) responsible for ensuring compliance with federal, state, and local laws.	[Name, Credentials] is our Chief Compliance officer and will be responsible for ensuring compliance with federal, state, and local laws.
Will you work with partner organizations? **If yes, briefly describe how you will work with partner organizations for this program.** • What is your past experience working with similar organizations? • Attach a completed Table I: Partnership table. • Attach partnership documents, such as contracts or memoranda of understanding.	• Health Organization Inc. has successfully partnered with a local physical therapy and massage clinic for three years resulting in improved patient outcomes for chronic pain management and a 40% reduction in opioid prescriptions. • Health Organization Inc. has experience with a two-year pilot program with Mental Health Counseling practice achieving a 65% improvement in patient reported anxiety and depression scores. Please see the attached partnership table detailing roles, responsibilities, and resource commitments. Also attached are the memorandum(s) of understanding or agreement(s) and organizational charts showing partnership integration points.

Questions	Example responses
Note: Ensure any required partner costs are included in your budget and budget narrative.	
What is your prior experience in the implementation of the proposed intervention? (It may have been in a pilot study, less rigorous study design, or a non-Medicare population.) • What challenges did you face, and how did you overcome them? • Please summarize data (qualitative and quantitative) that shows the impact of your prior interventions on utilization, quality and cost of care, and patient experience. • How was the work managed?	Health Organization Inc. has implemented nutrition education interventions for weight management over the past 6 years beginning with a pilot study in 2020 that served 150 patients with diabetes and obesity. Our comprehensive approach combined group nutrition education classes and 15-minute individual nutrition counseling sessions plus ongoing support via telehealth and secure group chat. Initially we focused on non-Medicare population of working adults aged 35-64 with BMI >30 and at least one comorbidity. The program evolved into a full-scale intervention serving over 800 patients annually including Medicare beneficiaries. • **Challenge 1:** Patient engagement and retention- initial dropout rate was 35% after first month ◦ **Solution:** Incorporated evening and weekend schedule sessions and peer support group that increased retention to 78% • **Challenge 2:** Physicians did not make sufficient nutrition referrals due to busy schedules ◦ **Solution:** Used EHR data to identify diabetic patients with high BMI, flagged their upcoming appointments, and implemented a screening workflow where office staff assessed patients and facilitated physician referrals during visits. Quantitative outcomes: • Average weight loss: 8.2% of starting weight. • HbA1c reduction: 0.9% among diabetics. • Decrease in waist circumference: 59% saw > 3 inch decrease. • Healthcare utilization: EDU down 23%. Qualitative outcomes: • Patient satisfaction scores: 4.6/5 average rating.

Questions	Example responses
	• 89% patients reported improved confidence in meal planning. • 56% maintained dietary changes and weight loss at 6 months after-program follow-up. The intervention utilized a collaborative team approach with our program director [Name, Credentials] who is a registered dietician, clinical team of 2 certified nutritionists and 2 community health workers, a program coordinator, and a student volunteer who helped with screening and analytics. We had monthly case reviews, situational debriefs, quarterly outcome assessments, team training events, and annual third-party patient experience vendor. We receive technical support from our EHR vendor and track data, schedule appointments, and communicate via our EHR. Finally, we hold regular stakeholder meetings with primary care providers and other committee members to ensure program alignment with goals and continuous quality improvement.
What is your experience conducting ethical, patient-centered data collection that included the use of institutional review boards?	We have never sought approval from an institutional review board. Our hospital system worked with [academic institution] on recruiting patients for an NIH-funded grant.
What coverage have you obtained for this intervention from any national or regional payer(s)? Note: This would not include a company that covers its own product or service for its own employees and/or family members.	Two of our state Medicaid managed care organizations, [Name 1] and [Name 2] cover four sessions of our nutrition counseling for adults age 21+ if they have diabetes, prediabetes, or a BMI over 30. They do not cover the virtual exercise group sessions.
List any CMS models in which you are participating now or have in the past, regardless of whether they included functional or lifestyle medicine. Participation in other models will not affect your score, but we will determine overlaps policies for organizations that are seeking to participate in multiple models.	• Several primary care practices within our ACO were part of CPC and CPC+. Some of our providers are now participating in GUIDE.

