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CENTER FOR MEDICARE & MEDICAID INNOVATION

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TO: All Medicare Advantage Organizations

FROM: Sheila Hanley
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SUBJECT: Announcement of Medicare Advantage Value-Based Insurance Design Model Test

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This memorandum announces the Medicare Advantage Value-Based Insurance Design model and provides preliminary guidance to Medicare Advantage Organizations wishing to participate. CMS is conducting this model test through the Center for Medicare and Medicaid Innovation under Section 1115A of the Social Security Act.

The Value-Based Insurance Design model will test the utility of structuring patient cost-sharing and other health plan design elements to encourage patients to consume high-value clinical services, thereby improving quality and reducing costs.

The model test is scheduled to begin on January 1, 2017. CMS will conduct the model test in Arizona, Indiana, Iowa, Massachusetts, Oregon, Pennsylvania, and Tennessee. Organizations interested in participating are strongly encouraged to begin designing programs and preparing proposals in accordance with the guidance below, in advance of the formal Request for Application. However, the parameters of the Value-Based Insurance Design model described in this Announcement may change in the future, or CMS may ultimately decline to conduct the model test, at CMS's sole discretion.

CMS welcomes feedback and reactions to this Announcement from all interested parties. Instructions for supplying this feedback are found at the end of this Announcement.

I. Background

The phrase Value-Based Insurance Design (VBID) generally refers to health insurers' efforts to structure enrollee cost-sharing and other health plan design elements to encourage enrollees to consume high-value clinical services—i.e., those that have the greatest potential to positively impact on enrollee health relative to cost. In particular, VBID approaches often recognize that the relative value of a given service

can vary significantly depending on the enrollee's underlying health status, and that plan design should therefore vary accordingly—i.e., be "clinically nuanced."

VBID approaches have increasingly been used in the commercial market, and the inclusion of clinically nuanced VBID elements in health insurance benefit design may be an effective tool to improve the quality of care and reduce the cost of care for Medicare Advantage enrollees with chronic diseases. However, VBID approaches have generally not been incorporated into Medicare Advantage due to existing regulations. A key barrier to implementation of clinically nuanced VBID approaches is the uniformity requirement, which precludes varying benefit design within a plan based on health status or other enrollee characteristics.

The Medicare Advantage Value-Based Insurance Design (MA-VBID) model will test whether the introduction of clinically nuanced VBID elements into Medicare Advantage plans' benefit designs will lead to higher-quality and more cost-efficient care for targeted enrollees. To test this hypothesis, CMS will exercise its Section 1115A authority to grant a limited waiver of Medicare Advantage uniformity requirements, in order to permit organizations to so structure their benefit designs.

CMS will test this model in 7 states: Arizona, Indiana, Iowa, Massachusetts, Oregon, Pennsylvania, and Tennessee.

Eligible plans in these states, upon approval from CMS, can offer varied plan benefit design for enrollees who fall into certain clinical categories identified and defined by CMS. These categories are diabetes, congestive heart failure, chronic obstructive pulmonary disease (COPD), past stroke, hypertension, coronary artery disease, mood disorders, and combinations of these categories. Other chronic conditions that might benefit from a clinically nuanced VBID benefit design may be added in subsequent model years. Organizations may design their own interventions for each targeted population, but plan benefit changes must fit into four broad categories: (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, and (4) clinically targeted additional supplemental benefits. Changes to benefit design made through this model may only reduce cost-sharing and/or offer additional services; targeted enrollees can never receive fewer benefits or have to pay higher cost-sharing than other enrollees as a result of the model.

This model will have a five-year test period. The first model year will be Contract Year (CY) 2017, beginning January 1, 2017.

This model will be rigorously evaluated in order to answer several key research questions, including (a) does the model improve enrollee outcomes, satisfaction and out-of-pocket costs, (b) does the model result in lower expenditures for participating health plans, and if so, (c) do these lower costs translate into lower plan bids over time, resulting in savings for Medicare and/or for enrollees.

