



**Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation**

**Value-Based Insurance Design Model
Request for Applications for CY 2021**

March 13, 2020

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1. Background and General Information

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from eligible Medicare Advantage Organizations (MAOs) to participate in the Medicare Advantage (MA) Value-Based Insurance Design (VBID) Model for Calendar Year (CY) 2021. All eligible MAOs that wish to participate in the VBID Model for CY 2021, including MAOs that are participating in CY 2020, must apply for participation in the Model.

The VBID Model Request for Applications (RFA) is open to MA-only and Medicare Advantage-Prescription Drug (MA-PD) plan offerings for the following plan types:

- Coordinated Care Plans
 - Health Maintenance Organizations (HMOs), including those with a Point of Service (POS) option
 - Local Preferred Provider Organizations (PPOs) and Regional PPOs (RPPOs)
- All Special Needs Plans
 - Chronic Condition Special Needs Plans (C-SNPs)
 - Dual Eligible Special Needs Plans (D-SNPs)
 - Institutional Special Needs Plans (I-SNPs)

The following plan types are not eligible to participate in the VBID Model test: Private Fee-for-Service (PFFS) Plans, Employer Group Waiver Plans (EGWPs), Medicare-Medicaid Plans (MMPs) or other demonstration plans, and Medicare Advantage Medical Savings Account (MSA) Plans. In addition, Cost Plans and Programs of All-Inclusive Care for the Elderly (PACE) organizations are not eligible to participate in the VBID Model.

For CY 2021, the VBID Model continues to test a number of complementary health plan innovations, summarized below and described in detail in this RFA. CMS is conducting this Model test through the Center for Medicare and Medicaid Innovation under section 1115A of the Social Security Act (the Act).

1.1 Model Test Changes for CY 2021

CMS is making the following updates to the VBID Model for CY 2021.

Medicare Hospice Benefit: CMS announced, in January 2019, it was testing the incorporation of the Medicare Hospice Benefit into the MA program through the VBID Model beginning in CY 2021 in order to engage broadly with all stakeholders. "The following link will take you to CMS's outlines of how an MAO may participate in the Hospice Benefit Component: <https://innovation.cms.gov/initiatives/vbid/>. Interested MAOs should consult the VBID Hospice Benefit Component RFA in addition to this RFA.

President's Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors: CMS is also implementing the President's Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors by testing how to permit Medicare beneficiaries to share more directly in program savings by allowing participating MAOs to offer a mandatory supplemental MA benefit that is in the form of cash or monetary rebates to all enrollees in Model PBPs. MAOs must propose the amount, the frequency, and any restrictions on the provision of the cash or monetary rebates.

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Further, in accordance with the President’s Executive Order, to remove any disincentives for MA plans to cover items and services that make use of new and existing technologies that are not covered by original Medicare, MAOs may propose covering new and existing technologies (which for the purposes of the Model are defined as FDA approved medical devices and novel technologies, items, and services that do not fit into an existing Medicare Part A or Part B benefit category) as a supplemental benefit, when those items and services can save money and improve the quality of care.

Through the Model, CMS will allow MAOs to identify certain parameters for eligibility for an enrollee to receive these medical devices and novel technologies to better understand the population, utilization, costs, and benefits of specific medical devices and novel technologies, items, and services not covered under original Medicare today. For more information on these Model Components and the President’s Executive Order 13890 on Protecting and Improving Medicare for Our Nation’s Seniors, please refer to sections 2.2.g. and 2.2.h.

1.2 Scope and General Approach

The VBID Model began in January 2017 with the goal of testing the impact of varied supplemental benefit designs through service delivery and payment flexibilities in Medicare Advantage to promote patient-centered care, provide greater price transparency, increase enrollee choice and access to timely and clinically-appropriate care, improve quality, and reduce costs. For 2018 and 2019, the Model was broadened to all states and territories and to allow MAOs greater flexibility in designing their plan benefit packages (PBPs).

Beginning in CY 2020, CMS required participating MAOs to test Wellness and Health Care Planning (WHP) strategies to improve the awareness and availability of advance care planning. Additionally, beyond testing how MAOs could further target benefit design to enrollees based on chronic conditions, CMS began testing an additional targeted benefit design by using certain socioeconomic characteristics in order to better address potential unmet social and medical needs. For 2020, the VBID Model is also testing Part C and Part D Rewards and Incentives (RI Programs).

As announced in January 2019, beginning January 1, 2021, CMS is testing a carve-in of the Medicare hospice benefit into the original Medicare benefits that MAOs coordinate and offer. Information on the hospice benefit component of the Model is available on the VBID Model website at <https://innovation.cms.gov/initiatives/vbid>.

For CY 2021, the VBID Model will test the following Model Components (see Table 1). MAOs that wish to participate in the Model must apply and receive approval from CMS for one or more of the optional components. All participating MAOs must participate in the mandatory Wellness and Health Care Planning component of the VBID Model in 2021.

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Table 1: CY 2021 VBID Model Components

VBID Model Component	Scope	Mandatory/Optional Component
1. Wellness and Health Care Planning	All beneficiaries; All Model PBPs.	Mandatory
2. VBID Flexibilities: a. Targeted to beneficiaries based on chronic condition and/or socioeconomic status. i. Primarily and Non-primarily health-related Supplemental Benefits, which may include new and existing technologies or FDA approved medical devices ii. Use of high-value providers and/or participation in care management programs/disease management programs iii. Reductions in cost sharing for Part C items and services and covered Part D drugs;	Participating MAOs may also limit these to select Model PBPs.	Optional
b. Offered Uniformly Across All Beneficiaries (i.e., non-targeted) i. NEW – Flexibility to Share Beneficiary Rebates Savings More Directly with Beneficiaries in the form of cash or monetary rebates	For all enrollees in the Model PBPs.	Optional
3. Part C and D Rewards and Incentives Programs (RI Programs)	For targeted beneficiaries; in select Model PBPs. (Participating MAOs may elect to make RI Programs available to all enrollees in Model PBPs.)	Optional
4. NEW - Medicare Hospice Benefit Component (Separate RFA)	For all enrollees in select Model PBPs.	Optional

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Model Geography and Model Performance Period

In accordance with section 50321 of the Bipartisan Budget Act of 2018, eligible MA plan types in all states and territories may apply to participate in the VBID Model. The overall Model performance period will be through CY 2024. MAOs must apply every year. However, CMS reserves the right to not open the application to new MAOs each year.

1.3 Statutory Authority

Section 1115A of the Act (42 U.S.C. § 1315a, added by section 3021 of the Patient Protection and Affordable Care Act) authorizes CMS to test innovative health care payment and service delivery models that have the potential to lower Medicare, Medicaid, and Children's Health Insurance Program (CHIP) spending while maintaining or improving the quality of beneficiaries' care.

1.4 Waiver Authority

CMS will exercise this authority here to test this Model in the Medicare program.

Under section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. Consistent with this standard, and for aspects of this Model that will be new for the 2021 plan year, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act.

No fraud and abuse waivers are being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Thus, notwithstanding any other provision of this RFA, all parties 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) of the Act specifically for the VBID Model. Any such waiver would apply solely to the VBID Model and could differ in scope or design from waivers granted for other programs or models, or those described below.

No programmatic waivers are being issued in this document. To the extent necessary to facilitate the Model test, certain limited programmatic waivers, as described in Section 1.5, are anticipated to be provided in connection with the Model.

1.5 Medicare Program and Payment Waivers

In support of the VBID Model, the Secretary intends to waive certain title XVIII provisions and their implementing rules, to the extent described below and as necessary to conduct the tests described in this RFA. No program or payment waivers of any kind are being issued in this document, which merely describes the waivers contemplated at this time for the Model; waivers, if any, would be set forth in Model documentation (such as an appendix to the contract addendum for participation in the VBID Model).

- **Uniformity and Accessibility of Benefits:** To be waived to the extent necessary to permit MAOs to offer supplemental benefits to the targeted enrollee population, rather than to all enrollees, subject to the terms of the Model. The targeted enrollee population may be identified

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based on (i) one or more chronic conditions, or (ii) Low-Income Subsidy (LIS) eligibility, or (iii) a combination of both these health conditions and socioeconomic statuses.

- Sections 1852(d)(1)(A) and 1854(c) of the Act [42 U.S.C. 1395w-22(d)(1)(A) and 1395w-24(c)];
 - 42 CFR §§ 422.2 (definition of an MA plan), 422.100(d)(2), 422.102(a)(2), 422.254(b)(2), and 422.262(c)(1);
 - Section 1860D–2(a) of the Act [42 U.S.C. 1395w-102(a)]; and
 - 42 CFR §§ 423.104(b)(2) and 423.265(c).
- **Uniform Cost Sharing:** To be waived to the extent necessary to offer reductions in cost sharing to the targeted enrollee population, but not to the entire membership, consistent with the terms of the Model. The targeted enrollee population may be identified based on (i) one or more chronic conditions, or (ii) LIS eligibility, or (iii) a combination of both these health conditions and socioeconomic statuses.
 - Sections 1852(d)(1)(A) and 1854(c) of the Act [42 U.S.C. 1395w-22(d)(1)(A) and 1395w-24(c)]
 - 42 CFR §§ 422.2 (definition of an MA plan), 422.100(d)(2), 422.254(b)(2), and 422.262(c)(1); and
 - Section 1860D–2(a) of the Act [42 U.S.C. 1395w-102(a)]; and 42 CFR §§ 423.104(b)(2) and 423.265(c).
- **Provision of Supplemental Benefits that are Non-Primarily Health Related:** To be waived to the extent necessary to allow MAOs to offer to certain enrollees additional supplemental benefits that are “non-primarily health related” supplemental benefits subject to the terms of the Model. Such supplemental benefits must have a reasonable expectation of improving or maintaining the health or overall function of the enrollee with regard to the chronic condition or socioeconomic status of the targeted enrollee population. The targeted enrollee population may be identified based on (i) one or more chronic conditions, or (ii) LIS eligibility, or (iii) a combination of these health condition and socioeconomic statuses. In using one or more chronic conditions to identify eligible enrollees, an MAO may propose for CMS consideration and approval a targeted population that does not meet the statutory definition of “chronically ill enrollee” in section 1852(a)(3)(D)(iii).
 - Section 1852(a)(3)(D)(i), (ii)(I), and (iii) of the Act [42 U.S.C. 1395w–22(a)(3)(D)(i), (ii)(I), and (iii)] and any implementing regulations, including 42 CFR 422.100(c)(2) and 422.102.
- **Provision of Supplemental Benefits in the form of Cash or Monetary Rebates:** Section 1852(a)(3)(A) of the Act and 42 C.F.R. 422.100(c)(2), 422.102, and 422.266(b) to the extent necessary to permit mandatory supplemental benefits in the form of cash or monetary rebates that are not limited to paying for health care and are provided subject to the terms of the Model. This includes a waiver, to the extent necessary, of the requirement that participating MAOs incur a non-zero direct *medical* cost in the provision of these specific mandatory supplemental benefits under the Model.
- **Communications, Disclosures, and Marketing:** To be waived to the extent necessary for MAOs to comply with Model-specific guidance on communications, including disclosures and marketing, with enrollees or potential enrollees.