Scoring criteria (Template 3)

Criteria	Points (Maximum = 15)
Key personnel: Organization and key personnel are qualified to deliver the intervention as described in the organization, administration, and capacity plan. Resumes are provided.	5
Prior experience and capabilities: Organization has extensive experience delivering and measuring the intervention and describes resources required to deliver intervention.	10

Data Management Plan

Description of data reporting plan

Please refer to additional details about data collection and reporting included in the quality measures and data reporting section when writing responses to the items below.

Questions	Example Responses
What experience do you have collecting and reporting beneficiary-level data to CMS? If none, what capabilities do you have to do so?	Our CEHRT electronic health record can produce configurable reports, including patient identifiers and clinical measures. We have previously reported similar data to CMS when we were part of Making Care Primary via QRDA.
How will you collect patient and provider information for submission to CMS? • Include any partnerships or affiliations that may assist with data collection and submission.	We will use our electronic health record to produce reports on both our enrolled treatment patients and our delayed-start control group patients. We have a vendor, [name], that configures specialized reports from our EHR that we can use for report submission.
What prior experience do you have collecting and securely storing protected health information (PHI) and personally identifiable information (PII)?	Our yoga studio uses [name] software to track membership information, including PII such as names, addresses, phone numbers, emergency contacts, and billing information. All of this is securely stored according to [vendor standards], particularly because it includes stored credit card information. We also offer a dashboard where members can track their fitness goals, including PHI such as weight, blood pressure, and self-reported mood. The dashboard is managed by [vendor] who uses [safety standards], including two-step identify verification to log in.
What experience do you have in collecting and documenting your chosen clinical, cost, and utilization measures?	Yoga center members who set specific weight loss goals can currently have an instructor or coach measure their weight on a digital scale and their waist circumference in centimeters and then log it into the dashboard. We have been offering this option since 2018. We do not have experience measuring cost or utilization directly.
How will you monitor for any potential harmful effects from the intervention? How will you mitigate or avoid harm?	We will use a screening tool to ask enrollees if they have any health conditions, such as hypertension, joint problems, cardiovascular disease, etc. We will ask enrollees to reach out to their primary care physician before starting our

Questions	Example Responses
	exercise program. Enrollees will attest to us that they have their doctor's permission to participate.
Attach a completed copy of Table J: Program-level data.	See Table J.
Do you have Certified Health IT Product (CEHRT)? If yes, what is your CEHRT Certified Health IT Product List (CHPL) ID?	Note: CEHRT is not required to be eligible.

Scoring criteria (Data management plan)

Criteria	Points (Maximum = 10)
Capability: Applicant has experience and capability for data collection and reporting.	6
Patient safety: Applicant has robust plan to monitor for patient harm.	2
Applicant has CEHRT: 2 points. **Applicant does not have CEHRT:** 0 points.	2

Budget narrative

The budget narrative supports the information you provide in Standard Form 424-A. See other required forms.

It includes added detail and justifies the costs you ask for. As you develop your budget, consider:

- If the costs are reasonable and consistent with your project's purpose and activities
- The restrictions on spending funds. See funding policies and limitations.
- HHS now uses the definitions for equipment and supplies in 2 CFR 200.1. The new definitions change the threshold for equipment to the lesser of the recipient's capitalization level or $10,000 and the threshold for supplies to below that amount.

To create your budget narrative, see detailed instructions and a template on our website.

In your budget narrative, you will:

- Identify a PI/PD who will dedicate sufficient time and effort to manage and provide oversight of the grant program.
- Include a yearly breakdown of costs for each line item in your SF-424A.
- Describe the proposed costs for each activity or cost within the line item.
- Define the proportion of the requested funding designated for each activity.
- Justify the costs, including how you calculated them.
- Explain how you separate costs and funding administered directly by you as the lead agency, from funding you subcontract to other partners.
- Be clear about how costs link to each activity and the goals of this program.
- Include a per patient cost of each intervention that you are proposing.

To create your SF-424A and budget narrative, see detailed instructions in Guidance for Preparing a Budget Request and Narrative on our website.

As noted in the funding details, you must prepare two 18-month budget periods.