II. The Model Design

A. Research Questions

The MA-VBID model is designed to test the impact of providing Medicare Advantage organizations regulatory flexibility to integrate clinically nuanced VBID approaches into their benefit design. The model will test the hypothesis that these approaches will increase enrollee satisfaction, improve enrollee clinical outcomes, reduce overall plan expenditures, and result in lower plan bids, leading to savings for both Medicare and beneficiaries.

B. Model Duration

The proposed duration of the initial MA-VBID model test is five years, from CY 2017 through CY 2021.

C. Changes to Model Design in Subsequent Model Years

CMS retains the right to modify any model policy or parameter on an annual basis, or more frequently in accordance with procedures to be agreed upon in the model's contractual addendum. However, CMS's general intention is to limit changes to model design in the first three model years to minor modifications to correct any unexpected technical or operational problems, to address program integrity issues or to address any observed unintended adverse consequences of the model. CMS may also consider adding new targeted conditions to the model in the initial three-year period, based on feedback from organizations and other stakeholders.

CMS will consider more broad-reaching policy changes in the later model years (i.e., Years 4 and 5). Such changes might include:

- Modifying target conditions;
- Modifying the permissible plan interventions;
- Modifying the restrictions on plan marketing or communications;
- Setting more stringent financial requirements for plans—e.g., requiring plans to accept a lower benchmark in return for the flexibility offered by the VBID model (this modification might be appropriate if initial evaluation results showed plan savings that were not being reflected in lower plan bids);
- Adding or eliminating requirements for plan participation.

Any such model design changes would be based on the experience of the first two-to-three years of the model, including both qualitative feedback from model participants and interim evaluation results. Any changes to the model would be announced well in advance of implementation.

D. States

In order to test the Value-Based Insurance Design Model in a way that produces generalizable and significant results, CMS has carefully selected 7 states in which to test the model. CMS will conduct the model test in Arizona, Indiana, Iowa, Massachusetts, Oregon, Pennsylvania, and Tennessee.

These states have been selected in order to be generally representative of the national Medicare Advantage market; collectively, they include urban and rural areas, areas with both high and low average Medicare expenditures, high and low prevalence of Low-Income Subsidies and areas with varying levels of penetration of and competition within Medicare Advantage. Test states have also been selected based on the availability of appropriate paired comparison areas for the purposes of evaluation.

Organizations may only enter plans into the model when all or a portion of that plan's service area is located within a test state. A plan's service area need not cover the entire state, but a plan must participate as to all of a plan's approved counties and segments. If a plan covers counties or segments both inside and outside of a model test state, the organization must offer model interventions to all eligible plan enrollees, both inside and outside. See Section IV.B below for more information on multi-state plan participation.

Organizations with multiple qualifying plans may enroll some of those plans, but not others, at their discretion.

E. Model Waivers

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. In support of the model intervention, the Secretary intends to waive certain Title XVIII statutes and their implementing rules, to the extent described below.

No 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 separately issued documentation. Thus, notwithstanding any other provision of this Announcement, 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 Value-Based Insurance Design Model. Any such waiver would apply solely to the Value-Based Insurance Design Model and could differ in scope or design from waivers granted for other programs or models, or those described below.

- **Uniformity and Accessibility of Benefits**
  - SSA §§ 1852(d)(1)(A) [42 USC §§ 1395w-22(d)(1)(A)];
  - 42 C.F.R. §§ 422.2 (definition of an MA plan), 422.100(d)(2) & 422.254(b)(2);
  - SSA § 1860D–2(a) [42 USC § 1395w-102(a)];
  - 42 C.F.R. §§ 423.104(b)(2), 423.265(c).

To be waived to the extent necessary to permit organizations to offer supplemental benefits to the clinically targeted enrollee population, rather than to the entire membership.

- **Uniform Cost Sharing**
  - 42 C.F.R. §§ 422.2 (definition of an MA plan), 422.100(d)(2), 422.254(b)(2) 422.262(c)(1);
  - SSA § 1860D–2(a), 42 USC § 1395w-102(a);
  - 42 C.F.R. §§ 423.104(b)(2) & 423.265(c).