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- Section 1852(c)(1)(B) & (F) of the Act [42 U.S.C. 1395w-22(c)(1)(B) and (F)]; 42 CFR §§ 422.111(a) and (b);
 - Section 1860D-4(a)(1)(A) of the Act [42 U.S.C. 1395w-102(a)]; and
 - 42 CFR §§ 423.128(a) and (b)(2).
- **Increased Value for Rewards and Incentives:** To be waived to the extent necessary, to allow participating MAOs to offer rewards and incentives, subject to the terms of the VBID Model, that: are available only to targeted enrollees; are based on the anticipated benefit (rather than the value) of the associated health care item or service; and other rewards and incentives programs approved by CMS on a case-by-case basis. The targeted enrollee population may be all enrollees or limited to those who would receive the greatest health care value from receiving the associated benefits. The value of the reward and incentive health care is subject to an annual limit of \$600.00 per enrollee for all rewards received by the enrollee.

In addition, CMS is authorizing, subject to the terms of the VBID Model, the offering by MA-PD plans of rewards and incentives tied to the Part D benefit.

- 42 CFR §§ 422.134(b)(1), (b)(2), (c)(1)(i) and (c)(1)(ii), related to availability and eligibility for rewards and incentives;
- 42 CFR 422.134(c)(1)(i), related to completion of the entire activity or service prior to receiving the reward and incentive; and
- 42 CFR 422.134(c)(1)(iii), related to the monetary limit on rewards and incentives.

Note: "The following link will take you to the CY 2021 VBID Hospice RFA for information on programmatic waivers related to the Hospice Benefit Component of the VBID Model:
<https://innovation.cms.gov/Files/x/vbid-hospice-rfa2021.pdf>

CMS is not proposing to waive title XVIII's anti-discrimination provisions. Such a waiver is not necessary for the Model test because participating MAOs are required to implement Model interventions in a non-discriminatory manner. MAOs shall comply with Section 1852(b)(1) of the Act concerning discrimination against enrollees in offering in Model interventions.

Program waivers, once issued, are: (1) each contingent on compliance with the terms and conditions of the Model test, including the contract addendum for participation in the Model test and documents incorporated therein; (2) are granted only to the extent necessary for the Model test and to implement an MAO's approved proposal for participation; (3) are granted only to MAOs for those PBPs for which CMS has approved a proposal; and (4) are granted only for the term of the addendum for participation in the Model test. CMS reserves the right to revoke one or more of the title XVIII waivers or to suspend Model testing (or both) at any point. Further, all other (i.e., non-waived) requirements will continue to apply and be enforced.

2. Model Design Elements

The VBID Model for CY 2021 consists of the following components:

1. Wellness and Health Care Planning (WHP) (required for all participating Model PBPs);
2. VBID Flexibilities:
 - a. For select enrollees in the Model PBPs: Targeting by Condition and/or Socioeconomic Status or a combination of both:

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- i. Primarily and Non-Primarily Health-Related Supplemental Benefits, which may include new and existing technologies or FDA approved medical devices as a mandatory supplemental benefit;
 - ii. Use of High-Value Providers and/or participation in care management program/disease state management program;
 - iii. Reductions in Cost Sharing for Part C items and services and covered Part D Drugs; and/or
- b. For all enrollees in the Model PBPs: Offered uniformly across all enrollees (i.e. non-targeted):
 - i. **NEW**-Flexibility to Share Beneficiary Rebates Savings More Directly with Beneficiaries in the form of cash or monetary rebates.¹
3. Part C and Part D Rewards and Incentives Programs; and
4. **NEW**-Medicare Hospice Benefit Component (please refer to CY 2021 VBID Hospice RFA for information on the Medicare hospice benefit component).

These components allow CMS to broadly test payment and service delivery reform in the MA program to improve quality while reducing costs.

MAOs applying to participate in the VBID Model must submit an application proposal to CMS by April 24, 2020 that outlines each of the VBID Model Components that they propose to implement for CY 2021. CMS will review and approve application proposals prior to the June 1, 2020 bid submission. Additional information and requirements for each VBID Model Component is described below.

2.1 Wellness and Health Care Planning

As a condition of receiving any program waiver granted in connection with the VBID Model, MAOs must describe in their applications, receive approval for, and implement a strategy regarding the delivery of timely Wellness and Health Care Planning (WHP) services, including advance care planning (ACP) services, to all enrollees. Participating MAOs must implement a WHP strategy that reaches all enrollees in the PBPs included in the Model. ACP provides an opportunity for patients to discuss with their provider preferences for the kind of care they would like to receive, should they not have the capacity to do so at some time in the future, and if they so choose, to prepare documents, including advance directives, explaining their wishes. CMS seeks to promote innovations in care delivery - in partnership with participating MAOs - that promote patient autonomy in health care and ACP decisions with the goal of improving the quality of care beneficiaries receive.

Currently, MAOs are required under 42 CFR 422.128 to maintain written policies and procedures concerning advance directives for all adult enrollees. The regulation requires that MAOs provide their policies regarding advance directives and written information, at the time of initial enrollment, regarding an enrollee's rights under applicable state law to make health care decisions (including accepting or refusing treatment), and to formulate an advance directive. MAOs are

¹ This VBID Model Component represents an innovative new way to use beneficiary rebates available under section 1854(b)(1)(C) of the Act.

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similarly required to provide for community education regarding advance directives and to ensure documentation is maintained in a prominent part on an individual's current medical record as to whether or not the individual has executed an advance directive.

Building on existing requirements regarding advance directives, CMS aims to improve the timely creation and availability of actionable health care planning documents - across providers and places of care - by testing the impact of making the timely offering of an opportunity for WHP to each enrollee an integral part of the Model. Through this Model, CMS is seeking to further existing plan and private sector efforts and to partner with MAOs in connection with testing how timely and systematic WHP, including ACP, for all VBID plan enrollees has an impact on cost and quality of care.

In their applications, MAOs must address: how the plan will implement an evidence-based strategy and approach to furnish appropriate and timely WHP services across its enrolled population in the participating PBP; the mechanisms it will use to reach all enrollees and ensure each enrollee is offered a timely opportunity for WHP; how the effectiveness of that strategy will be tracked, summarized, and reported to CMS for monitoring; and how participating MAOs will work with their network providers to engage patients and ensure they are offered timely opportunities to discuss their goals and preferences for care. As noted above, all VBID plan enrollees must be included in the WHP component.

While enrollees are allowed to decline any WHP discussion opportunity, the strategy must include how the participating MAO will capture and track the number and proportion of enrollees who have been engaged, the mechanism(s) used to engage the enrollee and if the enrollee either accepted or declined WHP, and other data to track timely performance of WHP. MAOs must be prepared to submit summary WHP information to CMS for monitoring and note trends and best practices for WHP among network providers based on the above data.

The broad scale of this WHP test, the engagement of health care provider practices within it, and the aligned efforts of private and public payers and integrated delivery systems are expected to lead to improvements in the delivery system infrastructure for accessing, maintaining, and updating advance directives. Better access to ACP documentation resulting from this test should improve its effectiveness and impact in avoiding unwanted and unnecessary care.

As part of their application, MAOs must include information such as:

- The mechanism (e.g., Annual Wellness Visit, Health Risk Assessment, care/case management program, etc.) proposed to ensure the offering of WHP services;
- Any rewards and incentives offered to enrollees for participating in WHP activities, as well as any rewards and incentives offered to physicians or clinicians for offering WHP services to enrollees; and
- Ways that the MAO is leveraging technology (e.g., Electronic Health Record, Electronic Medical Record, provider/patient portal) to document and communicate WHP activities.

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Each MAO must propose a robust approach and rationale towards supporting the effective implementation of WHP. MAOs must have a plan for capturing the data needed to monitor and track the provision of WHP and be prepared to report this information to CMS. CMS will provide additional guidance to approved participants on WHP tracking and reporting and may request a review of an MAO's plan for tracking and reporting WHP if necessary. MAOs may propose, for CMS's consideration and potential approval, enrollee and/or provider rewards and incentives to promote WHP, including proposals for groups or subsets of enrollees.

CMS will review and consider the appropriateness of the proposed groups or subsets of enrollees and the extent to which proposals demonstrate: that enrollees of similar circumstances will receive similar benefits; that safeguards protecting against fraud, waste and misuse are in place; and that monitoring of the appropriate receipt of rewards and incentives occurs. CMS also reserves the right to terminate an accepted proposal based on a practice of inadequate enrollee protections.

2.2 VBID Supplemental Benefit Flexibilities

In this section, CMS outlines how plans can target VBID enrollees, additional supplemental benefits, and safeguards for protecting beneficiaries.

All benefits and flexibilities described in this section 2.2 of the Model and provided under the Model by participating MAOs must be mandatory supplemental benefits and must comply with all rules and requirements that apply to mandatory supplemental benefits. While certain benefits under the Model may be available only to certain targeted categories of enrollees, the benefit will be funded by rebates and/or premiums paid by all PBP enrollees, just like all mandatory supplemental benefits pursuant to 42 C.F.R. 422.100(c)(2)(i). In this respect, model benefits would be similar to existing enhanced disease management programs, which may be offered as a mandatory supplemental benefit but are only available to enrollees with a targeted disease.

2.2.1 Targeting by Condition and/or Socioeconomic Status or a Combination of Both

Participating MAOs may provide non-uniform supplemental benefits to targeted enrollees so long as it is in a non-discriminatory manner. The supplemental benefits that can be offered on a non-uniform and non-discriminatory basis include: (i) "non-primarily health-related supplemental benefits" that have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee; (ii) reductions in cost-sharing; and/or (iii) additional items and services. MAOs are also permitted to reduce cost sharing for High-Value Providers. MAOs may target enrollees for VBID benefits and services based on the following:

- 1) Chronic conditions(s);
- 2) Low Income Subsidy (LIS) eligibility²; or a
- 3) Combination of both (e.g., enrollees who are LIS eligible and have COPD).