Scoring criteria (Budget narrative)

Criteria	Points (Maximum = 10)
Funds for activities: Funds requested are reasonable based on the total available funding and each activity is linked to the goals of this NOFO and consistent with the MAHA ELEVATE Model requirements.	6
Funds for personnel: Funds requested are reasonable to support personnel costs. If using a subrecipient to carry out the Required Core Functions or Optional Functions, then the applicant has described how the subrecipient will operate functions of the intervention.	2
No funds for prohibited costs: Funding request does not include unallowable costs, such as food or services that Medicare FFS already covers. Note: Once an applicant is recommended for an award, CMS will contact the applicant to negotiate a budget that contains allowable, allocable, and reasonable costs. Under no circumstances will food or any other unallowable cost be covered in that budget.	2

Required format for budget narrative

Page limit: 10

File name: Budget narrative

File format: PDF

Font size: 12-point font

Font color: Black

Margins: 1-inch

Page Size: 8.5 x 11

Include consecutive page numbers throughout.

Attachments

You will upload attachments in Grants.gov using the Other Attachments form.

Indirect cost agreement

If you include indirect costs in your budget using an approved rate or cost allocation plan, include a copy of your current agreement approved by your cognizant agency for indirect costs. If you use the *de minimis* rate, you do not need to submit this attachment.

Proof of nonprofit status

If your organization is a nonprofit, you need to attach proof. We will accept any of the following:

- A copy of a current tax exemption certificate from the IRS.
- A letter from your state's tax department, attorney general, or another state official saying that your group is a nonprofit and that none of your net earnings go to private shareholders or others.
- A certified copy of your certificate of incorporation. This document must show that your group is a nonprofit.
- Any of these documents for a parent organization. Also include a statement signed by an official of the parent group stating that your organization is a nonprofit affiliate.

Table G: Outcome measures

Please fill in the table to show the changes you expect your intervention to demonstrate. The first three rows offer examples, which you may delete before submitting your information.

Outcome to change	How intervention affects outcome	Expected effect size	Timeline	Data source
Blood Sugar control	Education improves self-management	0.7 HbA1c reduction	3 months	Lab results
Mental Health	Social interaction improves mood	25% depression score improvement	6-8 weeks	PHQ-9 surveys
Decreased hospital use	Early intervention prevents exacerbations	15% readmission reduction	6 months	Claims data
1.				
2.				

Identify which patient groups will likely see the greatest improvements below.

Table H: Logic model

Please fill in the table to show how your inputs will deliver the desired results for the program.

Project objective 1: [State the project objective and answer each objective. Add rows as necessary to report on all project objectives.]

Needs	Inputs	Activities	Outputs	Outcomes	Impact

Organizational chart

Please submit an organizational chart that identifies the Authorized Organizational Representative and the lines of authority.

Resume and job descriptions

For key personnel, attach resumes for positions that are filled. If a position isn't filled, attach the job description with qualifications.

Table I: Partnerships and roles

If you work with other partners, please describe their roles in the program in the following table. The table includes two examples that you may delete before submitting your own information. If you are not working with any partners, you do not need to submit this attachment.

Partnership organization	Primary contact name	Role in the program	Number of patients	Partnership document
Joe's Yoga Studio	Joe Smith	Will deliver the chair yoga sessions to our patients, both virtually (3 times a week) and in-person (once a week).	45 patients per month for three months at a time, 180 patients per year	MOU
Sam's Yoga Studio	Sam Lee	Will deliver chair yoga sessions to our patients, both virtually (3 times a week) and in-person (once a week).	250 patients per month for three months at a time, 750 patients per year	MOU

Partnership documents

For partner organizations, include one or more of the following:

- Those who will refer patients to you.
- Those to whom you will refer patients for the FLM intervention.
- Those who will provide clinical oversight or assist with data collection **and/or**
- Those who will join you in delivering the intervention to increase enrollment numbers.

Include documents that show the partnership, such as a letter of support, memorandum of understanding, contract, etc.

Table J: Program-level data

To demonstrate your past experience with data collection and with delivering this intervention, please fill out the following table. It has one example that you may delete before submitting your own information.