To be waived to the extent necessary to permit organizations to offer reductions in cost-sharing to the clinically targeted enrollee population, but not to the entire membership.

- **Communications, Disclosures and Marketing**
  - SSA § 1852(c)(1)(B) & (F) [42 USC §§ 1395w-22(c)(1)(B) & (F)];
  - 42 C.F.R. § 422.111(a) & (b);
  - SSA § 1860D–4(a)(1)(A) [42 USC § 1395w-102(a)];
  - 42 C.F.R. § 423.128(a) & (b)(2).

To be waived to the extent necessary for organizations to comply with model-specific guidance on communications, including disclosures and marketing with enrollees.

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

Waivers are contingent on compliance with the terms and conditions of the model, and are granted only to the extent necessary to implement a participant's approved programmatic proposal. CMS reserves the right to revoke the waiver and suspend model testing at any point. Further, all other (i.e., non-waived) requirements will continue to apply and be enforced.

F. Model Evaluation and Learning Systems

CMS will rigorously evaluate whether and to what extent the flexibilities offered in this model improve the quality of enrollee care and reduce spending in the Medicare Advantage program. This evaluation 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, PDE data, HEDIS, CMS Star Ratings, and MA and PDP CAHPS and Disenrollment Survey. The use of existing data sources is intended to reduce the administrative burden imposed on participating plans. However, CMS may require organizations to report additional data, when that data is of significant importance to the evaluation. Organizations' submission of this additional data is a condition of participation for the model.

We anticipate that the model will also provide CMS, participating organizations and the health insurance benefit design community at large with valuable insight into effective implementation of VBID principles. To this end, CMS will facilitate learning activities related to the implementation and outcomes of VBID so that organizations can improve their designs over the course of the model test. CMS may also engage in efforts to study the various VBID interventions in the model and diffuse findings about VBID implementation to payors and other stakeholders nationwide. Cooperation with these efforts will be a

condition of participation in the model. In designing any learning activities, CMS will take into consideration that model participants exist in a competitive marketplace, and that some participants may consider some elements of their interventions proprietary. CMS will work closely with participating organizations to develop learning and diffusion strategies that attempt to accommodate this limitation.

III. Key Proposal Requirements

A. Targeted Conditions

For the purposes of the MA-VBID model test, CMS has identified a limited number of chronic conditions that organizations may choose to target. Participating organizations will be responsible for applying the CMS-defined criteria to identify enrollees who fall within each of the clinical categories selected by an organization. Organization determinations will be subject to retrospective, randomized audits by CMS to determine if all VBID-eligible enrollees actually received the VBID interventions.

The targeted conditions are:

- Diabetes
- Chronic Obstructive Pulmonary Disease (COPD)
- Congestive Heart Failure (CHF)
- Patient with Past Stroke
- Hypertension
- Coronary Artery Disease
- Mood disorders

CMS selected these conditions based on (1) their relatively high prevalence within the Medicare Advantage population, (2) their potential for high-cost complications, and (3) the existence of known low-cost, high-value interventions that may improve the disease course and/or reduce complications.

Each of these conditions is formally defined by ICD-10 code. A table listing the codes included in each category can be found in Appendix A.

In addition to selecting specific chronic conditions, organizations have the flexibility to identify specific combinations of the listed chronic conditions for one or more "multiple co-morbidities" groups and establish tailored VBID interventions for each group. For example, organizations may develop a suite of VBID interventions for a "CHF and mood disorders" group. CMS will review all groups selected for estimated cohort size and may reject those proposals not calculated to extend to a group large enough for meaningful evaluation of the intervention.

This list is exclusive—organizations may not modify benefit design for enrollees with conditions not on this list or for any other subgroup of enrollees. However, based on organization feedback and the initial observations of the model's implementation, CMS may consider adding additional conditions to the list in the later model years. Organizations may vary their selected conditions from one participating plan to another.

While participating organizations will have the opportunity to modify their benefit design for any or all of the targeted conditions listed above, plan benefit design still must be uniform among enrollees within each condition.