CMS will review and may approve proposals from MAOs that vary the target population and the supplemental benefits offered among participating MAOs' PBPs.

² For information on LIS eligibility and for reports that contain LIS indicators, please refer to the Plan Communication User Guide at https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html

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2.2.2 Allowable Targeting Criteria

Chronic Conditions: As for 2020, MAOs may choose both the chronic condition(s) and a targeting methodology to identify enrollees with the chronic condition or combination of chronic conditions. The targeting methodology may be broad (using diagnoses or other means to identify enrollees with related diagnoses or conditions) or narrow (such as using ICD-10 codes or other data to identify enrollees with a specific level or intensity of a condition).³

As part of the application, CMS will review and approve proposed targeting methodologies for use by the participating MAO. Targeting methodologies may be rejected if they do not reach a large enough cohort for meaningful evaluation of the intervention. While participating MAOs will have the opportunity to modify their benefit design for any or all of the targeted conditions, plan benefit design still must be uniform for enrollees within each condition category. This means that every enrollee who meets the criteria (including the targeting methodology) established by the MAO and approved by CMS must be treated the same and have access to the intervention benefits. MAO determinations will be subject to retrospective, randomized audits by CMS to determine if all VBID-eligible enrollees actually received the VBID interventions.

Socioeconomic Status: As in 2020, MAOs may choose to target enrollees for VBID interventions based on socioeconomic status but may only use LIS status, as defined in the Plan Communication User Guide (PCUG) for Medicare Advantage and Prescription Drug Plans to identify those targeted enrollees. For the territories where the LIS status is not available, participating MAOs may identify targeted enrollees based on dual eligibility for both Medicare and Medicaid, using CMS identification of a dual-eligibility status in MARx.

MAOs have the option of targeting enrollees eligible for LIS at any of the LIS subsidy levels. MAOs must propose the subsidy level in their application.

MAOs must identify how the socioeconomic determinants of health for targeted enrollees will be addressed by ensuring access to high-value care, disease management programs, and/or additional supplemental benefits, including an expanded list of non-primarily health related benefits allowed under the VBID Model (see section, Additional Non-Primarily Health Care Related Supplemental Benefits, for more information about non-primarily health related benefits).

In sections 2.2.c through 2.2.f and 2.2h, CMS outlines the options under the VBID Flexibilities component that may be offered by participating MAOs to targeted enrollee populations. These include primarily and non-primarily health related supplemental benefits (including new and existing technologies or FDA approved medical devices), reduced cost sharing for Part C services and reduced cost sharing for covered Part D drugs, and use of high-value providers and/or participation in disease state management program.

³ ICD-10 Codes may be found at <https://www.cdc.gov/nchs/icd/icd10cm.htm>

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2.2.3 Primarily and Non-Primarily Health-Related Supplemental Benefits

Participating MAOs are permitted to make supplemental benefits available only for targeted enrollees. See section 2.2.2 for requirements for targeting enrollees. Unless waived and the conditions for the waiver are met, supplemental benefits offered by a participating MAO must comply with all Medicare Advantage program rules and requirements. (See e.g., 42 CFR 422.102; Managed Care Manual, Ch. 4, section 30).

Additionally, through the Model, participating MAOs have the ability to offer non-primarily health related supplemental benefits to targeted enrollees, beyond the statutorily-defined “chronically ill enrollee,” provided that such benefits have a reasonable expectation of improving or maintaining the health or overall function of the targeted enrollee. For purposes of this intervention, participating MAOs may use one of the following targeted populations:

- (1) Enrollees who qualify for the LIS.
Enrollees who are within the scope of section 1852(a)(3)(D)(iii) of the Act, which defines a “chronically ill enrollee” as an enrollee who:
 - (I) has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;
 - (II) has a high risk of hospitalization or other adverse health outcomes; and
 - (III) requires intensive care coordination.
- (2) Enrollees who have one or more chronic conditions, but that are not within the scope of the statutory definition of “chronically ill enrollee” in section 1852(a)(3)(D)(iii) of the Act. To be approved for this type of targeted population, the MAO must specify in its application what non-primarily health related benefits it will provide for this intervention and to which targeted enrollee group the benefits will be available.
- (3) A combination of the factors identified in categories (1) – (3) above.

Primarily health-related items or services must diagnose, prevent or treat an illness or injury; compensate for physical impairments, act to ameliorate the functional or psychological impact of injuries or health conditions; or reduce avoidable emergency and healthcare utilization. For a non-primarily health-related item or service, participating MAOs may – in a targeted way outlined above – address a specific deficit for a set of enrollees that results in deteriorated health and any resultant increase in the utilization of health care services or costs of care. MAOs that target supplemental benefits must offer and cover the benefit uniformly for all eligible enrollees targeted for intervention.

The additional non-primarily health related supplemental benefits that CMS will consider include, but are not limited to, meals (beyond the current allowable limits), transportation for non-medical needs, disease-specific household items such as air purifiers or air conditioners, pest control, and/or food and groceries.

In providing Model benefits, MAOs must use the same processes as currently allowed for coverage of OTC supplemental benefits, including, where appropriate, requiring documentation from an enrollee’s provider or care team of the necessity of an item or service. MAOs must include safeguards that prevent fraud, waste, and abuse, including any misuse or inappropriate provision

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of these items or services and potential resale (see section, Enrollee Safeguards, for information on general enrollee safeguards). Where appropriate, MAOs may also propose spousal sharing of non-primarily health related supplemental benefits when spouses are enrolled in the same participating plan and meet the eligibility requirements for the non-primarily health related supplemental benefit.

MAOs must identify in their applications the items and services that they propose to offer under this flexibility, and must be prepared to provide the rationale for offering the non-primarily health-related supplemental benefits, included expected improvements in health outcomes.

2.2.4 Enrollee Safeguards

MAOs must not propose reductions in targeted enrollee benefits or increases in targeted cost-sharing amounts as VBID interventions.

MAOs shall permit eligible enrollees to opt out of additional supplemental benefits provided under the VBID Model at any time. Additionally, if after opting out of the benefits provided under the VBID Model or out of a component of the Model, an enrollee who meets the criteria to be a Targeted Enrollee wishes to regain eligibility for or access to the benefits provided under the VBID Model or a VBID Component, MAOs must honor that request and begin or resume providing benefits provided under the VBID Model or eligibility for or access to a VBID Component to the enrollee prospectively.

CMS reserves the right to reject proposals that may pose an undue risk of enrollee harm or confusion, have potential to impose excessive costs on the Medicare program, or are inconsistent with the implementation and evaluation objectives of the Model. CMS also reserves the right to reject proposals that discriminate against non-targeted populations, for example in cases where VBID interventions are coupled with changes made to the plan-at-large in ways that decrease the benefits available to enrollees with non-targeted clinical conditions.

CMS will carefully review proposals using VBID flexibilities for non-uniform benefit designs, including proposals for administering primarily and non-primarily health related benefits, for protections against misuse of the reduced cost sharing or supplemental benefits. Finally, CMS will review the plan's projections and justification of expected cost savings and quality of care improvements for the population(s) of focus that are anticipated as a result of the reduced cost sharing or targeted supplemental benefits.

CMS also reserves the right to reject proposals that, as determined solely through CMS' discretion, may result in beneficiary inducement, potential fraud, waste, and abuse, decreased beneficiary plan choice or mobility, or other negative impact to plan beneficiaries or CMS generally.

CMS reserves the right to terminate an MAO's participation in the Model or exercise other available remedies at any time if the MAO has failed to comply with the terms of the Model, is subject to investigation or sanctions for program integrity issues, or if CMS determines that the organization's participation in the Model, or its performance of model activities, may compromise the integrity of the Model, including by resulting in lower quality care or adverse outcomes for enrollees or the Model.

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2.2.5 Reductions in Cost Sharing for Part C items and services and covered Part D Drugs

Participating MAOs may reduce or eliminate cost sharing for items or services covered by the MA plan, including covered Part D drugs covered by a participating MA-PD plan. These items and services must be identified by the MAO in its application as high-value for a given target population. Participating MAOs have broad flexibility to choose which items or services are eligible for cost sharing reductions (including for high-value services and services offered by high-value providers); however, these items or services must be clearly identified and defined in the application and in advance to the eligible target population. Reductions in cost sharing must be uniformly available to all enrollees within the target population and administered in a non-discriminatory fashion.

Reductions in cost sharing may include: (a) elimination or reduction of co-pays, (b) elimination or reduction of co-insurance, or (c) exemption of a given service from the plan deductible. These examples of modification to cost sharing are not exhaustive; MAOs can propose other approaches to reducing cost sharing.

Examples of cost sharing reductions within this category might include the elimination of co-pays for eye exams for enrollees with diabetes; the elimination of co-pays for primary care or specialist visits for enrollees who qualify for LIS status; or the reduction of condition-specific covered Part D drug co-pays (e.g., all generic ACE inhibitors, ARBs, calcium-channel blockers, beta-blockers, diuretics, and statins) for enrollees with cardiovascular disease.

2.2.6 Use of High-Value Providers and/or Participation in Care Management/Disease State Management Programs

MAOs may also make the provision of additional supplemental benefits conditional on: (i) the use of high-value providers and/or (ii) participation in a care management/disease state management program.

For participating MAOs utilizing this approach, targeted enrollees must be clearly informed which providers and/or services are considered high-value, along with any supporting rationale to encourage uptake and enrollee engagement and understanding. In their applications, MAO must provide the rationale and standards for how it will identify high-value providers for use in this intervention. CMS will only accept proposals where it agrees that the criteria used to select the providers are reasonably constructed to ensure that the providers identified are high-value for enrollees in the selected clinical condition group.

MAOs determination of high-value providers cannot be solely based on cost or efficiency, and therefore must also include relevant quality considerations and/or criteria. Identification of high-value providers must be prefaced on a sound evidence-base, such as independent, external metrics when determining whether a provider is high-value. Examples of such metrics might include whether a primary care practice is a National Committee for Quality Assurance (NCQA) certified medical home, whether a hospital has American Heart Association advanced certification in heart failure, or whether a provider meets certain performance metrics on National Quality Forum (NQF) validated quality measures. However, more or locally specific approaches also may be

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proposed with accompanying clinically justification. In addition, organizations cannot identify high-value providers based on coding accuracy or intensity alone.