Intervention	Enrollee demographics	Length of intervention	Operational process measures	Health outcome changes	Cost changes
Tai chi	Medicaid members ages 50+, total enrollment 230.	Once-weekly sessions for 4 months (16 sessions); each sessions was 40 minutes.	80% attended 14+ sessions, 92% responded to a survey that they felt better balance and mood after participating.	25% of participants achieved one-inch reduction in waist circumference (WC); the 80% who attended 14+ sessions had an average 5 mmHg reduction in systolic blood pressure and 4 mmHg reduction in diastolic blood pressure.	A one-inch WC reduction translates to about [dollars] saved per person over [length of time] per [citation].

Business assessment of applicant organization

Maximum 12 pages, single-spaced.

We must assess your organization's risk before we can make an award. This analysis includes your organization's:

- Financial stability.
- Quality of management systems.
- Internal controls.
- Ability to meet the management standards in 2 CFR Part 200.

For us to complete your assessment, you must review, answer, and attach the completed business assessment questions found on our website in Business Assessment of Applicant Organization on our website.

Peer-reviewed evidence—articles

For evidence discussed in your project narrative, attach PDF copies of the articles you cited. Reviewers will not consider links or citations without the article.

For each cited PDF submitted as an attachment, you must make it easy for reviewers to locate your supporting evidence either by:

- Highlighting the relevant text directly in the PDF.
  or
- Including a written narrative that explains exactly where to find the supporting information (specific page numbers, sections, paragraphs, tables, or figures).

Other required forms

You will need to complete some other required forms. Submit the following required forms through Grants.gov. You can find them in the NOFO application package or review them and their instructions at Grants.gov Forms.

Form	Submission requirement
Application for Federal Assistance (SF-424)	With the application. See extra instructions in the next section.
Budget Information for Non-Construction Programs (SF-424A)	With the application.
Project/Performance Site Location(s) form	With the application.
Disclosure of Lobbying Activities (SF-LLL)	With the application.

Extra instructions for SF-424: Application for Federal Assistance

Special instructions include:

- Check No to item 19c. State review under Executive Order 12372 does not apply.
- Your authorized organizational representative (AOR) must electronically sign this form. The AOR is the person who can make legally binding commitments for your organization. When the AOR authorizes an application, they agree to assume all award obligations.

Important: public information

When filling out your SF-424 form, pay attention to Box 15: Descriptive Title of Applicant's Project.

We share what you put there with USAspending. This is where the public goes to learn how the federal government spends their money.

Instead of just a title, insert a short description of your project and what it will do.

See instructions and examples [PDF]. You can also see Writing a Strong Descriptive Title on our website.

Step 4: Understand Review, Selection, and Award

In this step

Application review

Initial review

We review each application to make sure it meets basic requirements.

We will review your application to make sure that it meets both the completeness criteria and the responsiveness criteria. If your application does not meet these criteria, we will not move it to the merit review phase.

We will not review any pages that exceed the page limit.

Scoring process

A merit review panel reviews all applications that pass the initial completeness and responsiveness review. The panel members use the criteria described in the previous section. For more information, see Merit Review and Selection Process on our website.

See the project narrative and budget narrative sections to see the specific criteria that apply to each.

Criterion	Total number of points = 100
Whole-person FLM intervention design	**45 points**
• Intervention and outcomes	10 points
• Approach	10 points
• Cost savings plan	10 points
• Description of evidence base ◦ Strength and quality of study design (6 points) ◦ Sample size (5 points) ◦ Direction and magnitude of effect (4 points)	15 points
Beneficiary recruitment/retention plan	**20 points**
• Beneficiary recruitment plan	10 points
• Study design (randomization)	10 points

Criterion	Total number of points = 100
Organization, administration, and capacity	**15 points**
• Key personnel	5 points
• Prior experience and capabilities	10 points
Data management plan	**10 points**
• Capability	6 points
• Patient safety plan	3 points
• CEHRT	1 point
Budget narrative	**10 points**
• Funds for activities	6 points
• Funds for personnel	2 points
• No funds for prohibited costs	2 points

We do not consider voluntary cost sharing during merit review.

Risk review

Before making an award, we review the risk that you will mismanage federal funds or fail to complete the project objectives. We need to make sure you've handled any past federal awards well and demonstrated sound business practices.

We use SAM.gov Responsibility/Qualification to check this history for all awards likely to be over $350,000. We also check Exclusions.

