Centers for Medicare & Medicaid Services

Center for Medicare and Medicaid Innovation

# Value-Based Insurance Design Model

# Request for Applications for CY 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 Value-Based Insurance Design (VBID) model for CY 2020. All eligible organizations that wish to participate in the VBID model for CY 2020, including organizations that are participating in CY 2019, must apply for participation in the model.

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

- Coordinated Care Plans
  - Health Maintenance Organizations (HMOs), including those with a Point of Service (POS) option
  - Local and Regional Preferred Provider Organizations (PPOs)
- 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 Plans, Employer Group Waiver Plans, Medicare-Medicaid Plans or other demonstration plan, Medicare Advantage MSA Plans, Cost Plans, or PACE organizations.

For CY 2020, the VBID model has been broadened to allow CMS to test a number of complementary health plan innovations, summarized below and described in detail throughout this RFA. CMS is conducting this Model test through the Center for Medicare and Medicaid Innovation under Section 1115A of the Social Security Act.

## 1.1 Model Test Changes for CY 2020

CMS is broadening the VBID model by introducing significant new enhancements for participating MA organizations for CY 2020. In designing these new model components, CMS considered stakeholder responses to the Centers for Medicare and Medicaid Services: Innovation Center New Direction Request for Information (RFI) for Medicare Advantage Innovation Models, academic research, private sector innovation, and health plan benefit design literature.

Through the VBID model, CMS is testing the impact of 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, including through telehealth, to improve quality and reduce costs.

For 2020, the VBID model incorporates broader changes than those proposed or introduced into MA in recent years. In comparison to recent MA programmatic changes, the VBID model not only allows organizations to further target benefit design to enrollees based on chronic condition but also certain socioeconomic characteristics. Additionally, the VBID model will require all participating plans to better engage their enrollees through structured and timely Wellness and

Health Care Planning and allows participating plans to provide a potentially more meaningful rewards and incentives program and to meet network adequacy requirements using access to telehealth services.

The CY 2020 VBID model components are summarized briefly in this Section, with additional detail provided for each component in Section 2 of this RFA. All interested organizations should review this RFA in its entirety in order to prepare and submit their applications.

*Model Geography*

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 beginning in CY 2020.

*Model Performance Period*

CMS is extending the original performance period of the Model by three years. The Model will be tested through 2024, with opportunities to apply for participation anticipated for each year.

*Model Components*

The Center for Medicare and Medicaid Innovation (CMMI) is revising the voluntary VBID model to test a broader array of health plan innovations.

The payment and service delivery components of the Model available to plans for CY 2020 are the following:

1. Wellness and Health Care Planning (required for all participating plans)
2. Value-Based Insurance Design by Condition and/or Socioeconomic Status
3. Rewards and Incentives
4. Telehealth Networks

Through the Wellness and Health Care Planning component, CMS is testing the provision of timely and structured Wellness and Health Care Planning benefits, including advance care planning, for plan enrollees. As tested through the VBID model in 2017 through 2019, CMS continues to test the impact on cost and quality of targeted benefit design by chronic condition. For CY 2020, CMS is also testing the impact on overall cost and quality of targeted benefit design based solely on socioeconomic status, as defined by low-income subsidy (LIS) status. CMS will also allow organizations to propose providing to targeted populations (whether based on chronic condition, or LIS eligibility) additional non-primarily health related supplemental benefits, including additional Over-the-Counter (OTC) benefits, when there is a reasonable expectation that the benefits will improve or maintain the health or overall function of the enrollee with regard to the chronic condition or socioeconomic status. Organizations may also propose potentially more impactful Rewards and Incentives programs to change or encourage enrollee behaviors, including for covered Part D drugs provided by MA-PD plans. Additionally, in allowing telehealth network flexibility, CMS is testing an alternative service delivery approach where telehealth can best augment and complement care networks in order to enhance enrollee access to timely and quality care.

## 1.2 Scope and General Approach

Designed to reduce Medicare program expenditures, enhance the quality of care for Medicare beneficiaries (including low income subsidy (LIS) eligible beneficiaries), and improve the coordination and efficiency of health care service delivery, the Model tests the impact of an array of payment and service delivery health plan innovations to reduce costs and improve quality in Medicare Advantage.

CMS is exercising its Section 1115A authority to grant limited program waivers to participating Medicare Advantage Organizations in order to test inclusion by permitting eligible participating organizations to include approved VBID components in their plan designs as part of the model test.

The array of model components provides for a robust test of the core VBID premise that the relative value of a given service can vary significantly depending on an enrollee's underlying health status and certain socioeconomic circumstances. The inclusion of VBID elements that are tailored to chronic conditions or an enrollee's LIS status in health insurance benefit design may be an effective tool to improve quality and reduce the cost of care that enrollees receive, particularly those with chronic diseases and/or unmet needs related to specific social determinants of health.

Additionally, the Model tests the impact of an alternative service delivery approach that require providing timely and structured Wellness and Health Care Planning, and how to best incentivize better health behaviors in Medicare enrollees through more impactful Rewards and Incentives programs, and the ways that telehealth and telemedicine may be taken into account to ensure that MA provider networks enable adequate access to quality care.

## 1.3 Statutory Authority

Section 1115A of the Social Security Act (the Act) (42 U.S.C. § 1315a, added by Section 3021 of the Patient Protection and Affordable Care Act) authorizes CMS to test innovative healthcare 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

Section 1115A of the Social Security Act (the Act) (42 U.S.C. § 1315a, added by Section 3021 of the Affordable Care Act) authorizes CMS to test innovative health care payment and service delivery models that have the potential to lower Medicare, Medicaid, and CHIP spending while maintaining or improving the quality of beneficiaries' care. 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) as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b). For this Model and consistent with this standard, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act.

No 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.

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 Request for Applications, 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) 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.

## 1.5 Medicare Program and Payment Waivers

In support of the 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 contractual addendum for participation in the Model).

- **Uniformity and Accessibility of Benefits:** To be waived to the extent necessary to permit organizations 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 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 USC § 1395w-22(d)(1)(A) and § 1395w-24(c)];
  - 42 C.F.R. §§ 422.2 (definition of an MA plan), 422.100(d)(2), 422.102(a)(2), 422.254(b)(2), 422.262(c)(1);
  - Section 1860D–2(a) of the Act [42 USC § 1395w-102(a)]; and
  - 42 C.F.R. §§ 423.104(b)(2), 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 USC § 1395w-22(d)(1)(A) and § 1395w-24(c)]
  - 42 C.F.R. §§ 422.2 (definition of an MA plan), 422.100(d)(2), 422.254(b)(2), 422.262(c)(1);
  - Section 1860D–2(a) of the Act [42 USC § 1395w-102(a)]; and 42 C.F.R. §§ 423.104(b)(2) & 423.265(c).

- **Provision of Supplemental Benefits that are Non-Primarily Health Related:** To be waived to the extent necessary to allow plans 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 both these health condition and socioeconomic statuses. In using one or more chronic conditions to identify eligible enrollees, an applicant 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 USC §§ 1395w–22(a)(3)(D)(i), (ii)(I) and (iii)] and any implementing regulations.

- **Communications, Disclosures and Marketing**: To be waived to the extent necessary for organizations to comply with Model-specific guidance on communications, including disclosures and marketing, with enrollees or potential enrollees.
  - Section 1852(c)(1)(B) & (F) of the Act [42 USC §§ 1395w-22(c)(1)(B) & (F)]; 42 C.F.R. §§ 422.111(a) & (b);
  - Section 1860D–4(a)(1)(A) of the Act [42 USC § 1395w-102(a)];
  - 42 C.F.R. §§ 423.128(a) & (b)(2).

- **Increased Value for Rewards and Incentives:** To be waived to the extent necessary to allow participating plans to offer rewards and incentives, subject to the terms of the Model, that: are available only to targeted enrollees; are based on the anticipated benefit (rather than the value) of the associated healthcare item or service; and other rewards and incentives programs 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 may be based on anticipated benefit (rather than the value) of the associated healthcare item or service and 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 Model, the offering by MA-PD plans of rewards and incentives tied to the Part D benefit.
  - 42 C.F.R. §§ 422.134(b)(1), (b)(2), (c)(1)(i) and (c)(1)(ii), related to availability and eligibility for rewards and incentives;
  - 42 C.F.R. § 422.134(c)(1)(i), related to completion of the entire activity or service prior to receiving the reward and incentive;
  - 42 C.F.R. § 422.134(c)(1)(iii), related to the monetary limit on rewards and incentives.