B. Permissible Interventions

For each of the target populations, participating organizations may select one or more plan design modifications from a menu of four general approaches. Within each approach, organizations have significant flexibility on how (and to what extent) to implement that approach. Organizations may vary their proposed interventions from one target population to another, and from one enrolled plan to another.

Only interventions consisting of additional benefits or lower cost-sharing are acceptable. Organizations may not propose reductions in targeted enrollee benefits or increases in targeted cost-sharing amounts as VBID interventions.

CMS will reject proposals that 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 will also 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.

Each of the four approaches, along with the restrictions and rules around each, are described in greater detail below.

1. Reduced Cost Sharing for High Value Services

Organizations can choose to reduce or eliminate cost-sharing for items or services, including covered Part D drugs, they have 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 services must be clearly identified and defined in advance, and reductions in cost-sharing would need to be made available to all enrollees within the target population.

Reductions in cost-sharing could 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 interventions within this category might include the elimination of co-pays for eye exams for diabetics or the reduction of co-pays for ACE inhibitors for enrollees who have previously experienced an acute myocardial infarction.

2. Reduced Cost Sharing for High Value Providers

Organizations can choose to reduce or eliminate cost-sharing when targeted enrollees are treated by providers that the organization has identified as high-value. Within this approach there may be several potential variants, but all parameters must be described in the application, and administered in a non-discriminatory fashion. One is to simply reduce or eliminate cost-sharing for a given provider, regardless of the specific service provided to a targeted enrollee. Another is to reduce or eliminate cost-sharing only when a high-value provider delivers a specific high-value service, or one of several high-value services, to targeted enrollees. Both approaches are permissible and organizations can vary their approach by target population, provider type, or service type.

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

As part of the application and approval process, organizations must propose their methodology 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 assure that the providers identified are high-value for enrollees in the selected clinical condition group. Providers not individually considered high-value might be enrolled as such by a plan when affiliated with high-value providers through a multi-specialty provider group or other clinically integrated arrangement.

CMS will encourage 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 an NCQA certified medical home, whether a hospital has American Heart Association advanced certification in heart failure, whether a provider meets certain performance metrics on NQF validated quality measures. However, more idiosyncratic or locally specific approaches also may be proposed, so long as they can be clinically justified. 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. Organizations also cannot identify high-value providers based on coding accuracy or intensity.

Proposals will also be reviewed for potential adverse consequences, including enrollee confusion. Where a plan 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., if a high-value hospital's physicians were typically out-of-network, leading to higher co-pays for the physician services received at the hospital).

Organizations need not meet any specific network adequacy or access standards as to the subset of high-value providers selected as part of this approach. 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 impacts performance in a manner inconsistent with the goals of the model; certain patterns of inaccessibility may constitute discrimination. Notwithstanding the

intervention, organizations must still meet all standard Medicare Advantage network adequacy requirements (*see* out in 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 for 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 (available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-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 non-emergency surgeries at cardiac centers of excellence (potentially including centers geographically remote from the plan's service area, for which intervention CMS may establish additional safeguards, such as travel and accommodation requirements).

3. Reduced Cost Sharing for Enrollees Participating in Disease Management or Related Programs

Participating organizations can reduce cost-sharing for an item or service, including covered Part D drugs, for enrollees who choose to participate in a plan-sponsored disease management or similar program. This could include an enhanced disease management program, offered by the plan as a supplemental benefit, or it could refer to specific activities that are offered or recommended as part of a plan's basic care coordination activities.

This intervention is intended to be complementary to the newly established flexibility within the Medicare Advantage program to offer Rewards and Incentives, under 42 C.F.R. § 422.134. However, the model goes beyond this existing flexibility in that participating organizations may offer reduced cost sharing for participation.

Organizations using this approach can condition cost-sharing reductions on enrollees 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., a plan cannot condition cost-sharing reductions on enrollees achieving certain thresholds in Hba1c levels or body-mass index. In general, this intervention 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 and approval process, 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, to ensure they are not discriminatory, and to ensure there is no other likely adverse impact on enrollees. The underlying disease management or similar program must comply with all existing CMS rules and regulations.