If we find a significant risk, we may choose not to fund your application or to place specific conditions on the award.

You can see more details about risk review at 2 CFR 200.206.

Selection process

CMS selects recipients at our sole discretion unless the authorizing statute says otherwise. Our selections are not subject to administrative or judicial review, per Section 1115A(d)(2)(B) of the Social Security Act.

When making funding decisions, we consider:

- Merit review results. These are key in making decisions but are not the only factor.
- The larger portfolio of agency-funded projects, including project type and geographic distribution.
- The past performance of the applicant. We may choose not to fund applicants with management or financial problems.

We may:

- Fund applications in whole or in part.
- Fund applications at a lower amount than requested.
- Decide not to allow a prime recipient to subaward if they may not be able to monitor and manage subrecipients properly.
- Choose to fund no applications under this NOFO.

Award notices

If you are successful, your authorized organizational representative (AOR) will receive an email notification from GrantSolutions. You can then retrieve your Notice of Award (NoA). We will email you if your application is incomplete or unresponsive.

The NoA is the only official award document. The NoA tells you about the amount of the award, important dates, and the terms and conditions you need to follow. Until you receive the NoA, you don't have permission to start work.

By drawing down funds, you accept the terms and conditions of the award. The NoA incorporates the requirements of the program and funding authorities, the grant regulations, the HHS Grants Policy Statement (GPS), and the NOFO.

If you want to know more about NoA contents, go to Notice of Award on our website.

Step 5: Submit Your Application

In this step

Application submission and deadlines

See Find the Application Package to make sure you have everything you need.

Make sure you are current with SAM.gov and UEI requirements. See get registered. You will have to maintain your registration throughout the life of any award.

Required letter of intent

Due by Friday, April 10, 2026.

A letter of intent (LOI) is required if you are interested in applying for this opportunity.

Prior informal expressions of interest, including but not limited to emails or other correspondence submitted before publication of this NOFO, do not satisfy this requirement and will not be considered as valid LOI submissions. LOIs are required and will also allow CMS to gauge serious interest as well as plan for the number of expert reviewers needed to evaluate applications.

To complete the letter of intent, use the letter of intent form on CMS's site.

Application

Due by Friday, May 15, 2026 by 11:59 p.m. ET.

Grants.gov creates a date and time record when it receives the application. If you submit the same application more than once, we will accept the last on-time submission.

The grants management officer may extend an application due date based on emergency situations such as documented natural disasters or a verifiable widespread disruption of electric or mail service.

Grants.gov submissions

You must submit your application through Grants.gov unless we give you an exemption for a paper submission. See get registered.

For instructions on how to submit in Grants.gov, see the Quick Start Guide for Applicants. Make sure your application passes the Grants.gov validation checks. Do not encrypt, zip, or password protect any files.

Intergovernmental review

Executive Order 12372, Intergovernmental Review of Federal Programs does not apply to this. You do not need to take any action other than checking “No” on the SF-424 box 19c.

Step 6: Learn What Happens After Award

In this step

Post-award requirements and administration

Administrative and national policy requirements

There are important rules you need to know if you get an award. You must follow:

- All terms and conditions in the Notice of Award. We incorporate this NOFO by reference.
- The rules listed in 2 CFR 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements. As of October 1, 2025, HHS adopted 2 CFR 200, with some modifications included in 2 CFR 300. These regulations replace those in 45 CFR 75.
- The HHS Grants Policy Statement (GPS). This document has terms and conditions tied to your award. If there are any exceptions to the GPS, they'll be listed in your Notice of Award.
- All federal statutes and regulations relevant to federal financial assistance, including those highlighted in the Grants Policy Statement, Appendix D: HHS Administrative and National Policy Requirements.
- All anti-discrimination laws: By applying for or accepting federal funds from HHS, recipients certify compliance with all federal antidiscrimination laws and these requirements and that complying with those laws is a material condition of receiving federal funding streams. Recipients are responsible for ensuring subrecipients, contractors, and partners also comply.

Reporting

If you are successful, you will have to submit financial and performance reports. Reporting requirements include:

- Progress reports.
- Federal Financial Report (FFR).
- Federal Funding Accountability and Transparency Act (FFATA).
- SAM.gov Responsibility/Qualification records.
- Payment Management System (PMS).