- **Network Adequacy and Telehealth Services:** To be waived to the extent necessary to allow MA plans to use telehealth providers in lieu of in-person providers to meet network adequacy requirements, subject to the terms of the Model. CMS will consider proposed networks use of telehealth services, regardless of whether the telehealth services are: (a) "additional telehealth benefit" provisions and requirements under section 1852(m) of the Act (and implementing regulations) or (b) telehealth services provided as supplemental health care benefits. MA plans flexibility for proposed telehealth services are subjected to CMS approval as clinically appropriate and evidence-based.
  - Section 1852(d) of the Act [42 USC § 1395w-22(d)];
  - 42 C.F.R. § 422.112;

CMS is not proposing to waive Title XVIII's anti-discrimination provisions and does not believe such a waiver is necessary for the model test. Participating organizations are required to implement model interventions in a non-discriminatory manner.

Program waivers, once issued, are (1) each contingent on compliance with the terms and conditions of the model test, including the contractual addendum for participation in the model test and documents incorporated therein; (2) are granted only to the extent necessary to implement an organization's approved proposal for participation; (3) are granted only to organizations as to those Plan Benefit Packages (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 2020 consists of a total of four components:

1. Wellness and Health Care Planning (required for all VBID-participating plans)
2. Value-Based Insurance Design by Condition and/or Socioeconomic Status
3. Rewards and Incentives
4. Telehealth Networks

Combined, these components allow CMS to broadly test payment and service delivery reform in the Medicare Advantage program to improve quality while reducing costs.

## 2.1 Wellness and Health Care Planning

As a condition of receiving any program waiver granted in connection with the VBID model, participating plans will be required to submit, receive approval for, and comply with a strategy regarding the delivery of timely Wellness and Health Care Planning (WHP) services, including advance care planning (ACP) services, to all enrollees. 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 plans - that protect 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 C.F.R. § 422.128 to maintain written policies and procedures concerning advance directives for all adult enrollees. The regulation requires that MAOs provide 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, and the MAO's policies regarding advance directives. MAOs are 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 Wellness and Health Care Planning 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 Wellness and Health Care Planning, including ACP, for all plan enrollees has an impact on cost and quality of care.

Accordingly, as a condition on any program waiver granted in connection with this Model, participating plans (including plans that previously participated), will be required to comply with the WHP requirements described in this RFA. Each organization applying to participate in the VBID model must submit, for CMS review and approval, a strategy for implementing timely WHP, as part of its application. The strategy must address: how the plan will implement the "WHP timeliness standard" for the provision of WHP services across its enrolled population in the participating PBP; how the effectiveness of that strategy will be tracked, summarized, and reported to CMS for monitoring; and how participating plans will work with their network providers to engage patients and ensure they are offered timely opportunities to discuss their goals and preferences for care. The WHP timeliness standard stipulates that each enrollee's provider must attempt to conduct an initial discussion of the enrollee's wishes and choice of a surrogate by the earlier of the second visit with the patient, the annual wellness visit, or any health risk assessment conducted by the provider. While enrollees are allowed to decline any WHP discussion opportunity, the strategy must include how the participating plan will capture the number and proportion of enrollees that have been engaged, when, by whom, and then either accepted or declined WHP, and other data to track performance against the timeliness standard. 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.

CMS expects 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 will lead to improvements in the delivery system infrastructure for accessing, maintaining, and updating advance directives. CMS believes that better access to ACP documentation resulting from this test will improve its effectiveness and impact in avoiding unwanted and unnecessary care.

As part of their application, organizations must describe the following:

- Any current tactics the organization uses to promote WHP, including possible network, beneficiary, community, IT, or measurement and tracking initiatives as well as how they are complying with current regulations under 42 C.F.R. § 422.128;
- Ways that the organization believes the provision of WHP, including ACP, can be improved and operational specifics for how they will advance and track WHP using the WHP timeliness standard;

- As part of VBID, any proposed differential cost-sharing or co-payment reductions it would use as well as any rewards and incentives proposed to incentivize WHP, including the population to be targeted.
- Any strategies, best practices, and barriers overcome for offering WHP. Examples may include network engagement, training and management; beneficiary awareness and engagement; payment incentives; coordination with national, community-based, and professional organizations; technology-based approaches that facilitate creating, updating, storing, and accessing WHP documents; coordination with plan care management and disease specific initiatives; targeting of specific populations, diagnosis or settings; and specific tools, legal documents, or types of advance directives used by the plan.

CMS will review applications for the rationale supporting the effectiveness of the proposed WHP strategy, the activities and timeline proposed to implement the strategy, and how the strategy addresses WHP needs and opportunities in the plan's service area. As noted above, organizations' applications must include how they intend to capture the data needed to monitor and track their program (including compliance with the WHP timeliness standard), and how they will be prepared to report this information to CMS. Organizations may propose, for CMS consideration and potential approval, enrollee rewards and incentives to promote WHP or reductions in cost-sharing for WHP outside the Annual Wellness (AWV), 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 Value-Based Insurance Design Flexibilities

For CY 2020, participating MA plans may provide supplemental benefits, such as reduced cost-sharing and/or additional benefits, to certain enrollees. Further, participating plans may offer additional "non-primarily health related" supplemental benefits to certain enrollees. For both types of flexibility, the non-uniform benefits may be provided to certain enrollees based on chronic conditions(s); LIS eligibility[1]; or a combination of both (e.g., enrollees who are LIS eligible and have COPD).

In using any of the VBID flexibilities described in this section, MA organizations must comply with certain general parameters. Organizations may not propose reductions in targeted enrollee benefits or increases in targeted cost-sharing amounts as VBID interventions. Furthermore, organizations may not discriminate against non-targeted populations, for example, in cases where

[1] 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/Downloads/Plan-Communications-User-Guide-v123-November-30-2018.pdf

VBID interventions are coupled with changes made to the PBP-at-large in ways that decrease the benefits available to enrollees with non-targeted clinical conditions. Organizations must strictly adhere to CMS-approved[1] definitions of the target population, and are responsible for proactively identifying each enrollee with an eligible data source based on information known to the organization. Organizations must offer all VBID benefits specific to the condition category to all eligible enrollees within the chronic condition category identified in the VBID model's chronic condition list or the targeted condition category as identified through the participating plan's flexible methodology. Organizations must limit advertisement of their participation in the Model to that permitted by CMS. Organizations are required to communicate the benefits of the Model to all VBID eligible enrollees, and CMS will review and approve specific communications.

### 2.2.1 Targeting Enrollees by Chronic Conditions

For the first two years of the VBID model, 2017 and 2018, CMS identified a limited number of chronic conditions from which organizations could choose to target enrollees for VBID interventions. Participating organizations were responsible for applying CMS-defined criteria to identify enrollees who fell within each of the clinical categories selected. In 2019, in addition to the CMS-identified chronic conditions, CMS allowed MA organizations additional flexibility in targeting and identifying enrollees eligible for the non-uniform benefits: participating plans could use, upon CMS approval of the proposal, a methodology that either 1) identifies enrollees with different chronic conditions than those previously established by CMS; or 2) modifies the existing CMS-approved chronic condition category to target a broader or smaller subset of the existing chronic condition based on the use of new or different data sources to identify and target VBID-eligible enrollees with the CMS-approved chronic condition category.

For 2020, participating MA organizations will be able to choose a broad targeting methodology, such as targeting all enrollees with a specific chronic condition (from among the original CMS-identified list or a new condition proposed by the participating plans), or a tailored methodology, such as targeting enrollees with a specific level of a condition, as defined by ICD-10 codes[2] or other data. The targeting criteria chosen and used by the plan must be able to be replicated by CMS, applied uniformly to all enrollees who meet the defined criteria, be evidence-based, and be expected to materially impact the health of the targeted population.

For reference, VBID applicants may continue to target enrollees using the previously defined chronic conditions provided below:

- Diabetes
- Chronic Obstructive Pulmonary Disease (COPD)
- Congestive Heart Failure (CHF)
- Patient with Past Stroke

[1] This includes both target populations based on CMS-approved targeted conditions and on MA organization proposals approved by CMS that use other conditions as provided in section 2.2.1 above.
[2] ICD-10 Codes may be found at https://www.cdc.gov/nchs/icd/icd10cm.htm

- Hypertension
- Coronary Artery Disease
- Mood Disorders
- Rheumatoid Arthritis
- Dementia

CMS provided the ICD-10 codes for use in identifying enrollees with these conditions in Appendix B of the CY 2019 RFA, available here: https://innovation.cms.gov/Files/x/vbid-rfa2019.pdf.