High-value providers can include physicians and practices, hospitals, skilled-nursing facilities, home health agencies, ambulatory surgical centers, and others. MAOs do not need to meet any specific network adequacy or access standards for the subset of high-value providers selected. However, all VBID interventions must be available and accessible to applicable targeted enrollees. CMS may require an MAO to modify its intervention in cases where accessibility is inadequate and lack of accessibility impacts performance in a manner inconsistent with the goals of the Model. Certain patterns of inaccessibility of care may constitute prohibited discrimination or a failure of the MAO to meet access standards. Notwithstanding the Model intervention(s), MAOs must still meet all current MA network adequacy standards (see 42 CFR 422.112 and CMS guidance). All plan enrollees, including those targeted by this Model, retain the right to see any provider in network at any time (at non-VBID levels of cost sharing), without penalty or restriction.

Participating MAOs may not remove a provider from the roster of high-value providers during a contract year; unless the provider is terminated from the network, the provider requests exclusion from the high-value network or, with the concurrence of CMS, exclusion from the high-value network is warranted in the best interests of enrollees. All changes to the roster of high-value providers must be treated, with respect to VBID-eligible enrollees and notification to the Model administration team, in the same manner as if they were significant changes to networks under Chapter 4, section 110.1.2 of the Medicare Managed Care Manual (refer to <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-ManualsIOMs-Items/CMS019326.html>) regardless of whether such changes are considered “significant” with respect to the network-at-large.

Additionally, participating MAOs can condition reductions in cost sharing for an item or service, including Part D drugs covered by MA-PD plans, on participation in a plan-sponsored disease management or similar program. A plan-sponsored disease management or similar program could include an enhanced disease management program, offered by the plan as a supplemental benefit, or it could refer to specific activities that are offered or recommended as part of a plan’s basic care coordination activities. Examples of interventions within this category might include elimination of primary care co-pays for diabetes patients who meet regularly with a case manager or reduction of prescription drug co-pays for patients with cardiovascular disease who regularly monitor their blood pressure and are part of a plan’s disease state management program.

Participating MAOs cannot make cost sharing reductions conditional on achieving any specific clinical goals (e.g., an organization cannot condition cost sharing reductions on enrollees achieving certain thresholds in HbA1c levels or body-mass index). In general, this reduced cost sharing approach may not be structured in a discriminatory manner, and all applicable targeted enrollees must have the opportunity to participate in the activities in question (or an alternative), regardless of health status, location, or disability. The underlying disease management or similar program must comply with all otherwise applicable rules and regulations.

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2.2.7 Flexibility to Share Beneficiary Rebates Savings More Directly with Beneficiaries in the form of Cash or Monetary Rebates

Section 1852(a)(3) of the Act authorizes MAOs to offer “supplemental health care benefits” to their enrollees. CMS requires a benefit to meet three criteria to be a permissible supplemental healthcare benefit: (i) the item or service may not be a Medicare Part A, Part B, or Part D covered benefit; (ii) the item or service must be primarily health related; and (iii) the MA plan must incur a non-zero direct medical cost in providing the benefit, and if the MA plan only incurs an administrative cost, this requirement is not met.⁴ For Special Supplemental Benefits for the Chronically Ill, offered pursuant to section 1852(a)(3)(D), the latter two criteria are applied as requiring the benefit to have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee and requiring the MA plan to incur a non-zero direct non-administrative cost.⁵

Through this VBID Model Component, CMS is providing participating MAOs additional flexibility to choose to share rebates under section 1854 of the Act with all of their enrollees in Model PBPs through a new mandatory supplemental benefit, in the form of cash or monetary rebates.

CMS is testing the different ways that sharing the beneficiary rebates (in the form of cash or monetary rebates) (a) incentivize Medicare beneficiaries to choose MA plans with lower costs and/or higher quality (per Quality Star Ratings) and (b) incentivize MAOs to offer lower bids and/or earn higher Star Ratings. The rationale behind testing this new payment model is that the incentives created by permitting these cash or monetary rebates will encourage plans to (1) bid lower and (2) earn higher star ratings to increase the benchmark, because both of these scenarios would increase the amount of rebates available to the MAO to provide to the enrollee in the form of cash or monetary rebates, making the plan itself more attractive to enrollees who want the cash or monetary rebates instead of another health care benefit. CMS, therefore, believes that giving MAOs the flexibility to share the beneficiary rebate portion of the savings created when an MA bid is less than the benchmark as cash or monetary rebates, via a new mandatory supplemental benefit, has the potential to drive down Medicare costs and improve quality.

For MAOs participating in this component of the VBID Model, CMS will waive the applicable Title XVIII statutory and regulatory provisions to the extent necessary for the participating MAO to provide cash or monetary rebates to plan enrollees on the terms and within the limits of the Model. The cash or monetary rebates can be used for a purpose that does not fit into the Medicare Advantage definition of primarily health care-related (i.e., cash or monetary rebates do not have to be used for health care-related items or services).

⁴ CMS has recently proposed to codify its interpretation and implementation of this term as requiring a benefit to meet the three criteria. The following link will take you to the Contract Year 2021 and 2022 Medicare Advantage and Part D Proposed Rule (CMS-4190-P) Fact Sheet at <https://www.cms.gov/newsroom/fact-sheets/contract-year-2021-and-2022-medicare-advantage-and-part-d-proposed-rule-cms-4190-p-1>. For additional guidance, the following link will take you to CMS’s Medicare Managed Care Manual. Chapter 4. Benefit and Beneficiary Protections. 30.1. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

⁵ The following link will take you to the CY 2020 Call Letter (<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Downloads/Announcement2020.pdf>), pp. 189-191.

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An MAO applying to offer cash or monetary rebates must include in its application a proposal on how it intends to implement this Model Component and this proposal would be subject to CMS review and approval. As part of this proposal, the MAO must specify the amount, frequency, and the form of the cash or monetary rebate (e.g. debit card, check, etc.), and administrative plan for distributing the cash or monetary rebate. MAOs are prohibited from selectively advertising or offering cash or monetary rebates based on the beneficiaries' health status or risk profile, and must have a protocol in place to monitor and track all cash or monetary rebates issued to guard against potential abuse. CMS will also monitor implementation of this Model Component to ensure the appropriate provision of the cash or monetary rebates to beneficiaries, which will include review of VBID participant reporting on this component. As part of the application process MAOs must be able to produce additional detail or information on this Model Component, if requested by CMS.

This flexibility is distinct from Part C and D Rewards and Incentives Programs because it must be funded using the rebate authorized by section 1854(b)(1)(C) of the Act (rather than administrative costs). The cash or monetary rebates that may be distributed under this component of the Model are limited to the beneficiary rebate available to the MA Plan under section 1854 of the Act; a participating MAO that is approved to use this flexibility must identify in its bid the amount of the beneficiary rebate that will be used for this purpose. This flexibility is distinct from other VBID Flexibilities in that it must be offered to all enrollees in the Model PBP(s). Participating MAOs cannot use the cash or monetary rebates to incentivize rationing of care or avoidance of medically necessary care or mere enrollment in the MA plan; the MAO shall not offer or furnish cash or monetary rebates to reward an enrollee for failing to obtain medically necessary services.

Each MAO that chooses to offer cash or monetary rebates will have the flexibility to determine the amount of the beneficiary rebate available under section 1854 of the Act that the MAO wants to share via this supplemental benefit option; however, the MAO must notify beneficiaries, via an explicit notice, of tax consequences associated with the provision of the cash or monetary rebate (*Note: This notice must address the combined impact or consequences of the cash or monetary rebate and any Rewards and Incentives (if applicable) also provided by the MAO.*) While the cash or monetary rebates covered under this Model Component are not subject to an annual limit of \$600 per enrollee, the Part C or Part D Rewards and Incentives Programs will continue to adhere to this annual limit of \$600, consistent with the MA program rules governing Rewards and Incentives Programs. CMS will provide additional guidance to MAOs about any other notice requirements as part of, or in conjunction with, its VBID Contract Addendum.

2.2.8 Flexibility to Cover New and Existing Technologies or FDA Approved Medical Devices

The Executive Order directs and encourages more streamlined and timely Medicare coverage of breakthrough medical devices and FDA approved medical devices.

This goal is supported by the VBID supplemental benefit flexibility, which allows MAOs to propose to cover new technologies that are FDA approved and that do not fit into an existing benefit category for targeted populations (chronic conditions and/or LIS status) that would receive the highest value from the new technology. As an option available under the VBID supplemental benefit flexibility, this Model Component allows MAOs to offer supplemental benefits on a non-

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uniform basis to determine whether these technologies will reduce program costs or improve the quality of care for enrollees targeted for these technologies.

By executing on this aspect of the President's Executive Order in this manner, CMS is further strengthening the MA program and increasing choice and competition to reduce costs and improve the quality of care Medicare beneficiaries receive.

Today, MAOs may elect to cover new and existing FDA approved technologies that are not covered by Original Medicare. Such additional healthcare items or services can be covered as a supplemental benefit paid using the rebate under section 1854 of the Act or supplemental premiums paid by enrollees. Currently, MAOs cover many additional healthcare items and services, including some newly developed or newly FDA approved technologies and medical devices. The VBID supplemental benefit flexibility may allow for more coverage of technologies for targeted populations that would receive the highest value from the new technologies.

Consistent with existing MA rules for supplemental benefits, participating MAOs would be permitted to provide coverage for: (i) an FDA approved medical device or new technology that has a Medicare coverage determination (either national or local) where the MA plan seeks to cover it for an indication that differs from the Medicare coverage determination and the MA plan demonstrates the device is medically reasonable and necessary; and (ii) for new technologies that do not fit into an existing benefit category.

Under MA bidding requirements (e.g., § 422.254), MAOs must treat this coverage as a mandatory supplemental benefit that is paid using rebates as part of bid development and must factor in any projected reduction in utilization of Part A or Part B benefits in the A/B bid.

In order to ensure at least budget neutrality of the VBID Model, as part of their application, MAOs must project or show, in year one or over multiple years, the accounting of costs and utilization of the new or existing technology or device (covered as a supplemental benefit paid for using the rebates) and a resultant direct reduction in A/B utilization due to the use of the technology or device. CMS will require MAOs to share negotiated costs and other information as necessary to inform Medicare coverage determination and pricing.