- Audit reporting (Federal Audit Clearinghouse).
- Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification.

For more information on reporting, see Post-Award Reporting Requirements on our website.

Continued eligibility

Continued funding is contingent on the availability of funds, program authority, satisfactory performance, and compliance with the terms and conditions of the Federal award.

For CMS to issue you continuation funding, you must demonstrate satisfactory progress. If we issue all the funding in the first year, then you must continue to show satisfactory progress to maintain access to your funds.

At any time, we could decrease funding or terminate your award if you fail to perform the requirements of the award. See 2 CFR 200.340, Termination.

Satisfactory performance includes, but is not limited to, meeting or exceeding performance standards detailed in this NOFO such as meeting milestone deadlines, proper financial management and budget compliance, accuracy and completeness of data submissions, responsive communication and effective collaboration with CMS.

Cybersecurity requirements

You must create a cybersecurity plan if your project involves both of the following conditions:

- You have ongoing access to HHS information or technology systems.
- You handle personal identifiable information (PII) or personal health information (PHI) from HHS.

See the Grants Policy Statement, Appendix D: HHS Administrative and National Policy Requirements for fuller information.

Health Information Technology (IT) interoperability language

You are subject to Health Information (IT) Interoperability requirements as stated on CMS's Notice of Award webpage.

Contacts and Support

In this step

Agency contacts

Program and eligibility

MAHAELEVATE@cms.hhs.gov

Financial and budget

MAHAELEVATE@cms.hhs.gov

Review process and application status

MAHAELEVATE@cms.hhs.gov

Help with systems

Grants.gov

Grants.gov provides 24/7 support. Hold on to your ticket number.

- Phone: 1-800-518-4726
- Email: support@grants.gov

SAM.gov

If you need help, you can:

- Call 866-606-8220
- Live chat with the Federal Service Desk

Reference websites

- U.S. Department of Health and Human Services (HHS)
- CMS Grants and Cooperative Agreements
- Grants.gov Accessibility Information
- Code of Federal Regulations (CFR)
- United States Code (U.S.C.)

Appendices

Appendix A—Beneficiary minimums

Examples of sample sizes needed to see changes in health outcomes

When designing a study, researchers need to include enough people to be confident that any changes they see are real and not due to chance. This is called having enough statistical power. The examples below show how many participants are needed to detect meaningful changes in common health measures.

How to read these results:

- To detect a 0.8-point change in the average body mass index (BMI) among adults age 65 and older, the study would need to enroll 1,000 patients in the treatment group and 1,000 patients in the control group. This sample size gives the study enough statistical power to detect meaningful effects.
- To detect a 4-point change in the average fasting glucose level among adults age 65 and older, the study would also need 1,000 patients in the treatment group and 1,000 patients in the control group for sufficient power to observe the effects.

Expected sample sizes for the treatment and control arms (n) based on effects sizes (e.g., double the Ns provided):

Clinical measure	Population mean	N=1,000	N=1,500	N=2,000	N=2,500	N=3,000
Body Mass Index (kg/m^2)	29.7	0.8-unit change	0.7-unit change	0.6-unit change	0.5-unit change	0.4-unit change
Waist circumference (cm)	103.5	1.8-unit change	1.6-unit change	1.4-unit change	1.2-unit change	1-unit change
Fasting glucose (mg/dL)	114.9	4-unit change	3.5-unit change	3-unit change	2.75-unit change	2.5-unit change
Glycohemoglobin (%)	6.0	0.13-unit change	0.11-unit change	0.09-unit change	0.08-unit change	0.75-unit change
Mean arterial pressure (mmHg)	91.7	1.6-unit change	1.3-unit change	1.2-unit change	1-unit change	0.09-unit change
Pulse rate (bpm)	70.0	1.5-unit change	1.4-unit change	1.2-unit change	1-unit change	0.09-unit change
Total cholesterol (mg/dL)	181.9	5-unit change	4-unit change	3.5-unit change	3.25-unit change	3-unit change
Vigorous physical activity (minutes/week)	35.8	18-unit change	15-unit change	13-unit change	12-unit change	11-unit change
Moderate physical activity (minutes/week)	130.5	34-unit change	27-unit change	24-unit change	22-unit change	20-unit change

Data source: National Health and Nutrition Examination Survey 2021-2023. Methods: Assuming a 1:1 randomized study design enrolling a similar number of patients into both the treatment and control arms. Results were similar among a general population of adults over 65 as well as among subgroups of adults with cognitive impairment, depression, diabetes, hypertension, cardiovascular disease, hyperlipidemia, arthritis, or cancer.