In addition to selecting specific chronic conditions, plans have the flexibility to identify specific combinations of these or other chronic conditions for one or more VBID interventions. This approach allows organizations to target a more specific group of enrollees. For example, an organization may choose to target enrollees with two chronic conditions when there is an evidence-base that doing so represents an opportunity to provide better overall management and improved quality of care. CMS will review proposed targeting methodologies and may reject those proposals that are determined to not reach a large enough cohort for meaningful evaluation of the intervention.

While participating plans will have the opportunity to modify their benefit design for any or all of the targeted conditions, plan benefit design still must be uniform among enrollees within each condition category. Plan determinations will be subject to retrospective, randomized audits by CMS to determine if all VBID-eligible enrollees actually received the VBID interventions.

Regardless of chosen approach, applicants must provide CMS with clear, replicable, and uniform targeting criteria. Applicants should include data such as ICD-10 codes (https://www.cdc.gov/nchs/icd/icd10cm.htm), encounter data, claims data or other data sources to which CMS has access. CMS will review these proposed methodologies, which must be approved by CMS to be used by a participating plan.

Proposed methodologies for identifying the targeted population must be submitted for the CMS-identified chronic conditions and other chronic conditions. In their applications and the explanation of the methodology, plans must explain how their selected chronic conditions represent an opportunity for better clinical outcomes and management of the condition. Additional chronic conditions may include lower back pain, chronic kidney disease, obesity/pre-diabetes, asthma, tobacco use, hypercholesterolemia, ophthalmology, end-of-life conditions, frailty, and palliative care. Plans must submit evidence-based supporting research or studies, if available, to demonstrate the probable success of the methodology and corresponding intervention to lower costs and improve quality be submitted with the proposal.

CMS will review and approve or reject the applicant's methodology as part of the application process. If an applicant's methodology is not approved, CMS will notify plans of any necessary updates that could be made for CMS to approve the application. CMS encourages applicants to work with CMS as part of the application process to identify any necessary adjustments in a timely manner so that approval can be granted for participation in the VBID model in CY 2020.

Flexibility on how (and to what extent) to implement their interventions based on chronic conditions. As in prior years, interventions may take the following forms:

1. Reduced cost-sharing for high-value services
2. Reduced cost-sharing for high-value providers
3. Reduced cost-sharing for enrollees participating in disease management or related programs
4. Coverage of additional supplemental benefits (now also including non-primarily health related supplemental benefits)

Additional detail about the permissible interventions is in Sections 2.2.3 and 2.2.5 below. CMS will consider proposals from organizations that vary the target population between participating plan's PBPs if deemed to be sufficiently justified. CMS will also consider proposals for related variants of the permissible interventions, such as allowing the provision of additional supplemental benefits conditional on participation in a disease management program.

### 2.2.2 Targeting Enrollees by Socioeconomic Status

Beginning in CY 2020, participating MA organizations may offer reduced cost-sharing and/or additional supplemental benefits to low income enrollees who qualify for low-income subsidy (LIS) status, as defined in the Plan Communication User Guide (PCUG) for Medicare Advantage and Prescription Drug Plans found here: https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Downloads/Plan-Communications-User-Guide-v123-November-30-2018.pdf. Plans have the option of targeting LIS eligibles at any of the LIS subsidy levels also available in the PCUG. Plans must propose the subsidy level in their application. For the territories where the LIS status is not available, participating plans may identify targeted enrollees based on dual eligibility for both Medicare and Medicaid, using CMS identification of a dual-eligibility status in MARx. Applicants' proposals must outline specifically how the plan's proposal will address socioeconomic determinants of health for targeted enrollees 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 2.2.3 for more information about non-primarily health related benefits).

For plans targeting enrollees based on LIS eligibility, a clear rationale must be included in the application that outlines how deficits in care may occur stemming from enrollees' lower socioeconomic status. Applications to target enrollees based on these socioeconomic factors must identify and discuss the evidence base and theory of action, estimated number of targeted enrollees, and potential to improve quality of care and decrease costs. For CY 2020, plans may include reduced cost-sharing or additional supplemental benefits for medical services and reduced cost-sharing for one or more classes of covered Part D drugs for LIS eligible enrollees. For example, organizations may propose lower cost-sharing or co-pays for targeted enrollees for high-value services, such as primary care or specialist visits, or seeing high-value providers. Through allowing plans to target enrollees based on LIS eligibility, CMS believes organizations will be able to more fundamentally address how socioeconomic status has a direct impact on these types

of enrollees' health utilization. Coupled with the availability of additional non-primarily health related benefits (See Section 2.2.3), CMS believes this flexibility will result in MA organizations proposing innovative approaches to broadly address deficits that represent real barriers to improved health outcomes for targeted plan enrollees.

Participating organizations may also choose to reduce cost-sharing or co-pays for targeted enrollees based on both these socioeconomic parameters and chronic condition(s). Proposals must include the estimated number of enrollees who will be targeted and engaged, and, as noted above, must be large enough for CMS to be able to conduct a meaningful evaluation of the intervention.

CMS will review and approve or reject applicants' proposals for interventions based on the proposed evidence base and theory of action, estimated number of targeted enrollees, and potential to improve quality of care and decrease costs. Interested organizations are encouraged to work with CMS as part of the application process to discuss the specifics of their proposed interventions, including targeting methodology.

### 2.2.3 Additional Non-Primarily Healthcare Related Supplemental Benefits

CMS is testing both how offering these additional non-primarily health related supplemental benefits in a value-based plan design service delivery model and offering these benefits to additional groups than those identified in section 1852(a)(3)(D) of the Act impact cost and quality of care. Pursuant to section 1852(a)(3)(D) of the Act, additional supplemental benefits that are non-primarily related to health and that have a reasonable expectation of improving or maintaining the health or overall function of the targeted enrollee may be offered to "chronically ill enrollees" of an MA plan, consistent with the statutory definition of that term.

An additional flexibility permitted for participating plans in CY 2020 will be the ability to offer additional supplemental benefits that are non-primarily healthcare related 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 plans may use one of the following targeted populations:

(1) Enrollees that qualify for low-income subsidy (LIS).
(2) Enrollees that are within the scope of the statutory definition of "chronically ill enrollee" in section 1852(a)(3)(D)(iii). Section 1852(a)(3)(D)(iii) of the Act defines a "chronically ill enrollee" as an enrollee that:

    (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.

(3) Enrollees that 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). To be approved

for this type of targeted population, the MA plan must explain in its application what non-primarily health related benefits they will provide for this intervention, to which enrollee group or subset of an enrollee group the benefits will apply, and a description of how the plan expects the benefits will improve the targeted population's health or overall functioning.

In addition to the information otherwise required in the application - identification of what non-primarily health related benefits they will provide for this intervention, to which enrollee group or subset of an enrollee group the benefits will apply, and a description of how the plan expects the benefits will improve the targeted population's health or overall functioning - an MA plan proposing to use this category of targeted group must explain how targeting the benefits beyond the statutory definition of "chronically ill enrollee" for purposes of providing the benefits will lead to greater or more likely cost or quality of care impacts.

(4) A combination of the factors identified in categories (1) – (3). For example, a participating plan may target the population of enrollees that are LIS eligible, and/or have Alzheimer's Disease, and/or have a high risk of hospitalization or other adverse health outcomes, and/or require intensive care coordination for a specific additional non-primarily health related supplemental benefit.

If a participating plan is approved to target the enrollee population for this intervention based on LIS eligibility status or based on a chronic condition but without using the statutory definition of "chronically ill enrollee," the waivers of section 1852(a)(3)(D) will be applied as necessary to permit coverage of non-primarily health benefits authorized by the statute to those different groups.

While primarily health related items or services have the primary purpose of preventing, curing, or diminishing an illness or injury, by offering items or services that are non-primarily health related, participating organizations may – in a targeted way – 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. In their applications to offer these additional non-primarily health related supplemental benefits under the VBID model, applicants must provide evidence that there is a reasonable expectation that the non-primarily health related item or service improves or maintains the health or overall function of the targeted enrollee. For enrollee populations that are targeted based on using the definition of "chronically ill enrollee" or otherwise based on chronic condition, the evidence must illustrate that reasonable expectation with regard to the health or overall function of the enrollee as it relates to that chronic condition. For enrollee populations that are targeted based on LIS eligibility status, the evidence must illustrate that reasonable expectation with regard to the health or overall function of the enrollee.