2.3 Part C and Part D Rewards and Incentives

Currently, MAOs are authorized to offer rewards and incentives programs (RI Programs) under 42 CFR 422.134; additional guidance is provided in Chapter 4 of the Medicare Managed Care Manual. Under the regulation, a reward and incentive must not exceed the value of the health-related services or activity for which the reward and incentive is provided. These rewards and incentives align with the President's Executive Order on Protecting and Improving Medicare for Our Nation's Seniors by incentivizing enrollees to seek high-value care. In the past, MAOs have leveraged this authority to offer rewards and incentives in the form of gift cards and grocery cards to enrollees who participate in activities expected to improve their health care or address healthcare needs.

In order to test the cost and quality of care impact of a service delivery model that permits MAOs offering MA-PD plans to provide higher-value rewards and incentives and RI Programs in connection with Part D prescription drug benefits, MAOs participating in this Model for CY 2021 will continue to be permitted additional flexibility as described in this section. We anticipate that

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these flexibilities may also reduce barriers to greater MA plan uptake of RI programs. MAOs may propose to use rewards and incentives with a value that reflects the benefit of the service, rather than just the cost of the service, up to \$600 annually. MAOs offering MA-PD plans may propose to use a RI program for the Part D benefit in the participating MA-PD plan.

All RI programs offered by participating MAOs must promote improved health, prevent injuries and illness, and promote efficient use of health care resources. Unless waived or additionally authorized under this Model, participating MAOs must follow all of the Rewards and Incentives requirements at 42 CFR 422.134 as well as in the Medicare Managed Care Manual, Chapter 4, section 100. See section 1.5 above for a discussion of programmatic provisions in 42 CFR 422.134 that may be waived to provide participating MAOs additional flexibility in offering RI programs.

Specifically, MAOs may propose, subject for CMS review and approval, the following RI programs in their applications for the VBID Model:

1. Use of a reward or incentive that has a value beyond the cost of the health-related service or activity itself but limited to the value of the expected benefit of using the service or item, up to an annual per enrollee limit of \$600.00 in the aggregate for all rewards, incentives, debit cards, and gift cards provided under the Model in the VBID PBP;
2. For MA-PD plans, a reward and incentive associated with the Part D benefit;
3. An RI program specific to participation in a disease management or transition of care program; and
4. Similar RI programs approved by CMS on a case-by-case basis as evidence-based and justified by MAOs.

MAOs must implement Part D RI programs in a manner that complies with all applicable fraud and abuse laws, including the anti-kickback statute and civil monetary law prohibiting inducements to beneficiaries, except, and only to the extent applicable as explicitly provided in any such separately documented waiver issued pursuant to section 1115A(d)(1) of the Act for the VBID Model.

In the application, MAOs must demonstrate that the reward or incentive include information on the nature, frequency and goals of the rewards, and eligibility criteria the enrollee must satisfy to receive the reward.

Participating MAOs that offer a prescription drug plan (participating MA-PD plans) may propose Part D RI programs that, in connection with medication use, focus on promoting improved health, medication adherence, or the efficient use of health care resources. All proposed Part D RI Programs must be designed to encourage enrollees to use Part D covered medications in ways that lead to improvement in at least one of these three areas (i.e., health outcomes, medication adherence, and the efficient use of health care resources).

Provided below are general rules for the Part D RI programs CMS will permit, or not permit, under the VBID Model. Any Part D RI program must aim to strengthen the linkage between enrollees and the care team, including pharmacists and providers, in understanding clinically-equivalent

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therapeutic options, coverage provided by the MA-PD plan, and the overall value to their health of adherence to their prescribed drug therapy.

Permissible MA-PD Part D RI Program Designs Generally

1. Part D RI Programs may be designed to target enrollees with specific conditions or enrollees who would benefit from participating in disease state management programs.
2. Part D RI Programs may be designed to provide rewards and incentives for participating in plan sponsor medication therapy management (MTM) programs.
3. Part D RI Programs may be designed to provide rewards and incentives for enrollees who participate in preventive health services, such as receiving covered Part D vaccines.
4. Part D RI Programs may be designed to allow enrollees to better understand their Part D plan benefits, costs, and therapeutic-equivalent coverage alternatives, including biosimilars and generics.

Impermissible MA-PD Part D RI Programs

1. Part D RI Programs for enrollees not taking any, or few, Part D covered drugs and vaccines. MAOs may not structure a Part D RI Program to discourage clinically-indicated medication use.
2. Part D RI Program proposals that are solely reliant on prescription fills or adherence as the basis for providing the reward and incentive.
3. Part D RI Programs used to steer beneficiaries to mail service pharmacies, preferred pharmacies, or any other specific network providers. Rewarding a beneficiary's choice of pharmacy is not an appropriate activity to influence through rewards and incentives, nor should choice of pharmacy negatively affect an enrollee's ability to earn rewards and incentives under a RI program.
4. MA-PD plans may not, in connection with the Part D RI programs under this Model, receive funding, in-kind resources, or any kind of payment provided by a drug manufacturer nor may an MA-PD plan's Part D RI Program make use of personnel affiliated with a drug manufacturer, manufacturer-financed coupons, or discounts provided to a beneficiary, or manufacturer-supplied education materials. Further, MA-PD plans may not, in connection with the Part D RI programs under this Model, receive funding, in-kind resources, or any kind of payment from pharmacies nor may an MA-PD plan's Part D RI Program make use of personnel affiliated with a pharmacy, pharmacy-financed coupons, or discounts provided to a beneficiary, or pharmacy-supplied education materials.

Requirements for Part D RI Programs

1. Rewards and incentives must be tangible items that align with the purpose of the Part D RI Program and must directly benefit the enrollee. For example, a plan's charitable contribution made on behalf of the enrollee does not satisfy the CMS criteria as a permissible reward or incentive because the enrollee who earned the reward does not benefit directly from such a contribution by the MA-PD plan. However, the use of points (which are not themselves tangible) to purchase a tangible reward does satisfy CMS criteria

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because the points are used by each enrollee to obtain a tangible reward that is of value to the enrollee.

2. Part D RI Programs must be completed by the end of a plan year. For MAOs using a programmed debit card for a reward or incentive, any unspent value could carry over into the next plan year for enrollees' use.
3. Any rewards or incentives offered under RI programs must be: (i) limited to a value that may be expected to impact enrollee behavior; (ii) limited to the value of the expected benefit of the associated activity or service (but may exceed the cost of the activity or service); and (iii) subject to a cap of \$600 per enrollee per year (in the aggregate for all rewards, incentives, debit cards, and gift cards provided under the Model in the VBID PBP).

For Part D RI programs, MA-PD plans must reasonably establish value for the successful medication adherence or formulary compliance for which they offer rewards and incentives.

4. MAOs must implement Part D RI programs in a manner that complies with all applicable fraud and abuse laws, including the anti-kickback statute and civil monetary law prohibiting inducements to beneficiaries except, and only to the extent applicable, as explicitly provided in any such separately documented waiver issued pursuant to section 1115A(d)(1) of the Act for the VBID Model.
5. Part D RI Programs are prohibited from providing rewards or incentives in the form of cash or other monetary rebates. Rewards and incentives may not be used to decrease cost sharing or plan premiums.
6. Part D RI Programs must comply with all un-waived provisions of 42 CFR 422.134 as if those provisions directly applied to a Part D RI program. For example, CMS will not approve or will terminate use by a participating plan of RI programs that (a) largely serve to market the plan or to encourage beneficiaries to remain with a specific plan based on a reward and incentive; (b) are (or can be) used to, in any way, choose or solicit healthier enrollees over enrollees who may be, or the MA organization believes may be, less healthy; or (c) discriminate against enrollees based on race, national origin, limited English proficiency, gender, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty status, health status, or other prohibited basis.
7. Consistent with section 100.5 of Chapter 4 of the Managed Care Manual, rewards and incentives that are designed to be won based on probability, including programs in which an enrollee may earn entries into a lottery or drawing in order to receive a reward or incentive of a significant value, are prohibited.

As part of monitoring VBID Model participation, CMS will require participating MAOs that have RI Programs to report to CMS the form and manner of any RI Program it offers; the number of enrollees targeted; the number of enrollees that received the reward or incentive, including trends over time; and any evaluations of the effectiveness of such programs. If CMS determines that a RI Program is not in compliance with the Model, CMS may impose sanctions or civil monetary penalties on the MAO in accordance with 42 CFR 422.723 or 423.752.

More generally, CMS will review all proposed RI Programs based on the rationale and theory for the reward or incentive; the population of focus; how the plan defines the value of the reward to

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total cost of care; and the expected health outcomes and cost and savings effect of its proposed intervention. As part of the application process, CMS may offer guidance on what may or may not be acceptable in an MAO's specific proposal. The RI program must be included in the participating plan's bid as a non-benefit expense. CMS, in its sole discretion, reserves the right to accept or reject any RI program proposal.

3. Model Requirements

The VBID Model eligibility requirements are outlined below for interested MAOs. Participating MAOs must meet the requirements of the Model communication and marketing guidance, monitoring, bidding, and other general CMS oversight to ensure beneficiary protections while participating in the Model. CMS will reserve the right to impose a corrective action plan or take other remedial actions, including termination from the Model test to rectify or address a failure to adhere to Model requirements. Further, an MAO's failure to adhere to the requirements of the Model test may result in rescission or invalidation of any program or payment waiver issued by CMS to that MAO, which could trigger enforcement action by CMS related to the waived requirements. All other regulatory and statutory requirements applicable to the MAO will remain in effect. Failure by an MAO to comply with those requirements could result in enforcement action consistent with the authority of the MA program, including intermediate sanctions or contract termination.

3.1 Eligibility Requirements

Participation in the VBID Model is voluntary. The Model is open for participation to MAOs at the individual plan benefit package (PBP) level (all segments of a PBP must participate in the same way for a segmented PBP). MAOs may propose one or multiple MA and MA-PD plans for participation. All MAOs applying to participate in the VBID Model in CY 2021, including existing participants, must submit an application to CMS by the application deadline.