Appendix B—Templates

Template 1: Whole-person FLM intervention design

Questions	Responses
What is your hypothesis statement?	
What chronic condition(s) will you target?	
What is your proposed intervention (e.g. what are the services provided)?	
How frequently will patients receive the services, and over what time period?	
What existing evidence supports the assumption that your intervention can create measurable improvements for your patients? Include citations and discuss both: • **Safety**: There is no harm to the health or quality of life of Medicare beneficiaries or their communities. The intervention must be safe for the target population. • **Effectiveness:** Your intervention directly improves health outcomes, such as fewer emergency department visits, reduced hospitalizations, or chronic disease management improvements like weight loss, lower HbA1c, or lower blood pressure). This should support the clinical measures you propose.	Note regarding citations: These publications may be your own published research or the published research of others. You will need to submit cited articles in PDFs as attachments. The reviewers will not be able to consider links in reviewing your application. For each cited PDF submitted as an attachment, you must make it easy for reviewers to locate your supporting evidence either by: • Highlighting the relevant text directly in the document, or • Including a written narrative that explains exactly where to find the supporting information (specific page numbers, sections, paragraphs, tables, or figures).
What outcomes do you expect to change because of your intervention? Attach a completed copy of Table G: Outcome measures. Attach a completed copy of Table H: Logic model.	
As part of your Cost Savings Plan, explain how your intervention has the strong potential to show Medicare FFS savings that exceed the	Cost savings plans will be highly individual and dependent on your available data, so no example is provided.

Questions	Responses
program costs based on at least one of the following: • Financial modeling. • Return on investment analysis. • Budget impact analysis.	Note: You don't need to prove cost savings during the three-year cooperative agreement, but you must show a time period when you expect your intervention will reduce health care spending in Original Medicare if it were covered. You must include all of the following: • **Your assumptions**: How many Medicare patients have your selected chronic condition, how many you think will participate and complete the intervention, and what are the expected clinical outcomes. • **Your calculations:** Cost of delivering the intervention to show net savings. • **Your evidence:** Peer-reviewed evidence that supports your assumptions and calculations, including evidence from your existing program (attach PDFs following citation guidelines). Note regarding citations: These publications may be your own published research or the published research of others. You will need to submit cited articles in PDFs as attachments. The reviewers will not be able to consider links in reviewing your application. For each cited PDF submitted as an attachment, you must make it easy for reviewers to locate your supporting evidence either by: • Highlighting the relevant text directly in the document, or • Including a written narrative that explains exactly where to find the supporting information (specific page numbers, sections, paragraphs, tables, or figures).

Template 2:
Beneficiary recruitment and study design

Questions	Responses
Who is your target population? Describe the criteria for determining whether a patient is eligible for the intervention, including tools, clinical indicators, and other factors you will use to screen patients.	
How many beneficiaries do you expect to screen, find eligible, and enroll? Please include: • What these estimates are based on. • How many patients are currently served by your providers or organization. Note: CMS will use your responses to determine a minimum beneficiary target for your program. See Appendix A for more information.	
Provide the following information about your plan to recruit for the program: • Service area (counties, cities, regions). • Health care providers who will refer patients and limit on referrals or services. • How you will assess patient needs. • Your specific dates for reaching enrollment goals and backup plan if enrollment is slower than expected. • How will you reach patients who haven't used your program or similar services before. • Strategies to keep people engaged and prevent dropouts. • Anything you will offer to patients to encourage participation (rewards, health tools, etc.).	