The additional non-primarily health related supplemental benefits that potentially fall within the scope of this flexibility include, but are not limited to, meals (beyond the current allowable limits), transportation, disease-specific household items such as air purifiers or air conditioners, and/or other OTC items that are not currently eligible for the OTC benefit as listed in Chapter 4 of the Medicare Managed Care Manual (e.g. weight scales, fans, heaters, gloves and outwear,

magnifying and reading glasses, hygiene-related items secondary to a health-related condition, fiber or protein supplementation, meal plans, perishables, sugar and salt substitutes, and other items).

Applicants must identify in their applications the items and services that they propose to offer under this flexibility, the rationale and justification for how and why the item or service has a reasonable expectation of improving or maintaining the health or overall function of the enrollee as described here (including the evidence base for that expectation), and all the parameters that the participating plan will use in covering the non-primarily health related supplemental benefit(s) for the targeted enrollee population. Further, if targeting the provision of these additional items or services only to chronically ill enrollees, applicants should address how providing the special non-primarily health related supplemental benefit(s) fits into the MA organization's disease management approach.

CMS expects that organizations will utilize the same processes as currently allowed for the provision of OTC supplemental benefit items, including, where appropriate, requiring documentation from an enrollee's provider or care team of the necessity of an item or service. Organizations must also include safeguards that prevent fraud, waste, and abuse, including any misuse or inappropriate provision of these items or services and potential resale (See Section 2.2.4, Enrollee Safeguards, for information on general enrollee safeguards). For organizations utilizing a programmed debit card, any unspent value could carry over into the next plan year for enrollees' use. Where appropriate, organizations 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. Additional detail is provided in Section 2.2.5.d, Coverage of Additional Supplemental Benefits.

### 2.2.4 Enrollee Safeguards

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

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 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 organization'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, 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.

### 2.2.5 Benefit Design Options and Permissible Interventions

Participating plans may offer one or more of the interventions described in this section to approved targeted populations. The proposed approach should be fully described for CMS review and approval and must address all portions of Section 2.2.4 -- Enrollee Safeguards above. Additionally, Plans should refer to Sections 2.2.1 and 2.2.2 above for the requirements in identifying the targeted population(s) for any of the interventions described below.

### 2.2.5. a. Reduced Cost-Sharing for High-Value Services

Participating plans may reduce or eliminate cost-sharing for items or services, including covered Part D drugs offered by a participating MA-PD plan, that the plan has identified as high-value for a given target population. Participating organizations have broad flexibility to choose which items or services are eligible for cost-sharing reductions; 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; organizations 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 low-income subsidy (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.

### 2.2.5. b. Reduced Cost-Sharing for High-Value Providers

Participating plans may reduce or eliminate cost-sharing when providers that the organization has identified as high-value treat targeted enrollees. Applicants may propose several potential approaches and should describe all parameters in their application, including how the proposal will be administered in a non-discriminatory fashion. Plans may propose to simply reduce or eliminate cost-sharing for a given high-value provider, regardless of the specific service provided to a targeted enrollee, or plans may propose reduced or eliminated cost-sharing only when a high-value provider delivers a specific high-value service, or one of several high-value services, to targeted enrollees.

Organizations may identify high-value providers across all Medicare provider types. This can include physicians and practices, hospitals, skilled-nursing facilities, home health agencies,

ambulatory surgical centers, and others.

As part of the VBID application and approval process, organizations must propose their approach for identifying high-value providers for each target population. CMS will review and approve each proposal individually, with particular emphasis on the clinical rationale behind each proposal. 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. For organizations utilizing this approach, targeted enrollees must clearly understand which providers and/or services are considered high-value, along with any supporting rationale to encourage uptake and enrollee engagement and understanding.

CMS encourages organizations to rely on 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 idiosyncratic or locally specific approaches also may be proposed with accompanying clinically justification. Cost or efficiency can be part of organizations' criteria for identifying high-value providers, but must be combined with relevant quality measures; in other words, organizations cannot identify high-value providers based on cost alone. In addition, organizations also cannot identify high-value providers based on coding accuracy or intensity alone.

Proposals will also be reviewed for potential adverse consequences, including enrollee confusion. Specifically, when an organization offers cost-sharing elimination for a specific high-value service only, that service should be an easily discernable episode of care not subject to variable or unanticipated cost to the enrollee based on the provider's choice of coding, facility fees, or non-discounted services from other providers. For example, selected high-value providers should not be associated with higher or unexpected cost-sharing for enrollees for related services (e.g. a high-value hospital's physicians were out-of-network typically, which led to higher co-pays for the physician services received at the hospital).

Organizations do not need to meet any specific network adequacy or access standards for the subset of high-value providers selected as part of this intervention. However, all VBID interventions must be available and accessible to applicable targeted enrollees. CMS may require an organization 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 discrimination. Notwithstanding the model intervention(s), organizations must still meet all standard Medicare Advantage network adequacy requirements (See 42 C.F.R. § 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 organizations 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 interest 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 (See 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.

Examples of interventions within this category might include reducing cost-sharing for diabetics who see a physician who historically has achieved strong results in controlling her patients' HbA1c levels, or eliminating cost-sharing for heart disease patients who elect to receive nonemergency surgeries at cardiac centers of excellence (potentially including centers geographically remote from the PBP's service area, for which intervention CMS may establish additional safeguards, such as travel and accommodation requirements, beyond those found in Section 10.11 of Chapter 4 of the Managed Care Manual, that relate to Transplant Services).

### 2.2.5. c. Reduced Cost-Sharing for Enrollees Participating in Disease Management Programs

Participating organizations can reduce cost-sharing for an item or service, including Part D drugs covered by MA-PD plans, for enrollees who choose to participate 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 organization 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 copays 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. We note that participating MA-PD plans may also choose to reduce co-pays on certain Part D drugs in the absence of participation in a disease state management program by using the intervention for reduced cost-sharing for high-value services (see Section 2.2.5.b).

Participating plans may condition cost-sharing reductions on enrollees participating in a disease management program, including meeting certain participation milestones. For instance, an organization may require that enrollees meet with a case manager at some regular interval in order to qualify. However, organizations 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.

As part of the application, MA organizations must submit specific proposals for how they intend to link disease management or related programs to cost-sharing reductions or eliminations. CMS will review these proposals to determine that they are clinically reasonable, are not discriminatory, and there are no other likely adverse impacts on enrollees. The underlying disease management or similar program must comply with all otherwise applicable rules and regulations.

### 2.2.5. d. Coverage of Additional Supplemental Benefits

Under this approach, participating organizations can make coverage for supplemental benefits available only to targeted populations. Such benefits may include any service consistent with existing Medicare Advantage rules for supplemental benefits, which require that supplemental benefits be benefits that are covered by original Medicare, have a non-zero direct medical cost, and are primarily health related. Examples include nonemergency transportation to primary care visits for enrollees with multiple co-morbidities, meals or other nutritional services for enrollees with selected clinical or social circumstances, additional counseling or other covered services, and additional rehabilitation or other post-acute care (*See* 42 C.F.R. § 422.102; Managed Care Manual, Ch. 4, section 30).

Under this intervention in the Model, these benefits will be treated as mandatory supplemental benefits and would be subject to the same rules as any other benefit in that category. Note that while these benefits are available only to certain targeted categories of enrollees, they would be funded by rebate and/or premium dollars from all PBP enrollees. In this respect, the benefits would be similar to existing enhanced disease management programs, which may be offered as mandatory supplemental benefits but are only available to enrollees with a targeted disease.

Organizations proposing interventions must provide a rationale for how the additional services or items are reasonably expected to improve outcomes or lower costs for targeted enrollees. CMS will review the clinical and/or other justifications, such as SES status or cost savings that support the proposed intervention. In addition, supplemental benefits offered as part of this intervention may not be structured in a discriminatory way, and must be available uniformly to all enrollees within the targeted category.

Recently, in the CY 2019 Call Letter, CMS expanded its interpretation of the "primarily health related" standard as applicable to permissible supplemental benefits to use the standard that items or services used to "diagnose, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization". The CY 2019 Call Letter also notes that the Bipartisan Budget Act of 2018 (Public Law No. 115-123) further expanded supplemental benefits that are non-primarily health related for chronically ill enrollees beginning CY 2020. This intervention in the VBID model permits greater flexibility than these authorities and applicable policies for CY 2020 (e.g., the Model permits certain interventions to be tied to Part D drug coverage whereas the CY 2019 Call Letter policy and Bipartisan Budget Act provisions are limited to non-Part D benefits offered by MA plans).