Eligible MA PBPs must meet the following criteria:

- **Plan Type:**
 - The following MA only and Medicare Advantage-Prescription Drug (MA-PD) plan offerings are eligible to apply:
 - Coordinated Care Plans
 - Health Maintenance Organizations (HMOs), including those with a Point of Service (POS) option
 - Local Preferred Provider Organizations (PPOs) or Regional PPOs (RPPOs)
 - All Special Needs Plans
 - Chronic Condition Special Needs Plans (C-SNPs)
 - Dual Eligible Special Needs Plans (D-SNPs)
 - Institutional Special Needs Plans (I-SNPs)
 - The following plan types are **not** eligible to participate in the VBID Model:
 - Private Fee-for-Service (PFFS) Plans

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- Employer Group Waiver Plans (EGWPs)
 - Medicare-Medicaid Plans (MMPs) or other demonstration plans
 - MA Medical Savings Account (MSA) Plans
 - Cost Plans
 - Programs of All-Inclusive Care for the Elderly (PACE) organizations
- **Length of Plan Existence:**
 - At least one of the MAO's PBPs included in the Model must have been offered in at least three annual coordinated elections (open enrollment) periods prior to the open enrollment period for CY 2021 (i.e., open enrollment for 2018, 2019, and 2020).
 - **Plan Performance:**
 - The MAO offering the PBP is not under sanction by CMS, as described in 42 CFR § 422.750 and 423.750, under any contract. CMS may deny an application on the basis of information obtained from a program integrity screening.
 - The PBP's contract has at least a three-star overall quality rating for the most recently available year. PBPs that are not rated, due to newness or low enrollment, may participate in the Model if other contracts from the same parent organization meet these requirements or the MAO requests, and CMS grants, an exception.
 - The PBP does not have a "consistently low performing" icon on Medicare Plan Finder.
 - The MAO that offers the plan is not an outlier in CMS's Past Performance Review; more information about this review is available at the following link: <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDComplianceActions.html>

Outside of a CMS exception, which is outlined below, PBPs that fail to meet these criteria may not participate in the Model in CY 2021, although they may become eligible in subsequent years. Conversely, PBPs that meet these requirements initially, but fail to do so later (i.e., are later sanctioned by CMS or have a drop in overall Star Rating) may be disqualified from participation in later years or terminated by CMS from the Model, upon consideration of the best interests of the plan's enrollees and needs of the Model. Additionally, while segmented PBPs may participate in CY 2021, CMS will not approve any segmented PBP that provides for different interventions across segments or where a plan does not include all segments of a PBP.

In their applications, MAOs must disclose any present or past history of sanctions, investigations, probations, or corrective action plans for the MAO, affiliates, or other relevant persons and entities. CMS will conduct appropriate program integrity screens during the application process and may choose to not select otherwise qualified MAOs based on information found during a program integrity screen.

CMS will consider exception requests in limited circumstances and will reserve the right, in its sole judgment, to admit a PBP that does not strictly meet the criteria. For example, CMS might admit a plan offered for fewer than three years, where that plan is a successor to a previously offered plan, such that sufficient baseline data is available for evaluation. However, CMS will only

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exercise that discretion when that admission is consistent with the administration and goals of the VBID Model. In circumstances where a plan fails to meet quality-related criteria, CMS will apply a high degree of scrutiny to the request, and is unlikely to approve such an exception without consideration of additional monitoring or other conditions to be imposed upon the excepted PBP. In addition, CMS will consider applications for plans that do not meet the criteria at the time of application but are anticipated to qualify by January 1, 2021.

MAOs seeking an exception should do so in writing by submitting a request to VBID@cms.hhs.gov, specifying the specific contract and plan numbers for which an exception is sought, and the grounds for the exception. MAOs are strongly encouraged to make requests well in advance of the due date for responses to this RFA.

The participant selection requirements are in addition to any participation requirements generally applicable to the MA program. A condition of continuing participation in the VBID Model is that the participating PBP continues to be offered in the MA program.

3.2 Communication and Marketing Guidelines

All MA communications and marketing regulations and guidance, including but not limited to the Medicare Communications and Marketing Guidelines, remain applicable to materials and activities of the participating organization and other MA and MA-PD plans and should serve as the main reference for plans. (See, e.g., 42 CFR parts 422 and 423, subparts V, and <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html>).

In addition to compliance with those existing requirements, participating MAOs must comply with marketing and communication standards within the Model. Participating MAOs may choose to cite their participation in most components of this Model or any or all specific benefits available under the Model in pre-enrollment marketing materials; with regard to cash or monetary rebates funded out of the beneficiary rebates under section 1854(b) that may be provided to all enrollees, participating MAOs must seek and receive prior approval from CMS of marketing and communication materials. CMS will permit participating MAOs and their representatives to convey information about the benefits, including any approved VBID benefits, available as part of their plan offerings. As required based on the plan's approved model application, if eligibility for an intervention or flexibility available under the Model (e.g., the RI program) is not assured or cannot be determined before a model year for a specific enrollee or enrollees, participating plans must provide a disclaimer indicating that eligibility for interventions is not assured and will be determined by the organization after enrollment based on relevant criteria (e.g. clinical diagnoses, eligibility criteria, participation in a disease state management program). Moreover, the information must be conveyed in accordance with all other CMS communications and marketing guidelines, including those prohibiting misleading communications to enrollees.

CMS believes MAOs participating in the Model are aligned with CMS's implementation and evaluation goals, and the MAOs will create communication and marketing strategies that ensure beneficiaries are engaged and informed. CMS will provide guidance on model communications and marketing for CY 2021. Unless specifically waived, requirements for marketing and

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communications for MA plans under 42 CFR Part 422 continue to apply to participating MAOs; all communications and marketing materials communications must comply with the prevailing requirements for MA and MA-PD plans.

In addition to communications with enrollees, participating MAOs are expected to communicate their model participation to network providers that may be providing services to enrollees as part of the Model, including specifically to any providers who have been identified as high-value. Additionally, MAOs may communicate enrollees' eligibility status once established.

3.3 Monitoring and Data Collection

Participating MAOs will be subject to timely data collection and reporting that supports CMS's real-time monitoring of the Model's implementation, and can also be used as part of the Model evaluation. CMS monitoring activities are designed to track model progress and implementation, ensure beneficiaries are not harmed or discriminated against, and provide assurance that MAOs are in compliance with the terms and conditions of participation in the Model.

CMS will provide participating MAOs with Model Monitoring Guidance that will detail what reporting is necessary, when data should be reported, how data is being collected and should be shared with CMS, and who CMS expects to receive reporting on (e.g., beneficiaries targeted and engaged in receiving wellness and health care planning (accepted or declined)). Both beneficiary-level and contract-level reporting will be required. Specific guidance will be detailed in the contract addendum and other CMS guidance. In addition, CMS will provide training and support to participating MAOs to assist with these requirements and is actively working on approaches to data sharing and reporting that minimize burden and improve transparency to both CMS and participating MAOs.

Participating MAO data collection and reporting might include:

- For the Wellness and Healthcare Planning Component, participating MAOs must report to CMS the number and proportion of enrollees that have been engaged and then either accepted or declined WHP, and other data to track performance the MAO's WHP Strategy. CMS will specify the details and frequency of reporting in guidance or in the contract addendum. Participating MAOs may also be asked to provide raw data and narratives about their experience in implementing WHP and the development of best practices.

For the VBID Flexibilities Component, participating MAOs must monitor and report to CMS on enrollees that have been targeted (or are eligible to receive) and have received or used the VBID Flexibility being offered (e.g., reduced cost-sharing, additional supplemental benefits, etc.). For MAOs choosing to share beneficiary rebates savings more directly with beneficiaries in the form of a mandatory supplemental benefit for cash or monetary rebates, CMS will monitor in a manner similar to the Part C and D Rewards and Incentives Component: at the enrollee level and including details on the amounts and frequency in which these benefits are provided.

- For the Part C and D Rewards and Incentives Component, participating MAOs must monitor and report on enrollees who are targeted for rewards/incentives and keep track of the frequency and dollar amount for each enrollee during the year.

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- Please see the VBID Hospice Benefit Component RFA for information on data collection and reporting for the Medicare Hospice Benefit Component.

In addition to the information above, CMS will monitor and collect data about beneficiary opt-outs; complaints and grievances to the plan, 1-800-MEDICARE and the Medicare Complaint Tracking Module; enrollee appeals and grievances, including proportion of IRE appeals and the number overturned; increases in drug rebates or other utilization measures secondary to a Reward and Incentive program; and other items as deemed necessary to ensure compliance with all model terms, beneficiary protections, and program integrity.

The VBID Model's approach to monitoring is designed to protect all beneficiaries and assure the MAOs' compliance with the terms of the Model test. CMS or its contractor will conduct compliance monitoring on a regular basis to track MA organization compliance with the terms of the Model test. As with evaluation, while CMS or its contractor will monitor chiefly through existing data sources, participating plans will be required to provide additional data collected specifically for the Model test where no existing data are available. CMS or its contractor will also conduct specific audits of all participating organizations in identified risk areas, and may initiate audit activity that requires additional data or site visits, particularly in response to high levels of complaints or other indicators of poor performance.

CMS will request additional reporting only when it determines existing data sources are limited or insufficient. Likewise, CMS and its contractors will monitor the Model primarily through leveraging existing data sources, such as VBID application data and CMS encounter, enrollment, payment, survey, complaint, and bid data. CMS may also ask for additional information if model participant provided information needs clarification.

CMS will work with participating MAOs and may conduct on-site visits to allow for the direct observation of the model implementation. Overall, CMS expects to learn from the model implementation and reserves every right to make changes to the Model as necessary to ensure beneficiary safety and that CMS's aims are achieved.

CMS reserves the right to terminate an MAO's participation in the Model or exercise other available remedies at any time if the MAO has failed to comply with the terms of the Model, is subject to investigation or sanctions for program integrity issues, or if CMS determines that the MAO's participation in the Model or its performance of model activities may compromise the integrity of the Model, including by resulting in lower quality care or adverse outcomes for enrollees or the Model.

3.4 Bidding and Projected Savings

3.4.1 Overview

Each VBID Model Component must be detailed in the VBID application, and once approved, included as part of the MAOs PBP and Bid Pricing Tool (BPT) submission. WHP and Part C and D Rewards and Incentives Model Components will be priced in the BPT as an Administrative Costs. VBID Flexibility Model Components, including cash or monetary rebates, used as a means to share the beneficiary rebates with enrollees, will be priced under Mandatory Supplemental Benefits. Bids must be prepared according to the rules generally prevailing under Parts C and D.

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Benefits under the Model are subject to existing funding rules and other regulations for supplemental benefits unless specifically waived.

Participating PBPs will be required to satisfy all existing CMS requirements, such as service category cost sharing standards, without consideration of the VBID interventions. VBID interventions must be documented within separate areas of the PBP submission for benefits review.

MAOs must also provide in their applications projections of the impact that their participation will have, for CY 2021, on plan medical and prescription drug utilization, cost, and premiums.

These projections are to be prepared by an actuary who meets the applicable actuarial U.S. Qualification Standards and the analysis will be considered to be an Actuarial Communication in accordance with Actuarial Standards of Practice No. 41. CMS will review these projections as part of reviewing the application for compliance with the terms of the Model test; reasonableness of assumptions; potential detrimental impact to CMS, the Medicare program, or enrollees; and the sustainability of the proposal. In order for the plan to be approved to participate in the Model, these projections must show net savings to CMS over the course of five years and no net increase in enrollee cost over the life of the Model.