Questions	Responses
• Based on your own past experience, why would you say your enrollment goals are realistic? • How does the population you deliver(ed) your intervention to reflect or represent the broader Medicare FFS population?	
Please describe whether you will use randomization and, if so, how. If using randomization: • What type of randomization will you use? E.g., patient-level, provider-level, site-level? • How will you assign patients to the intervention or control groups? Will you use Medicare FFS enrollment and claims data to create these groups? If yes, how? If no, describe the challenges to using these data. • Will the control group receive any part of the intervention, and if so, when? If randomization is not possible: • How will you create a valid comparison group? • Can you use Medicare FFS enrollment and claims data to build that group? • What comparison data will you report to CMS? • Will the comparison group be exposed to any part of the intervention? Also describe whether all participants will start the intervention at the same time or if enrollment will happen on a rolling basis.	

Template 3: Organization, administration, and capacity

Questions	Responses
Please describe your organization, including any relevant background information. Attach an organizational chart that names the Authorized Organizational Representative and identifies lines of authority. Attach CVs or resumes of key personnel.	
List the name(s) and title(s) of individual(s) responsible for ensuring compliance with federal, state, and local laws.	
Will you work with partner organizations? If yes, briefly describe how you will work with partner organizations for this program. • What is your past experience working with similar organizations? • Attach a completed Table I: Partnership table. • Attach partnership documents, such as contracts or memoranda of understanding. Note: Ensure any required partner costs are included in your budget and budget narrative.	
What is your prior experience in the implementation of the proposed intervention? (It may have been in a pilot study, less rigorous study design, or a non-Medicare population.) • What challenges did you face, and how did you overcome them? • Please summarize data (qualitative and quantitative) that shows the impact of your prior interventions on utilization, quality and cost of care, and patient experience. • How was the work managed?	

Questions	Responses
What is your experience conducting ethical, patient-centered data collection that included the use of institutional review boards?	
What coverage have you obtained for this intervention from any national or regional payer(s)? Note: This would not include a company that covers its own product or service for its own employees and/or family members.	
List any CMS models in which you are participating now or have in the past, regardless of whether they included functional or lifestyle medicine. Participation in other models will not affect your score, but we will determine overlaps policies for organizations that are seeking to participate in multiple models.	

Data Management Plan

Description of data reporting plan

Please refer to additional details about data collection and reporting included in the quality measures and data reporting section when writing responses to these items.

Questions	Responses
What experience do you have collecting and reporting beneficiary-level data to CMS? If none, what capabilities do you have to do so?	
How will you collect patient and provider information for submission to CMS? • Include any partnerships or affiliations that may assist with data collection and submission.	
What prior experience do you have collecting and securely storing protected health information (PHI) and personally identifiable information (PII)?	
What experience do you have in collecting and documenting your chosen clinical, cost, and utilization measures?	
How will you monitor for any potential harmful effects from the intervention? How will you mitigate or avoid harm?	
Attach a completed copy of Table J: Program-level data.	
Do you have Certified Health IT Product (CEHRT)? If yes, what is your Certified Health IT Product CHPL ID?	

Endnotes

1. Throughout this document, the terms Medicare beneficiaries/patients and Original Medicare beneficiaries/patients will be used interchangeably to refer to Medicare Fee-For-Service beneficiaries. ↑
2. A microsimulation found that improved health outcomes and lower health care costs accrued over time based on dietary changes: Herman PM, Nguyen P, Sturm R. Diet quality improvement and 30-year population health and economic outcomes: a microsimulation study. *Public Health Nutrition* . 2022;25(5):1265-1273. http://doi.org/10.1017/S136898002100015X . ↑
3. CMS, Medicare Current Beneficiary Survey (MCBS), CMS . ↑
4. CDC, Fast Facts: Health and Economic Costs of Chronic Conditions . ↑
5. National Library of Medicine, "Healthcare Evolves From Reactive to Proactive." ↑
6. See also National Institutes of Health, " The Whole Person Health Index: A New Tool for Human Mechanistic and Clinical Studies ." ↑
7. A microsimulation found that improved health outcomes and lower health care costs accrued over time based on dietary changes: Herman PM, Nguyen P, Sturm R. Diet quality improvement and 30-year population health and economic outcomes: a microsimulation study. *Public Health Nutrition* . 2022;25(5):1265-1273. http://doi.org/10.1017/S136898002100015X ↑
8. Cooperative agreement funds cannot be used to pay for food but may support other nutrition services. ↑