Additionally, as described above, MA plans are permitted under the VBID model to propose non-uniform benefit designs that provide reduced cost-sharing or additional targeted supplemental benefits for all or a subset of enrollees based solely on LIS eligibility status to address social

determinants of health. Additionally, in their model applications, MA plans may propose offering "non-primarily health-related" supplemental benefits that address social determinants of health, such as transportation or meals for example, based solely on socioeconomic status as long as there is a reasonable expectation of improving the chronic disease or maintaining the health or overall function of the enrollee.

In their application, plans should propose what non-primarily health related benefits they will provide for this intervention, to which enrollee group or subset of an enrollee group the benefits will apply, and a description of how the plan expects the benefits will improve the group's health or overall functioning. See Section 2.2.3 for additional detail on how the Model permits offering of non-primarily health related benefits to targeted populations.

Further, the plan may propose use of supplemental benefits that are currently ineligible under the MA OTC benefit, in order to fill in benefit gaps, that may be beneficial to targeted enrollees to improve health outcomes and reduce costs. For example, if the plan were to propose use of a debit card or OTC vendor, it should describe how enrollees will be engaged and made aware of the benefit, whether the value of the benefits on the card could be shared among spouses who are enrolled in the same plan and also meet eligibility requirements, as well as what happens to any remaining balance on the card at the end of the plan year. For example, as described in 2.2.3 above, the plan would propose a carryover of remaining benefits on the card as long as the beneficiary continued enrollment in the plan and still had the qualifying eligibility for the benefit. How these additional benefits will be administered, as well as safeguards in place to avoid misuse, should be included.

For non-primarily health related supplemental benefits, CMS will review applications for appropriateness including the rationale for targeting and an evidence base that forms the reasonable expectation that the benefits will improve health or functioning for the targeted population. CMS will carefully review proposal 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.

## 2.3 Rewards and Incentives

Currently, MA plans are authorized to offer rewards and incentives programs (RI programs) under 42 C.F.R. § 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.

In order to test the cost and quality of care impact of a service delivery model that permits MA (including MA-PD) Plans to provide higher-value rewards and incentives and RI programs in connection with Part D prescription drug benefits, plans participating in this Model for CY 2020

will be permitted additional flexibility as described in this section. We anticipate that these flexibilities may also reduce barriers to greater MA plan uptake of RI programs. Applicants 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, and may propose to use a RI program for the Part D benefit offered by a participating MA plan. Standalone Part D plans are not eligible for participation in the VBID model. All RI programs offered by participating plans 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 plans must follow all of the Rewards and Incentives requirements at § 422.134 as well as in the Medicare Managed Care Manual, Chapter 4, Section 100. See Section 1.5 for a discussion of programmatic provisions in § 422.134 that may be waived to provide participating plans additional flexibility in offering RI programs.

Specifically, MA plans may propose 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 and incentives;
2. For MA-PDs, a reward and incentive associated with the Part D benefit;
3. A rewards and incentives program specific to participation in a disease management or transition of care program; and
4. Other rewards and incentives programs approved by CMS on a case-by-case basis as evidence-based and justified by plan sponsors. CMS will consider program designs that build on behavioral economic research, such as providing an entire reward up front and requiring an action to keep the reward.

In the application, organizations should describe the kind of RI program they intend to offer, the value of the reward or incentive, the expected decrease in cost derived from patient utilization of the covered item or service, the number of enrollees the participating plan expects to target, and the number of enrollees that ultimately may receive the reward or incentive. For example, if the plan is proposing to target healthy behaviors such as exercise frequency, smoking cessation attempts, weight, high blood pressure, or high cholesterol management, cancer screenings, and general preventive screenings in exchange for a reward or incentive, it should describe that in its application. Any proposed rewards and incentives programs must show a projected return on investment materially beyond the cost of the health-related service or activity.

Participating Medicare Advantage plans that offer a prescription drug plan (participating MA-PD plans) may propose Part D rewards and incentives programs that, in connection with medication use, focus on promoting improved health, medication adherence, and the efficient use of health care resources. All proposed Part D RI Programs need to 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 the general RI programs CMS will permit, or not permit, under the VBID

model, organized with specifics for MA-PD plans and requirements for all RI programs offered under the Model. Any Part D RI program should serve to strengthen the linkage between an enrollee and their care team, including pharmacists and providers, in understanding clinically-equivalent 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 that provide rewards and incentives for participating in plan sponsor medication therapy management (MTM) programs.
3. Part D RI Programs that provide rewards and incentives for enrollees that participate in preventive health services, such as receiving covered Part D vaccines.
4. Part D RI Programs that allow enrollees to better understand their Part D plan benefit, 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 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'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'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 reward does satisfy CMS criteria 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. Unless otherwise approved by CMS, Part D RI Programs may not allow enrollees to carry over rewards and incentives from one contract year to the next.
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 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.
   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. Notwithstanding the limited scope of any potential fraud and abuse waivers of the VBID model test, which are not being granted as part of this application, Part D RI programs must comply with all fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.
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 C.F.R. § 422.134. 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 plans that have RI Programs 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 we determine that a RI Program is not in compliance with the model test, we may impose sanctions or civil monetary penalties on the MA organization in accordance with § 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 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 applicant's specific proposal. The RI program must be included in the participating plan's bid as a non-benefit expense, but must not be entered in the Plan Benefit Package. CMS, in its sole discretion, reserves the right to accept or reject any rewards and incentives proposal.

## 2.4 Telehealth Networks

Through this component of the Model, CMS is testing how different service delivery innovations in telehealth can be used to both augment and complement an MA plan's current network of providers, as well as how access to telehealth services may appropriately allow MA plans to expand their service area to currently underserved counties where current MA network adequacy requirements could not be met without the use of telehealth. This component of the Model for CY 2020 is designed to complement the authority for MA plans to offer additional telehealth benefits pursuant to section 1852(m) of the Act.[1]

Under the Model, MA plans will have flexibility to provide additional services by telehealth, to the extent that the provision of these additional telehealth services are considered, and approved through the application process, by CMS to be clinically appropriate and evidence based. In the context of the Model, we are interpreting the term "clinically appropriate" to align with existing CMS rules for contract provisions at § 422.504(a)(3)(iii), which requires each MA organization to agree to provide all benefits covered by Medicare "in a manner consistent with professionally recognized standards of health care." As part of their application, organizations should include the providers and services, along with the appropriate clinical standards, that are being proposed for use in this component of the Model consistent with professionally recognized standards of health care. For the purposes of bids and payment, applicants must follow all CMS bid guidelines and rules in terms of any telehealth services provided through participation in the model.

Model participants may apply to use additional telehealth benefits and/or telehealth services provided as supplemental health care benefits in meeting MA plan network adequacy.

In certain circumstances, as described in the two approaches below, MA plans will be able to use telehealth providers in meeting network adequacy requirements; both approaches may be used for "additional telehealth benefits" (as defined in section 1852(m) of the Act and included in the basic benefit bid) and/or telehealth services that are supplemental health care benefits. Plans must ensure that all enrollees maintain the option for an in-person visit if that is the enrollee's preference, and

[1] We refer readers to the proposed rule Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS 4185-P) (83 FR 54982), published in the Federal Register on November 1, 2018, for a discussion of additional telehealth benefits authorized by section 1852(m).

that services are clinically-appropriate, and evidence-based, so that CMS will be able to evaluate the impact on cost, access to timely care, and quality of care as more beneficiaries and providers expand their use of telehealth and different modalities to provide care. Specifically, through the VBID model, CMS is testing two service delivery approaches to telehealth and MA provider networks based on the number of available providers and the impact on access to care.

First, CMS is testing how plans can use telehealth services to complement and augment their current network of providers. To that end, CMS will allow participating plans to propose how a network of both in-person and telehealth providers can enhance enrollee's access. As part of this, CMS will review plan network proposals, which may propose substituting up to one-third of the required in-network providers for a specialty or specialties.[1]

Specifically, applicants must demonstrate that the participating plan meets all existing MA network adequacy requirements for the service area, before any telehealth augmentation, and has three or more providers available to provide in-person services to enrollees in their network for the applicable specialty. Justification for the specialty or specialties included in the application must be provided, including the evidence base for why such services are clinically appropriate to be provided via telehealth. Through this application process, CMS solely will review and determine if the proposal is acceptable.