Examples of interventions within this category might include elimination of primary care co-pays for diabetes patients who meet regularly with a case manager, or reduction of drug co-pays for patients with heart disease who regularly monitor and report their blood pressure.

4. 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—examples might include non-emergency transportation to primary care visits for enrollees with multiple co-morbidities, meals or other nutritional services, additional counseling or other covered services, and additional rehabilitation or other post-acute care.

These benefits will be treated as mandatory supplemental benefits, and (excepting the points outlined above) would be subject to the same rules as any other benefit in that category. Note that while these benefits are available only to certain clinically targeted categories of enrollees, they would be funded by rebate and/or premium dollars from all plan enrollees. (In this respect, they 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 in this category must provide a rationale relating the additional services provided to improved outcomes or lower costs for targeted enrollees. CMS will review the clinical justification for this rationale. In addition, supplemental benefits offered as part of this intervention may not be structured in a discriminatory way, and must be available to all enrollees within the clinically targeted category.

Examples of interventions within this category might include physician consultations via real-time interactive audio and video technologies for diabetics, or supplemental tobacco cessation assistance for enrollees with COPD.

C. Plan Marketing and Enrollee Communications

Organizations cannot cite their participation in this model or specific benefits available under the model in pre-enrollment marketing materials targeted at potential enrollees. Similarly, organization sales representatives are not permitted to mention the plan's participation to potential enrollees who are not yet enrolled. All marketing regulations and guidance remain applicable to materials and activities of the participating plan and other MA plans. See, e.g., 42 C.F.R. parts 422 and 423, subparts V. CMS will permit participating organizations and their representatives to convey information about the benefits available through VBID interventions, but only when a potential enrollee specifically inquires about them. Such discussions must be accompanied by a CMS-standard disclaimer indicating that eligibility for interventions is not assured, and will be determined by an organization after enrollment based on clinical diagnosis data. Moreover, the information must be conveyed in accordance with all other CMS marketing restrictions, particularly those prohibiting misleading communications to enrollees. CMS will also issue

guidance to non-participating organizations limiting their communications about the model. These policies reflect the general goals of this model, which is intended to test the impact of offering organizations additional flexibilities in order to improve care for existing enrollees. The model is not intended to encourage or discourage enrollment either in Medicare Advantage generally or any specific participating plan.

At the beginning of each model year, organizations will be required to send all enrollees in target populations written materials summarizing the reduced cost-sharing and/or additional benefits available to them as a result of the plan's participation in the MA VBID model. If a plan is reducing cost sharing for certain high-value providers, a list of these providers must be included in the materials provided to enrollees. These materials should be mailed as part of the same package with the ANOC/EOC for new enrollees and the EOC for new enrollees. In addition, with the EOC will include standardized language with basic information on the VBID model, including enrollee protections. Enrollees who become eligible for participation in the VBID model in the middle of the year (those who are newly diagnosed with a targeted condition or the plan first learns of a diagnosis in the middle of a year) must receive this same information once they are identified by their organization. CMS will determine the extent it will require prior review and approval of these materials.

These mandated communications to eligible enrollees represent the minimum that is expected of organizations – however, organizations can go beyond this and communicate further with enrollees. Indeed, CMS believes that further and more intensive communications will likely be a prerequisite for the model's success. Examples of further communications with enrollees might include (a) regular (quarterly or monthly) follow-up mailings, reminding enrollees of the potential advantages available to them as the result of VBID, (b) follow-up phone calls with targeted enrollees, and (c) targeted phone calls or mailings, based on specific clinical or treatment patterns of a given enrollee. (For instance, an organization might remind an enrollee, when granting that enrollee prior approval for a service that she is eligible for reduced cost-sharing for a surgical procedure if she uses a high-value provider.) CMS will consider which of these materials and/or scripts for these follow-up communications, along with a general plan for distributing these materials, must be reviewed and approved by CMS if such review is not already required under existing requirements. CMS will specifically review those materials selected to ensure that all communications are factually accurate and are not discriminatory. Regardless of whether selected for review, all marketing materials communications must comply with the prevailing requirements for MA 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.