MAOs may be required to correct its projections or change its proposal, or establish a multi-year financial plan, in case of unacceptable submissions. Once approved by CMS for participation in the Model, MAOs must incorporate these assumptions into their annual bids in accordance with actuarial standards and CMS guidance. These instructions might require MAOs to supply additional plan-specific model information through the Health Plan Management System (HPMS) Bid Pricing Tool in connection with their bids for each of the Model years, demonstrating the specific impact of the Model on that year's bid. CMS will require annual updates to the projections to include actual historical experience when available. Outlined below is the information that plans are required to submit as part of their application to Model.

3.4.2 What to Submit for Projected Costs and Savings as part of the Application

Participating MAOs are required to submit to CMS projected costs for each VBID Model Component included in their application. Participating plans are also required to submit to CMS projected net savings to Medicare over the course of the Model. In submitting these projections as part of the application, plans must:

- Submit to CMS a supplemental document that clearly outlines the projected costs of the VBID Model Components that the MAO is proposing to be implemented under the Model, as well as how the proposal will generate net savings to Medicare over the term of the Model. The financial supplemental document must reflect the MAO's best estimate of projected enrollee engagement, program implementation costs, utilization changes, including the expected timeframe of those utilization changes.

MAOs are required to submit the following Supporting Documentation:

- Executive Summary (i.e., a summary in financial and actuarial terms of the Model strategy and expected PMPM changes). This should include any changes to an existing program if the MAO is current participating in the Model;

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- Summary of Projected Costs by each VBID Model Component (a projected utilization, unit or PMPM costs and NBE costs together with an indication of what experience base, etc., was relied on in setting the assumption. A projection of the member months eligible for each component and/or targeted population and estimates of those that will participate or otherwise be engaged, if applicable);
- Summary of Projected Savings over the Course of the Model;
- Additional Quantitative Support, as necessary; and
- Changes to Pricing (if returning MAO, i.e., increase to risk scores).

The purpose for requesting the above supporting documentation is to assist CMS in assessing the reasonability of the pricing assumptions intended to be used when providing VBID benefits under this Model. Additionally, the supporting documentation should describe how the proposed VBID Model Components may be expected to meet the Model's financial goals of net savings to Medicare expenditures without any net increase in costs for plan enrollees attributable to the VBID elements over the life of the Model.

Plan sponsors applying for the VBID Model must email documentation to VBID@cms.hhs.gov.

3.4.3 CY 2021 Bid Procedures and Special Considerations

It is anticipated that VBID Model Components of the bids for CY2021 will be covered by the general Actuarial Certification submitted in accordance with 42 CFR 422.254(b)(5), and actuaries preparing applications should keep this requirement in mind. Approval of model applications merely qualifies plan sponsors to include these VBID Model Components in their CY 2021 bid submissions; it does not guarantee that these elements will be approved during Bid Desk Review.

An authorized representative of the participating MAO must attest, as part of the application, the bid, and via the contract addendum, that the model-participating plan application and bid, as applicable, have been completed in a manner consistent with the actuarial assumptions and projections of VBID-Model impacts contained in the actuarial component of the plan's application for participation.

Wellness and Health Care Planning – Special Considerations

MAOs must address the inclusion of this benefit in the bids following the required bidding procedures. It is expected that some WHP costs are already incorporated into plan bids because of the need to comply with 42 CFR 422.128. To the extent that there may be additional costs, these may be factored into the bids per standard processes. It is also expected that plans will have opportunities to achieve net savings if the services result in reduced plan expenditures. It is further expected that these savings would accrue over the longer, extended period of performance for the Model. To the extent there are material assumptions related to either costs or savings from WHP, plans should address these separately, as is required for each selected component.

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3.5 General Model Oversight

CMS reserves the right to terminate an MAO's participation in the Model or exercise other available remedies at any time if the organization has failed to comply with the terms of the Model, is subject to investigation or sanctions for program integrity issues (e.g., if a participating MAO fails to provide a reward or incentive to an enrollee who meets the eligibility criteria, or a reward and incentive is offered for a purpose or on terms/conditions other than which is approved) or if CMS determines that the organization's participation in the Model, or its performance of model activities, may compromise the integrity of the Model, including by resulting in lower quality care or adverse outcomes for enrollees or the Model.

CMS will use a contractor to conduct regular monitoring to review compliance with the terms of the Model test. The contractor will monitor for compliance using existing data sources to the extent practicable, but may seek plan-provided data or conduct site visits, particularly in response to high levels of complaints or other indicators of poor performance. CMS will closely monitor model implementation, to ensure that plan performance is consistent with model rules and approved proposals and that the Model is not leading to any adverse beneficiary outcomes. This will include, but not necessarily be limited to, observing existing metrics of beneficiary access, outcomes, and satisfaction, and monitoring of increased beneficiary questions or complaints through 1-800-MEDICARE or the <https://www.medicare.gov> website. CMS will also monitor the impact the Model has on other CMS initiatives, such as the Part C and D Star Ratings.

CMS reserves the right to investigate an MAO if there is evidence that indicates that the MAO's participation in the Model is adversely impacting enrollee quality of care, and to exercise all available remedies in appropriate instances, including potential termination from the model test or termination of the MA contract.

CMS retains the right to change any model policy on an annual basis or more frequently, in accordance with procedures and parameters that will be established in the Model's contractual addendum to the MAO's agreement with CMS for participation in the MA program.

CMS may consider more broad-reaching policy changes, including changes to the permissible interventions and model components, setting additional financial requirements for participants, as well as adding or eliminating requirements for participation.

An MAO may withdraw a PBP from the Model test, or cease participating entirely, by providing advance notice to CMS in accordance with the timeframes stated in the contractual addendum for participation in the VBID Model. In each case of withdrawal from the Model, MAOs are required to provide adequate notice to participating enrollees, consistent with current requirements in the MA program for termination of the MA plan.

4. Evaluation

In addition to timely submission of required reports, all Model participants are required to cooperate with efforts to conduct an independent, federally funded evaluation of the Model, which may include participation in surveys, interviews, site visits, and other activities that CMS

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determines necessary to conduct a comprehensive formative and summative evaluation. The evaluation will assess the impact of the Model in meeting intended goals in order to inform policymakers about the effect of the model concepts relative to health care delivery. To do so, the evaluation will seek to understand the behaviors of plans, providers, suppliers, and beneficiaries, how each individual intervention is adopted and implemented (including WHP, VBID Flexibilities, Rewards and Incentives, and Hospice), the impacts of increased financial risk, the effects of various payment arrangements and benefit enhancements, the impact of the Model on beneficiary engagement and experience, and other factors associated with patterns of results. In situations where the evaluation uses non-publicly available data, CMS will report results at an unidentified, aggregate-level so as to avoid the disclosure of private and sensitive data of specific model participants.

5. Application Process and Selection

MAOs interested in applying to participate in the VBID Model should submit their application no later than April 24, 2020 11:59 pm EST. The application is accessible on the VBID Model website at: <https://innovation.cms.gov/initiatives/vbid/>.

Questions regarding the Model or application process may be sent by email to VBID@cms.hhs.gov. While CMS will not share the source of the question, CMS may publicly share questions and responses or compile them into a Frequently Asked Questions compendium to ensure that all MAOs have access to information regarding the VBID Model and the application process.

To participate in the Model, MAOs must follow the following process:

Step 1: CMS Technical Assistance (March 2020 through April 2020)

In an effort to provide MAO support for the VBID Model, CMS will provide feedback and technical assistance on a rolling basis between the release of this RFA through April 24, 2020. CMS expects to engage with MAOs to ensure the success of the Model and to offer technical assistance where possible in regards to model participation, model requirements, and beneficiary protections. CMS cannot interfere in MAO contracting with any provider and will not offer any guidance beyond that offered in this RFA.

Step 2: Application Due April 24, 2020 11:59 EST

Using the Application provided by CMS through the VBID Model website, MAOs may apply with one or multiple model-eligible PBPs under one or multiple MA contracts to include the components of the Model. MAOs must indicate to CMS the contract(s), PBP(s), and segment(s), if eligible, that they are proposing to include in the Model.

CMS will use the application process to capture concise, complete applications from MAOs on all of their proposed VBID intervention(s) and model components. MAOs are encouraged to provide

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specific, clear answers in their application that directly state what the plan proposes to do, for whom, how, and when. Where applicable, a supplemental document or presentation that better defines the overall narrative and specifics of the program may be uploaded.

MAOs must submit all accounting and actuarial assumptions associated with their Model participation to CMS at VBID@cms.hhs.gov. This includes projected costs for each proposed intervention, including any changes in administrative costs, specific projected changes to utilization, and projected changes to the plan bid. MAOs offering the Medicare hospice benefit through the VBID Model will be given any bid instructions by the CMS Office of the Actuary and **do not need to** include any costs or projections separately from those instructions.

CMS encourages MAOs to reach out prior to submitting the application. However, after each application has been submitted, CMS will review applications and reach out to MAOs for clarity, additional information, or to request changes.

After review and technical assistance, CMS will provide MAOs with a provisional approval by (TBD) for model participation. Of note, model participant selection is not competitive. CMS does not intend to set a maximum number of qualified MAOs participating in the Model test. CMS also reserves the right to reject any organization, PBP, or proposal to preserve the integrity of the Medicare program, the welfare of beneficiaries, or the efficient and advantageous administration of the Model.

In accordance with authorities granted in section 1115A(d)(2) of the Act, CMS is exempt from administrative or judicial review of its selection of organizations, sites, or participants to test models. Responders are advised that the U.S. government will not pay for any information or administrative costs incurred in response to this RFA; all costs associated with responding to this RFA will be solely at the interested party's expense. There is no requirement to respond to this RFA, as participation in the VBID Model is voluntary.

Step 3: Bid Submission (June 1, 2020)

A provisionally approved MAO will include participation in the VBID Model and all VBID Model Components it is participating in, as part of submitting its PBP(s) to CMS by June 1, 2020. MAOs must follow all bid guidance as provided by CMS.

In addition, provisionally approved MAOs will be required to confirm their participation in the Model by the bid submission date of June 1, 2020, concurrent with and as part of their plan bid submission. In addition to the bid submission requirements, MAOs that were provisionally approved must notify CMS in writing by June 1, 2020, of any changes from their provisionally approved application, including changes to participating PBP(s). MAOs should submit one application per contract.