Additionally, plans utilizing this approach must provide, as part of their application, how access to care, including time to schedule in-person office visits, will be positively affected and monitored as part of their proposal. Plans must also provide specifics for their telehealth program, including: estimated number, qualifications and standards (e.g. board certification), and types of telehealth providers; how enrollees may access the telehealth service (including any enrollees with disabilities); language services; accessible hours; average wait time to access a provider; additional health plan team members that serve to coordinate care, triage, or perform other functions as part of the care team; and other relevant information related to the provision of the telehealth service. CMS expects organizations to include in their proposals how participation in the telehealth networks component will improve the time to access care while maintaining or improving the quality of care beneficiaries receive.

Second, CMS will allow participating plans to use a combination of telehealth and in-person providers to meet network adequacy requirements, where:

1. All telehealth and in-person providers used are in-network (that is, members of the plan's provider network);

2. As part of current MA network adequacy requirements, the plan Minimum Provider Calculation requires less than three providers per specialty type. CMS expects this to apply in areas such as Counties with Extreme Access Considerations (CEAC), Rural, or Micro county types, etc.); and

[1] The Minimum Provider Ratio calculation can be found at: https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/2018-Network-Adequacy-Guidance.pdf.

3. Enrollee choice and access to all required plan covered services are ensured.

CMS expects this to facilitate allowing organizations to offer an MA plan in one or more counties where under current MA program rules, MA organizations frequently cannot meet current time and distance requirements. Testing of this approach under the Model may demonstrate how MA plans may be offered in more areas than they are today, which would extend the choice of electing the MA program to Medicare beneficiaries who do not have access today.

As part of their application, an organization's proposal should outline how the existing landscape of providers/facilities does not enable the organization to meet the current CMS network adequacy criteria for a given county and specialty type, as reflected in the HSD Reference File, and how the MA organization has contracted with other providers/facilities that, although may be located beyond the limits set in CMS's criteria for time and distance, do provide access that is consistent with or better than the original Medicare pattern of care for a given county and specialty type.

MA plans participating in this component of the Model must use in-network contracted providers (e.g., for example, physicians and certain other practitioners) to provide telehealth services and as telehealth providers for purposes of the network adequacy evaluation in the Model. Consistent with existing MA program requirements, these providers must be included in the MA Provider Directory. These providers must meet all the requirements necessary to provide services under an MA contract in the areas where they operate. They must be appropriately credentialed and licensed according to both federal and state laws; including the state laws where the beneficiary is located and receiving the service. Participating plans must comply with all applicable law that is not waived under the Model.

Under both approaches, applicants may choose the specialty or specialties for which the flexibility will be used to meet network adequacy requirements. CMS will evaluate the additional telehealth services that MA plans propose as part of their applications to participate in the Model to determine whether the services are clinically appropriate, based on evidence, to provide via telehealth.

As noted above, the statutory requirement for enrollee choice whether to receive services in-person or through telehealth will remain in effect. Therefore, each enrollee must have the option to receive a service that the MA plan would cover as a telehealth benefit either through an in-person visit or through telehealth. This will allow the beneficiary to have the option of an in-person provider visit, while maintaining the alternative of a telehealth visit where it is clinically appropriate and evidence based.

### 2.4.1 Model Parameters

Section 50323 of the Bipartisan Budget Act of 2018 created section 1852(m) of the Social Security Act to allow MA plans to provide "additional telehealth benefits" to enrollees starting in CY 2020. Additional telehealth benefits within the scope of the statute will be treated as basic benefits for purposes of bid submission and payment by CMS. CMS has proposed a regulation for implementing the statute in the 2020 MA and Part D proposed rule (CMS-4185-P), which also addresses which services may be "additional telehealth benefits." While participating MA plans

must comply with any new additional telehealth benefits provisions finalized in the rule, CMS will permit an MA plan to propose the particular provider specialties and services that will be used for network adequacy evaluations under the two approaches of this component of the Model.

As part of the Model application process, CMS will review whether the specialist/specialty services proposed to be furnished by telehealth-only providers are clinically appropriate to provide through telehealth (that is, electronic exchange).

The following example shows how a participating plan can operationalize the use of telehealth providers within a particular specialty in lieu of an in-person provider to meet network adequacy standards under the model, using the first approach:

| **Minimum Provider Calculation** | **2018 Reference File Example** |
|---|---|
| County | Baldwin, AL |
| County Type Designation | Metro |
| Beneficiaries Required to Cover | 6,162 |
| Specialty Type | Primary Care |
| Minimum Provider Ratio | 1.67/1,000 |
| Minimum Number of Providers | (1.67/1,000) * 6,162 = 10.29 = **11 Providers** |
| Minimum Number of In-person Providers | 11 Providers * 0.67 = **8 Providers** |

CMS will evaluate each application to ensure that beneficiary access to care is maintained. Participating plans must develop systems to monitor enrollee access to care, including timeliness of access to in-person care, specialist access, in and out of network provider feedback, complaints, out-of-network utilization trends, and other plan-derived metrics; information on these topics must be reported to CMS as part of monitoring under the model. CMS will leverage available monitoring tools as well as develop and apply additional access benchmarks where appropriate. The purpose of this monitoring will be to protect enrollee access to required benefit services. If through monitoring, CMS identifies barriers to access that pose a threat of immediately jeopardizing beneficiary safety, CMS may impose corrective actions on the participating plan.

Through the application process CMS intends to work with MA organizations on their proposals for telehealth networks. Ultimately, however, CMS in its sole discretion may accept or reject applications for telehealth networks.

# 3. Model Requirements

The VBID model eligibility requirements are outlined below for interested organizations. Participating organizations 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 organization'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 organization, which could trigger enforcement action by CMS related to the waived requirements. All other regulatory and statutory requirements applicable to the organization's MA plan will remain in effect. Failure by an organization 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 Model is voluntary. The Model is open for participation to MA organizations at the individual PBP or segment level. Medicare Advantage organizations may propose one or multiple MA and MA-PD plans for participation, so long as each PBP individually meets the criteria specified below. All MA organizations looking to participate in the VBID model test in CY 2020, including existing participants, must submit an application to CMS by the application deadline.

Eligible Medicare Advantage PBPs must meet the following criteria:

- Plan type
  - Coordinated Care Plan: HMO, HMO-POS, local PPO or Regional PPO (RPPO)
  - Special Needs Plan:
    - Chronic Condition Special Needs Plan (C-SNP)
    - Dual-Eligible Special Needs Plan (D-SNP)
    - Institutional Special Needs Plan (I-SNP)

The following are not eligible to participate in the VBID model: Medicare-Medicaid Plans (MMP); Employer Group Waiver Plans (EGWP) or other demonstration plans, cost plans, Medical Savings Account Plans (MSA), or Private Fee-For-Service (PFFS) Plans. In addition, PACE organizations may not participate in the VBID model.

- Plan Enrollment
  - At least one PBP for the applicant organization has at least 2,000 enrollees. Additional PBPs may be included with an enrollment of 500 or more beneficiaries.
  - The MA organization may request an exception from CMS for participation of a PBP that does not meet either of the enrollment requirements above.

- Length of Plan Existence
  - The PBP must have been offered in at least three annual coordinated election (open enrollment) periods prior to the open enrollment period for CY 2020 (i.e., open enrollment for 2017, 2018 and 2019).

- Plan Performance
  - The MA organization offering the PBP is not under sanction by CMS, as described in 42 C.F.R. § 422.750 and 42 C.F.R. § 423.750, under any contract. The MA organization and plan must also pass a program integrity screening.
  - The PBP's contract has at least a three-star overall quality rating for CY 2019; plans that are not rated, due to newness or low enrollment, do not qualify and may not participate in the Model.
  - The PBP does not have a "consistently low performing" icon on the Medicare Plan Finder.
    - The MA organization 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

PBPs that fail to meet these criteria may not participate in the Model in CY 2020, 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 test. Additionally, while segmented PBPs may participate in CY 2020, as a change from CY 2019, 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.

Applicants must disclose any present or past history of sanctions, investigations, probations or corrective action plans for the applicant, affiliates or other relevant persons and entities. CMS will conduct appropriate program integrity screens during the application process, and will exercise its existing rights to not select otherwise qualified applicants on the basis of 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 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, 2020.