D. Enrollee Protections

Multiple protections for enrollees are built into the design of this model. Most importantly, 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 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. Organizations

must strictly adhere to CMS definitions of the target population, and are responsible for proactively identifying each enrollee with an eligible diagnosis code based on information known to the organization. Organizations and may not advertise their participation in the model except as permitted by CMS. 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 targeted enrollees, and CMS will review and approve all plan communications.

In addition, CMS intends to layer several additional enrollee protections on top of those embedded in plan design. These include:

- Use of "secret shoppers" to ensure that plan marketing/sales representatives are not inappropriately citing plan participation in the VBID model;
- After-the-fact randomized or targeted auditing, to review plan compliance with CMS 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 model, if they so request;
- Standardized process for receiving and reviewing any provider complaints related to the model;
- Ongoing monitoring of incoming plan 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 plan data, to ensure there is no significant increase in coding intensity associated with plan participation in this model.

The model's monitoring plan is designed to protect all beneficiaries and assure organizations' compliance with the terms of the model test. As a component of this plan, CMS will use a contractor to conduct compliance monitoring on a regular basis that tracks compliance with the terms of the model test. As with evaluation, the contractor will monitor chiefly through existing data sources and not on additional data collected specifically for the model test. CMS's 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 there is evidence to suggest that the organization's participation in the model is resulting in lower quality care or any other adverse outcomes for enrollees.

E. Plan Bidding and Projected Savings

As part of the model application process, CMS will require organizations to include financial projections of the impact that their participation will have on plan medical utilization, cost, and premiums. 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 the life of the model (five years). CMS expects to provide plans with a standardized template that plans should use to present their financial projections. These projections must be actuarially certified, and the assumptions incorporated into the plan's annual bid. CMS will require annual updates to

the projections, to include new projections for additional targeted chronic conditions and actual historical experience when available, as a condition of continued participation in the model.

The VBID interventions offered by a plan 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, and are subject to existing actuarial equivalence requirements, funding rules and other regulations for supplemental benefits.

Participating plans will be required to satisfy all existing CMS requirements, such as service category cost sharing standards, Total Beneficiary Cost (TBC), and meaningful difference without consideration of the VBID interventions. VBID interventions will be documented within separate areas of the Plan Benefit Package (PBP) such as a supplemental notes field so as not to influence the evaluation of cost-sharing standards, meaningful difference and TBC.

F. Changes to Plans' Interventions in Subsequent Model Years

Organizations may make changes to their intervention to be effective at the beginning of each year, starting in Model Year 2 (CY 2018). In order to exercise this option, organizations must submit a request to CMS, outlining their proposed changes and requesting approval. If organizations are undertaking new interventions or significantly modifying existing interventions, this request will need to include supporting information comparable to what would have been required as part of the initial application to participate in the model, such as intervention methodology, clinical rationale, and updated actuarial projections.

Similarly, organizations that choose not to participate in the model in Year 1 may have the opportunity to begin participation in subsequent years, should CMS elect to reopen the model for new applications. In this case, an organization must submit a full application and be approved by CMS. CMS will consider these applications according to the established participation criteria and the impact of later entrants on the operation and evaluability of the model.

For each model year, CMS will set a deadline for organizations to submit modifications to their intervention or to apply to newly join the model. In general, this deadline will be sometime in the fall, two years before the model year in question (e.g., changes for CY 2019 would need to be submitted by the fall of 2017). This long lead time is necessary to allow CMS to review and approve any plan changes well in advance of plan bid submission the following June. Organizations must notify targeted enrollees of changes to the plan's VBID interventions in a notice that accompanies the plan's ANOC, with conforming changes made to documents provided to newly eligible enrollees.

An organization may withdraw a plan from the model test by providing advance notice to CMS in accordance with the timeframes applicable to withdrawals from the Medicare Advantage program. Organizations may withdraw participation for subsequent years by written notification by the first Monday in June of the year in which the participation would end. In each case of withdrawal from the model, plans will be required to provide adequate notice to participating enrollees, consistent with current requirements in the MA program.