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5.1 Timeline

Below outlines the timeline for the application period for the VBID Model:

Date	Milestone
March 2020	VBID Model – Request for Application and Application released.
March 2020 – April 2020	CMS provides feedback and technical assistance to MAOs
April 24, 2020	Completed Application due to CMS by 11:59 pm EST
Week of May 11, 2020	CMS completes review of applications and provides feedback to MAOs for inclusion in their CY 2021 PBP
June 1, 2020	CY 2021 MA and Part D Bids Complete; formulary submission deadline.
September 2020	Contract addenda for Model participation executed
October 2020	MAO communication of benefits under the Evidence of Coverage
January 1, 2021	CY 2021 performance period of the VBID Model begins

5.2 Withdrawal or Modification of Application

MAOs seeking to withdraw an entire application or requesting to modify a pending or preliminarily approved application should submit a written request on the MAO's letterhead that is signed by the primary point of contact named in the application submission. To submit a withdrawal request, MAOs must send the request in PDF format by e-mail to VBID@cms.hhs.gov.

Prior to bid submission, CMS will allow incremental changes to provisionally approved interventions or Model Components through (TBD), so that MAOs may incorporate feedback from CMS or otherwise improve the application to meet their goals for the Model. After application and bid submission on June 1, 2020, CMS will only allow changes of a type typically allowed for MA and Part D benefits after bid submission, such as those required in response to CMS bid desk review findings or made during rebate reallocation. Allowance of changes to preliminarily approved interventions is a matter of CMS discretion, and CMS may require resubmission of actuarial documentation to account for proposed changes.

5.3 Amendment of RFA

CMS may change the terms of the Model or cancel it entirely in response to stakeholder comments or other factors. The terms set forth in this RFA may differ from the terms set forth in the final addendum for participation in the Model test.

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Appendix

Appendix 1:

Rewards and Incentives Programs (“Appendix 2”) of CY 2020 Addendum to Medicare Managed Care Contract for Participation in the Medicare Advantage Value-Based Insurance Design VBID Model

Note: This “Appendix 2” is from the CY 2020 Addendum to Medicare Managed Care Contract for Participation in the Medicare Advantage Value-Based Insurance Design VBID Model, and is included as an additional resource for MAOs interested in including Rewards and Incentives programs as part of their application to the VBID Model for CY 2021. The Addendum used in CY 2021 may be different from this Appendix and inclusion here of this information is not a guarantee of the Addendum terms for CY 2021 participation in this aspect of the Model.

Appendix 2:

Rewards and Incentives Programs

The MA Organization may, subject to certain conditions and CMS approval, provide a Rewards and Incentives Program to Targeted Enrollees. The MA Organization shall implement any Rewards and Incentive Program (“RI Program”) under the VBID Model during the term of the Addendum in accordance with the terms of this Addendum, this Appendix 2, and the Approved Proposal.

1. Rewards and Incentives Programs

- A. The parties acknowledge that MA Organization has submitted as part of its application for participation in the VBID Model, a proposal to offer a Rewards and Incentives Program to Targeted Enrollees.
- B. MA Organization shall identify Targeted Enrollees without discrimination and using objective criteria that comply with the terms of this Appendix 2 and are specified in the Approved Proposal or are otherwise approved in writing by CMS. Such objective criteria must be designed to identify either (i) all enrollees or (ii) a subset of enrollees who would receive the greatest health care value from receiving the benefits or participating in the activities associated with a particular reward or incentive in the Part C RI Program or Part D RI Program.
- C. The parties acknowledge that that the Approved Proposal contains the following:
 1. The goals of each RI Program.
 2. The nature and scope of each RI Program, including the criteria for identifying Targeted Enrollees, the eligibility criteria that must be met for an individual enrollee to receive the reward or incentive, and the associated healthcare activity (or service) that must be completed for the reward or incentive to be available.

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3. The per unit value of the reward and incentive and the total value that an enrollee can receive (e.g., a gift card with a per unit value of \$25 offered quarterly for a total of \$100 per year) up to \$600 annually per enrollee.
 4. The amount and frequency of the reward or incentive that may be obtained by a Targeted Enrollee for participation in an RI Program.
 5. The evidence base and theory of change used to develop the reward or incentive and the intended goals of the RI program.
- D. MA Organization may implement a Rewards and Incentives Program that is specific to participation in a disease management program, transition of care program, or similar programs that are evidence-based and approved by CMS.
- E. The MA Organization shall:
1. Comply with the standards for reward programs outlined in Chapter 4, sections 100 through 100.5 of the Medicare Managed Care Manual (posted at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>), issued and effective 04-22-2016, except as waived or otherwise modified in the Addendum, Appendix 1, or this Appendix 2;
 2. Not provide any individual reward or incentive the value of which exceeds the value of the expected benefit of the health care item or service; an individual reward or incentive may have a value beyond the cost of the health-related service or activity itself, subject to this limit tied to the expected benefit of the health care item or service;
 3. Limit the provision of rewards and incentives to Targeted Enrollees to a maximum annual per enrollee limit of \$600.00 in the aggregate for all rewards and incentives, which applies across all RI Programs in the VBID PBP.

2. Part C RI Programs

Except to the extent that certain provisions are identified as waived in Appendix 1, MA Organization shall comply with 42 C.F.R. § 422.134 in connection with its Part C RI Program. Notwithstanding any other provision of this Addendum or its appendices, the MA Organization shall comply with all relevant fraud and abuse laws, including the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries, except as explicitly provided in any separately documented waiver issued pursuant to section 1115A(d)(1) specifically for the VBID Model. Any such waiver will apply solely to the VBID Model and may differ in scope or design from waivers granted for other programs and models.

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3. Part D RI Program Requirements

- A. MA Organization shall implement a Part D RI Program only in connection with a PBP for which the MA Organization has executed a Part D Addendum such that the PBP is an MA-PD plan.
- B. Except to the extent that certain provisions are identified as waived in Appendix 1, MA Organization shall implement any Part D RI Program in compliance with the terms of 42 C.F.R. § 422.134 (as if such regulation applied to Part D plans). Notwithstanding any other provision of this Addendum or its appendices, the MA Organization shall comply with all relevant fraud and abuse laws, including the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries, except as explicitly provided in any separately documented waiver issued pursuant to section 1115A(d)(1) specifically for the VBID Model. Any such waiver will apply solely to the VBID Model and may differ in scope or design from waivers granted for other programs and models.
- C. If the MA Organization offers a Part D RI Program, the rewards and incentives in any such Part D RI Program must be furnished to reward or incent one of the following:
 - 1. Participation in a plan sponsor medication therapy management program (MTMP).
 - 2. Participation in receipt of covered Part D vaccines and other drug therapies that focus on preventive health.
 - 3. Participation in a program that allows enrollees to better understand their Part D plan benefit, costs, and therapeutic-equivalent coverage alternatives, including biosimilars and generics.
- D. In offering any reward or incentive for participation in an MTMP, the MA Organization shall comply with existing CMS requirements for MTMPs, as set forth 42 C.F.R. § 423.153.
- E. In offering any reward or incentive for participation in preventive health services, the MA Organization may design a program with the overall goal of improving medication adherence, however the MA Organization shall not condition any such reward or incentive on prescription fills or clinical outcomes, and shall not furnish any such reward or incentive for a service that is not clinically indicated for the beneficiary.
- F. Consistent with the Approved Proposal, the value of the reward or incentive provided pursuant to a Part D RI Program may exceed the cost of the health-related service or activity on which receipt of the reward or incentive is based, but must not exceed the value of the expected benefit of using the service or item, up to an annual per enrollee limit of \$600.00 in the aggregate for all rewards and incentives.
- G. In implementing and operating its Part D RI Program, the MA Organization shall not:
 - 1. Use prescription fills or adherence as the sole basis for providing a reward or incentive.

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2. Incentivize enrollees to use mail service pharmacies, preferred pharmacies or any other specific network providers.
3. Identify Targeted Enrollees based on the identity of their pharmacy provider.
4. Receive or use funding, in-kind resources, or any kind of remuneration provided directly or indirectly by a drug manufacturer. This includes, but is not limited to, the use of personnel affiliated with a drug manufacturer, manufacturer-financed coupons or discounts provided to a beneficiary, or manufacturer supplied education materials.
5. Receive or use funding, in-kind resources, or any kind of remuneration provided directly or indirectly by a pharmacy or entity that owns or operates pharmacies. This includes use of personnel affiliated with a pharmacy, pharmacy-financed coupons or other discounts provided to a beneficiary, or pharmacy supplied education materials.

4. Record Retention

- A. In accordance with Article 4 of this Addendum (Additional Record Retention and Reporting Requirements), the MA Organization shall maintain the following records regarding all RI Programs under this Model:
 1. The identity of each enrollee who received a reward or incentive;
 2. The Part C RI Program, Part D RI Program, or both, pursuant to which the enrollee received a reward or incentive;
 3. The nature and date(s) of the activities or other conduct engaged in by the enrollee that enabled the enrollee to qualify for the reward or incentive; and
 4. The nature and amount of the reward or incentive received by the enrollee.
 5. The cost of the healthcare activities or services with which eligibility for a reward or incentive is associated and the value of the expected benefit of such healthcare activities and services.
- B. The MA Organization shall submit semi-annual reports to CMS, in a form and manner and by a deadline specified by CMS, regarding its implementation of any Part C RI Program or Part D RI Program. The MA Organization shall provide CMS with supplemental information upon request regarding its implementation of any Part C RI Program or Part D RI program.

5. Compliance and Enforcement

- A. MA Organization shall have in place a protocol for monitoring the implementation and administration of each approved Part C RI Program and Part D RI Program. MA Organization shall make this protocol available to CMS upon request.

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- B. In accordance with Article 5 of the Addendum (Termination of Addendum or MA Plan(s) Participation by CMS), CMS may terminate or suspend the MA Organization's implementation of any Part C RI Program or Part D RI Program, or take other remedial action, if -
1. The MA Organization fails to comply with the terms and conditions of the Addendum or this Appendix 2; or
 2. CMS determines that the MA Organization's implementation of such a program might compromise the integrity of the Model.
- C. If CMS determines that the MA Organization has failed to comply with the terms of Article 3.D of this Addendum or this Appendix 2, CMS may prohibit the MA Organization from participating in the VBID Component regarding Rewards and Incentives Programs, regardless of whether the MA Organization has corrected or otherwise resolved the noncompliance.