Applicants 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. Applicants 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 Medicare Advantage program. A condition of continuing participation in the VBID model is that the participating PBP continues to be offered in the Medicare Advantage program.

## 3.2 Marketing and Enrollee Communications

All Medicare Advantage 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 (See, e.g., 42 C.F.R. parts 422 and 423, subparts V) and should serve as the main reference for plans. (See, e.g., 42 C.F.R. 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 plans must comply with marketing and communication standards within the Model. Participating plans may choose to cite their participation in any or all components of this Model or any or all specific benefits available under the Model in pre-enrollment marketing materials. CMS will permit participating organizations and their representatives to convey information about the benefits, including any approved VBID benefits, available as part of their plan benefit. 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.

At the beginning of each model year, in addition to listing any offered VBID benefits in the appropriate portion of the ANOC/EOC, participating plans must send all targeted enrollees a "Notice of VBID Benefits." The Notice of VBID Benefits is a written notice summarizing the plan's participation in the Model, additional benefits being offered under the Model (such as the

Wellness and Health Care Planning services, reduced cost-sharing, additional supplemental benefits, etc.). If the participating plan reduces cost-sharing for certain high-value providers, a list of these providers must be included in the Notice of VBID Benefits materials provided to VBID-eligible enrollees. The Notice of VBID Benefits should be mailed with the ANOC/EOC for existing enrollees and the EOC for new enrollees, or contemporaneously with the mailing of those documents. In addition, the Notice of VBID Benefits for VBID-eligible enrollees must include language with basic information on this model, including enrollee protections. Enrollees who become eligible for participation in the VBID model in the middle of the year (e.g., those who are newly diagnosed with a targeted condition, newly eligible for LIS, or the organization first learns

of a diagnosis in the middle of a year) must receive this same information once they are identified by the participating plan.

These mandated communications to eligible targeted enrollees represent the minimum that is

required of participating plans. Organizations are encouraged to go beyond this and communicate further with targeted enrollees, including regular follow-up mailings or follow-up phone calls with targeted enrollees. CMS will issue guidance to participating plans about which of these materials (e.g., model notices or scripts for these follow-up communications, the general plan for outreach), must be reviewed and approved by CMS if such review is not already required under existing requirements. CMS will review those materials selected to ensure that all communications are factually accurate, are not discriminatory, and otherwise comply with the Model program requirements and guidance. Regardless of whether selected for review, all communications and marketing materials communications must comply with the prevailing requirements for MA and MA-PD plans (See, e.g., 42 C.F.R. parts 422 and 423, subparts V).

In addition to communications with enrollees, participating organizations will also be expected to communicate their participation in the Model with all members of their provider network, and may communicate enrollees' eligibility status once established. Providers who have been identified as high-value under the VBID model should also be specifically made aware of this fact.

## 3.3 Monitoring

Participating organizations will be subject to CMS monitoring of utilization, impact, and any unintended consequences of each aspect of the model test. Monitoring of each model component will serve to provide critical data to both participating plans and CMS. Additional detail is also provided in Section 2 for specific components. While further guidance about CMS monitoring and participating plan reporting requirements will be provided in the contract addendum and or other CMS guidance, outlined below are the general monitoring requirements plans must meet. Participating plans should also be prepared to support both participation in and evaluation of the VBID model test.

For Wellness and Healthcare Planning (Section 2.1), plans must report to CMS the number and proportion of enrollees that have been engaged, when, by whom, and then either accepted or declined WHP, and other data to track performance against the timeliness standard. Plans must

provide this information to CMS on a regular basis. CMS will specify the details and frequency of reporting in guidance or in the contract addendum. Participating plans may also be asked to provide raw data and narratives about their experience in implementing WHP and the development of best practices.

For VBID Flexibilities (Section 2.2), participating plans must monitor and report to CMS the number of enrollees that are eligible for reduced cost-sharing or additional supplemental benefits and the number of enrollees that actually receive or utilize this benefit. For reductions in cost-sharing tied to using a high-value provider or participating in a disease management program,

participating plans must report sufficient information for CMS to monitor trends in utilization relative to a baseline or program participation rates. Participating plans may need to provide an explanation or rationale if participation rates are below reasonable expectations, as well as provide steps for how to address low engagement. To the extent non-primarily health related supplemental benefits are offered and utilized, participating plans must report to CMS summary statistics regarding utilization, including enrollee characteristics such as LIS status, health status, demographic characteristics, and other pertinent information.

The Model's monitoring and reporting requirements for VBID Flexibilities build on other enrollee protections inherent in the model. CMS will review the clinical justification of organizations' proposed interventions and screen to ensure that they are not discriminatory. Organizations are required to communicate the benefits of the Model to all VBID eligible enrollees, and CMS will review and approve specific communications. CMS monitoring will be designed to ensure compliance with Model parameters:

1. Organizations may not propose reductions in targeted enrollee benefits or increases in targeted cost-sharing amounts as VBID interventions.
2. Furthermore, organizations may not discriminate against non-targeted populations, for example, in cases where VBID interventions are coupled with changes made to the PBP-at-large in ways that decrease the benefits available to enrollees with non-targeted clinical conditions.
3. Organizations must strictly adhere to CMS-approved definitions of the target population, and are responsible for proactively identifying each enrollee with an eligible data source based on information known to the organization.
4. Organizations must offer all VBID benefits specific to the condition category to all eligible enrollees within the chronic condition category identified in the VBID model's chronic condition list or the targeted condition category as identified through the Plan's flexible methodology.
5. Organizations must limit advertisement of their participation in the Model to that permitted by CMS.

CMS will layer several additional enrollee protections in its monitoring activities, on top of those embedded in plan design. These include:

- Use of secret shoppers to ensure that marketing/sales representatives are not inappropriately citing participation in the VBID model;

- Randomized or targeted auditing to review compliance with CMS-approved definitions of eligible target populations
- Construction of a customized script for any calls to 1-800-MEDICARE related to the VBID model and standardized process for following-up on any enrollee complaints;
- Enrollee right to opt-out of the VBID model, if they so request;
- Standardized process for receiving and reviewing any provider complaints related to the Model;

- Ongoing monitoring of incoming data, to ensure that there is no evidence of significant deterioration in enrollee outcomes or in enrollee satisfaction or other adverse enrollee impacts (e.g., limited access to high-value providers); and
- Ongoing monitoring of incoming data, to ensure there is no significant increase in coding intensity associated with participation in the VBID model.

For the Rewards and Incentives component (Section 2.3), CMS intends to monitor drug plan 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. Participating plans must operationalize a way to track and monitor the number and summary demographics of enrollees, by type of reward and incentive and associated activity or service.

For Telehealth Networks (Section 2.4), plans must monitor and report to CMS enrollee access to care, including timeliness of access to in-person care, specialist access, in and out of network provider feedback, complaints, out-of-network utilization trends, and other plan-derived metrics. CMS will also leverage other available monitoring tools as well as develop and apply additional access benchmarks where appropriate.

The Model's monitoring plan is designed to protect all beneficiaries and assure organizations' 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 reserves the right to terminate an organization'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, 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.

## 3.4 Bidding and Projected Savings

The VBID interventions offered by an organization will be treated for bid purposes as mandatory supplemental benefits. Cost-sharing reductions made and supplemental benefits offered as part of a plan's participation in this Model must be accounted for in the bid according to the rules generally

prevailing under Parts C and D. The benefits are subject to existing funding rules and other regulations for supplemental benefits. For plans utilizing the telehealth networks flexibility, all CMS MA bid and payment rules are still in effect, including authority to include additional telehealth benefits as part of the basic bid; telehealth services which do not meet the definition of "additional telehealth benefits" or are not consistent with section 1852(m) of the Act and implementing regulations must be provided as a mandatory supplemental benefit.

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

Organizations must also provide in their applications projections of the impact that their participation will have, for CY 2020, on plan medical and prescription drug utilization, cost, and premiums. These projections need not be accompanied by the certification of a qualified actuary, but will be considered an actuarial communication. 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. CMS may require the submission of financial projections to demonstrate compliance with this requirement.

Organizations may be required to correct projections or interventions, or establish a multi-year financial plan, in case of unacceptable submissions. Once approved by CMS for participation in the Model, organizations must incorporate these assumptions into their annual bids in accordance with actuarial standards and CMS guidance. These instructions might require organizations 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. Failure to adhere to these requirements may constitute grounds for dismissal from the model test, imposition of a corrective action plan, or other available remedy.