CMS will retain the right to modify any model policy or condition on an annual basis, or more frequently in accordance with procedures and parameters to be agreed upon in the model's contractual addendum.

IV. Participant Application, Selection and Contracting

Solicitation: CMS will solicit model participants via Request for Application. Model participant selection is not competitive. CMS will admit all interested organizations that submit timely applications to the model test, provided the organization and its proposed participating plans meet CMS's participation criteria, and the programmatic proposal is acceptable to CMS.

Contracting: CMS will formally obligate participating organizations to the terms of the model test via a model-specific supplemental addendum to their current agreement with CMS for participation in Medicare Advantage. CMS expects to enter into final addenda in September 2016 concurrently with the signing of other MA contract documents.

CMS will reserve the right to impose a corrective action plan as a condition of continued participation or to terminate a participating organization from the model test for 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 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.

A. Applications

Interested organizations must apply to participate by response to a Request for Application ("RFA"). CMS intends to release the RFA in the fall of 2015 through the Health Plan Management System. Persons interested in receiving the RFA who are not registered HPMS users may do so by subscribing to the Medicare Advantage listserv. Instructions for subscribing are provided on the CMS website (see https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/index.html?redirect=/medicareadvantageapps/).

Organizations must respond to the RFA with sufficient specificity for CMS to evaluate and understand their proposal in detail. Once contracted to participate in the model, each organization will be bound to adhere to its response to the RFA and to fully implement its proposal. Modifications will be permitted only with express written approval of CMS.

Organizations will be required, at the time of application, to specify the plans they will enroll in the model test, and the states in which those plans will participate.

The RFA will require that interested organizations describe their intervention plans, e.g., reduced cost sharing for high value services, as well as their assumptions concerning outcomes. The intervention plans in the applications will be reviewed to make a reasonableness assessment of the likelihood that the level and type of interventions proposed will yield improved results. Approved participants must submit updates to their plans on an as-needed basis.

As part of the application, applicants will (at a minimum) be required to provide the following information:

- Basic plan information, including contract ID, plan ID number(s), along with the names and contact information for key plan staff responsible for implementation of the model.
- Identification of the chronic disease categories selected, along with estimates of how many plan enrollees fall into each category of criteria.
- A description of the specific intervention(s) that the plan proposes to utilize for each chronic disease category and how such strategies would be expected to yield improvements in quality and/or costs; in other words, the mechanism by which they expect outcomes will be affected, the goals they will set, and how they will measure progress towards goals. Additional information for permissible interventions may include the following:
  - **Reduced Cost Sharing for High Value Services**: a clear description of which services are eligible for cost-sharing reductions, the reductions offered and a justification of their clinical appropriateness in the target population.
  - **Reduced Cost Sharing for High Value Providers:** the proposed methodology for identifying high-value providers for each target population, and a justification of the clinical reasonableness of the methodology.
  - **Reduced Cost Sharing for Enrollees Participating in Disease Management or Related Programs:** a description of how the plan intends to link disease management or related programs to cost-sharing reductions or eliminations, and a justification of how this link is clinically reasonable, non-discriminatory, and not likely to have other adverse impacts on enrollees.
  - **Coverage of Additional Supplemental Benefits:** a rationale relating the additional services provided to improved outcomes or lower costs for targeted enrollees.

As noted above, the application process will not be competitive; rather all qualified applicants with acceptable proposals within a geographic region will be accepted. CMS will reject plan proposals that 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 will also 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.

As part of the model application process, plans will be expected to include projections of the impact that their participation will have on plan medical utilization, cost, and premiums. CMS will review the projections at the application stage for reasonableness of assumptions, potential detrimental impact to CMS or enrollees including premium increases or decreases in non-VBID supplemental benefits, and the sustainability of the proposal. As a condition of CMS's acceptance of a proposal, organizations may be required to correct projections or interventions, or establish a multi-year financial plan, in case of unacceptable submissions. CMS expects to provide plans with a standardized template or instructions that plans should use to present their financial projections.

These projections must be actuarially certified, and the assumptions incorporated into the plan's annual bid. CMS will require annual updates to the projections, to include actual historical experience when available, as a condition of continued participation in the model.