CMS separately publishes further guidance on the financial and actuarial components of the application on the VBID model website. An application may be rejected for failure to comply with that guidance.

## 3.5 Data Collection and Quality Indicators

Data collection is central to the success of the Model's monitoring and evaluation. CMS will use several existing data sources to measure quality of care and impacts to cost, including enrollment and disenrollment files, plan bids, MA encounter data, Prescription Drug Event (PDE) data, Healthcare Effectiveness Data and Information Set (HEDIS), CMS Star Ratings, and MA CAHPS

and Disenrollment Survey. The use of existing data sources is intended to reduce the administrative burden imposed on participants and to provide historical baseline.

CMS will require organizations to report additional data, but only where that data is of significant importance to the evaluation so as to justify the additional burden. Organizations' submission of this data is a condition of participation for the Model.

Participating organizations are required to report their determination of enrollee eligibility for model components to CMS via a new MARx input transaction, transaction type 91. More information on this transaction is available in the June 29, 2016 Health Plan Management System Memorandum entitled "Announcement of the August 2016 Software Release." As noted in the monitoring section above, CMS also requests the submission of summary, and potentially enrollee-level, health record data for evaluation and monitoring purposes. As necessary, additional MARx guidance will be provided by CMS to support the implementation of this model.

Additional data collected may include, but is not necessarily limited to, measures of numbers of enrollees served, demographic information, participation in programs, the numbers and types of interventions in which enrollees participated, and other pertinent information to determine the reach of the project, when not available from existing reporting sources.

## 3.6 General Model Oversight

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

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 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 organization'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, 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 organization if there is evidence that indicates that the organization's participation in the Model is adversely impacting enrollee quality of care, and exercise all available remedies in appropriate instances, including potential termination from the model test.
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 MA organization'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 organization 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 test. In each case of withdrawal from the Model, organizations 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 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 policy makers 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,

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. CMS anticipates primarily relying on publicly available data sources in the evaluation of the Model. In situations where the evaluation uses non-publicly available data, CMS will report results at an aggregate-level so as to avoid the disclosure of private and sensitive data of specific Model participants.

# 5. Application Process and Selection

## 5.1 Questions

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 compendium to ensure that all applicants have access to information regarding the VBID model and the application process.

## 5.2 Accessing the Online Application Portal

Interested organizations must apply to participate by responding to this RFA through an online application portal. CMS will only accept applications via the online application portal. CMS expects the online portal to be available in early 2019 on the VBID model website. https://innovation.cms.gov/initiatives/vbid/. Interested participants should monitor the VBID website for a live link to be posted. Organizations will be expected to respond through the online application portal by the application deadline.

Organizations are encouraged to begin preparing responses prior to the opening of the portal. MA organizations should submit one application per contract.

## 5.3 Deadline for Applications

The deadline for receipt of applications in response to this RFA is 11:59 p.m. EST on March 15, 2019 for all applicants. Proposals in response to this RFA must be complete and submitted using the online portal before the deadline.

## 5.4 Applications from Current Participants

Organizations that applied to participate in the model test in CY 2017, 2018, and/or 2019 must submit an application to this RFA in order to participate in CY 2020.

Exceptions from model test participation criteria issued by CMS to individual applicants for CY 2017, 2018, and/or 2019 are granted as to those same PBPs for CY 2020, without need for a renewed exception request by the organization. The conditions of such exceptions also continue to apply. CMS may determine at a later date that renewal request will be required for subsequent years.

## 5.5 Application Process, Review, and Model Contracting

Model participant selection is not competitive. CMS does not intend to set a maximum number of qualified organizations participating in the model test.

Organizations are required, at the time of application, to specify the PBPs they will enroll in the

model test and all states (and service areas) in which those PBPs will participate. Organizations must submit a separate application for each Medicare Advantage contract held by that organization but one or more PBPs covered by that contract may be included in the application, even if the proposed VBID interventions vary from PBP to PBP.
CMS intends to utilize an online portal to capture concise, complete proposals from organizations on their proposed VBID intervention(s). Specifically, CMS will ask for the following:

- organization's current approaches to Wellness and Health Care Planning and strategies to implement timely WHP;
- proposals to provide value-based reduced cost-sharing and/or additional supplemental benefits to targeted enrollees. The proposal should include the methodology for identifying and targeting enrollees, the rationale and evidence behind this methodology, the expected number enrollees to be targeted and engaged (i.e. receive the intervention), and any specifics around the targeting, such as the specifics for the disease state management program, if required;
- proposals for rewards and incentives programs, including the amount of the reward or incentive, the expected clinical outcomes, how the plan proposes to implement and monitor the program, and the expected decrease in medical costs; and
- proposed ways that telehealth can augment and complement current in-person provider networks. This will include the requirement that plan's proposals are clear for how enrollee choice and in-person provider access is maintained.

Plans are encouraged to provide 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. CMS will review applications and reach out to plans for clarity, additional information, or to request changes.

Organizations must respond to the RFA with sufficient detail for CMS to evaluate and understand the proposal. CMS may negotiate with applicants and request application modifications as part of its review of applications, though it may also choose to reject unacceptable proposals outright.

CMS 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. Without limitation, CMS might reject an application where:

- The applicant organization or a specific PBP does not meet the criteria for participation in the model test;
- The proposal does not meet the specific general and component specific criteria and requirements described in this RFA;
- The proposed VBID benefits cannot be reasonably considered, based on available clinical evidence, to be of high value to the targeted class of enrollees;
- The proposal poses an undue risk of enrollee harm, such as discrimination, or confusion;
- The proposal has potential to impose excessive costs on the Medicare program;

- The proposal includes a proposed methodology for identifying and targeting beneficiaries that cannot be reliably replicated by CMS.
- The proposal is otherwise inconsistent with the implementation and evaluation objectives of the model test.

During the Model participant selection process, CMS will conduct program integrity screening and will exercise its rights to not select otherwise qualified applicants on the basis of information found during a program integrity screen.

In accordance with authorities granted in Section 1115A(d)(2) of the Social Security 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 test is voluntary.

### 5.5.1 Conduct Pending Acceptance and Contracting

Applicant organizations not already bound to a contractual addendum for participation in the Model test do agree, by submission of an application, to adhere to the terms of this RFA pending their formal acceptance into the Model test and execution of the contract addendum.

### 5.5.2 Contracting

Selected organizations will formally join the Model test by addendum to the organization's contract with CMS for participation in Medicare Advantage for the applicable year(s), anticipated to be signed in September 2019. This addendum is intended to reflect the requirements of this RFA, but may reflect changes to the Model made after the RFA's publication, or address matters not discussed in this RFA.

Participation in the Model may be conditioned on criteria to be specified at a later date, such as a successful readiness review, approval of policies, review of communication materials, requirements for participation in CMS Innovation Center learning and diffusion activities, sharing of quality and performance monitoring data, and cooperating with CMS monitoring and evaluation activities.

Once contracted to participate in the Model, each organization will be bound to adhere to its response to this RFA and to fully implement its proposal. Modifications to the proposal will be

permitted only with express written approval of CMS.

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 organization's failure to adhere to the requirements of the model test

may result in rescission or invalidation of a program or payment waiver issued by CMS to that organization, which could trigger enforcement action by CMS related to the waived requirements. All other regulatory and statutory requirements applicable to the organization's MA plan will remain in effect. Failure by an organization to comply with those requirements could result in enforcement action consistent with the authority of the MA program, including intermediate sanctions or contract termination.

## 5.6 Timeline

Below outlines the timeline for the VBID model application period:

| Date | Milestone |
|---|---|
| Early February 2019 | Online Application Portal is opened |
| March 15, 2019 | Model applications due to CMS (11:59pm EST) |
| April, 2019 | Provisionally approved model participants identified |
| June 3, 2019 | 2020 MA plan bids due |
| September 2019 | Contract addenda for model participation executed |

### 5.6.1 Withdrawal or Modification of Application

Applicant organizations seeking to withdraw an entire application or requesting to modify a pending or preliminarily approved application should submit a written request on the organization's letterhead that is signed by the primary point of contact named in the application submission. To submit a withdrawal request, applicants must send the request in a PDF format by email to VBID@cms.hhs.gov. Prior to bid submission, CMS will allow incremental changes to preliminarily approved interventions, but only where good cause is shown. After bid submission, CMS will only allow changes of a type typically allowed for Medicare Advantage 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.

## 5.7 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.