CMS expects that organizations will be required to supply additional plan-specific model information through the 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.

B. Selection

The model will be open for participation to Medicare Advantage and MA-PD plans at the individual plan level. Offering organizations may propose one or multiple plans for participation. CMS will accept plans supplying acceptable proposals and that meet the model's participation criteria, as outlined below.

In order to participate in this model a Medicare Advantage plan must meet the following criteria:

- The plan is an HMO, HMO-POS or local PPO plan type;
- The plan is not a Special Needs Plan (SNP), Medicare-Medicaid Plan (MMP) or other demonstration plan, Regional PPO, cost plan, Private Fee-For-Service Plan, Medical Savings Account plan, or Employer Group Waiver Plan (EGWP);
- All or part of the plan's service area lies within one of the model test states;
- The plan has at least 2,000 enrollees in a model test state;
- 50% of the plan's total enrollment resides in the model test states;
- The plan is offered in no more than two states total;
- The plan must have been offered in at least three annual coordinated election (open enrollment) periods prior to the open enrollment period for CY 2017;
- The organization offering the plan is not under sanction by CMS as described in 42 C.F.R. §422.750 and 42 C.F.R. §423.750;
- The organization offering the plan is not an outlier in CMS's Past Performance Review (more information about this review is available here: http://csm.gov/Medicare/Compliance-and-Audits/PartCandPartDComplianceActions.html
- The plan has at least a three star overall quality rating for CY 2015 (plans that are not rated, due to newness or low enrollment, do not qualify);
- The plan does not have a "consistently low performing" icon on the Medicare Plan Finder; and
- The plan's proposed intervention(s) meets the criteria in this ICIP.

CMS will consider exception requests in limited circumstances and will reserve the right, in its sole judgment, to admit a plan 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 MA-VBID model. 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, 2017. CMS reserves the right to reject any organization, plan or proposal on grounds required to preserve the integrity of the Medicare program, the welfare of beneficiaries, or the administration of model test.

CMS will also require all applicants to 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.

Plans that fail to meet these criteria may not participate in the model in CY 2017, although they may be eligible in subsequent years. Conversely, plans that meet these requirements initially, but fail to do so in subsequent years (i.e., are sanctioned by CMS) may be terminated from the model, at CMS's discretion.

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 Value-Based Insurance Design Model is that the enrolled plan continues to be offered in the Medicare Advantage program.

C. 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 2016.

Commencement of 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 and review communication materials.

V. Model Timeline

MA VBID Milestone	Projected Date
RFA released	September 2015
RFA responses due	November 2015
CMS reviews proposals and where necessary negotiates with plans	November 2015 – March 2016
2017 MA plan bids due (bids reflect negotiated agreement on VBID)	June 2016
2017 MA contracts signed (with addendum for model participation)	September 2016
Model Implementation Year 1 begins	January 2017

VI. Model Design Feedback

CMS welcomes feedback on this Announcement from all interested parties. Please direct responses to HealthPlanInnovation@cms.hhs.gov by September 15, 2015. To receive full consideration, correspondence should identify the sender and the organization represented. This email box is intended for model design feedback in advance of the Request for Application.

Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this Announcement; all costs associated with responding to this Announcement will be solely at the interested party's expense. There is no requirement to respond to this Announcement. Not responding to this Announcement does not preclude participation in the Value-Based Insurance Design Model or any future procurement, if conducted. It is the responsibility of the potential responders to monitor for additional information pertaining to the Value-Based Insurance Design Model.

Please note that CMS will not respond to questions about the policy issues raised in this Announcement. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review responses. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this Announcement may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. All submissions become Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

This is an Announcement only. This Announcement is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This Announcement does not commit the Government to contract for any supplies or services or make a grant award. This Announcement should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. Further, CMS is not seeking proposals through this Announcement and will not accept unsolicited proposals.

The list of ICD-10 Codes accompanying the September 1, 2015 Announcement has been revised.

Please view the model's Request for Applications for the current list.

innovation.cms.gov/initiatives/vbid