Value-Based Insurance Design, Opportunities for Cardiovascular Disease Prevention

Martina Gill:
[00:00:00] Thank for joining the webinar, "Value-Based Insurance Design and Opportunities for Cardiovascular Disease Prevention." I'll turn the presentation over to Sibel Ozcelik.

Sibel Ozcelik:
[00:00:14] Thanks so much, Martina, and good afternoon, everyone. We are so excited to get started today to talk with you all about the Value-Based Insurance Design, or VBID model, and the opportunities to improve medication adherence for cardiovascular disease prevention. This is an exciting joint presentation with both the CMS [Centers for Medicare & Medicaid Services] Innovation Center and the CDC's [Centers for Disease Control and Prevention] Million Hearts team. We're so thankful that you all have been able to join us today.

[00:00:40] We want to start off with a brief disclaimer here. Feel free to read the text on the screen but in short, this presentation is provided for informational purposes and should not be construed as legal advice or legal opinion. So, in terms of our agenda, after our welcome in just a moment, I'll pass the mic over to Abigale Sanft, who will provide a background on the VBID model and opportunities to address cardiovascular disease prevention and management through the model flexibilities.

[00:01:14] We'll then turn to our esteemed partners on the Million Hearts team: first, Dr. Laurence Sperling will highlight existing disparities in heart disease and stroke. Hilary Wall will then discuss strategies to improve medication adherence for patients with cardiovascular disease. Nicole Therrien will then move to sharing ways to address strategies to engage pharmacists to improve medication adherence. And then, we'll end with a much longer question and answer session moderated by Haley Stolp and then some closing remarks. We encourage you to ask questions throughout today's presentation and then we'll do the same. We'll pose some questions to you all to garner your feedback and hear a little bit more about the strategies you have to address cardiovascular disease within your patient population, as well as hear some of the challenges or barriers you may be facing. And so, with that, I'll pass it over to Abigale.

Abigale Sanft:
[00:02:11] Thanks, Sibel. So, today, CMMI has focused on testing flexibilities and how Medicare Advantage or MA benefits are provided through the VBID model. And, as you will know, the VBID model tests a broad array of complementary MA [Medicare Advantage] health plan innovations or programmatic flexibilities with the goal of reducing program expenditures while improving the quality of care for Medicare beneficiaries, including low-income beneficiaries.

[00:02:41] Overall, the model has grown tremendously, from 45 plans in 2017 to over 1,000 in 2022. And this number translates to an increase in the number and types of clinical and social needs-focused interventions and, more importantly, their reach with over 3.7 million underserved enrollees projected to receive model benefits in 2022. Even with the increase in model uptake and a substantial growth in the model's reach, there is still more work to do as the 2020 figures represent about 17% of all MAOs and 15% of the MA population.

[00:03:23] For CY [Calendar Year] 2022, we have a selection of complementary model components that can help address the variety of beneficiary needs by targeting socioeconomic status (SES), and chronic conditions. We have continued the flexibilities available for the past several years, including testing lower cost-sharing, targeted by SES and chronic conditions, MA and Part D rewards and incentives programs, and wellness and healthcare planning. We are also continuing with three innovative approaches unique to the VBID model that began this year, in 2021, which are: the hospice benefit component, cash or monetary rebates, and new and existing technologies.

[00:04:11] It's largely these flexibilities under the model that position health plans that participate in VBID to lead on health equity. And this ability to address health equity builds an important business case for MAOs participating in or considering participation in the model, from increasing member engagement, improving retention, to increasing quality and enrollee satisfaction. As noted at the bottom of the slide, in addition to improving health outcomes and lowering medical spending and utilization of low-value services, there's a strong evidence base for MAOs [Medicare Advantage Organizations] to participate in VBID and leverage the model's waiver authority to address health disparities, including the unique ability under the VBID model to target benefits by socioeconomic status.

[00:05:03] Within the VBID model, there are existing opportunities that would be well-suited to addressing the needs of beneficiaries with CVD [Cardiovascular Disease]. Within the literature surrounding CVD treatment and prevention, there's a well-established evidence base for the use of cardiac rehab programs, the DASH [Dietary Approaches to Stop Hypertension] diet, the use of high-intensity statins, and other interventions where VBID model components could encourage greater utilization. Some of these opportunities include VBID flexibilities, which are either reductions or eliminations in cost-sharing or the provision of additional supplemental benefits targeted by chronic condition, SES, or a combination. Specifically, some opportunities to address CVD disparities under this type of benefit targeting would be offering a healthy food card to LIS [low income subsidy]-eligible enrollees with hypertension paired with messaging around the DASH diet. And, the ability to use that card at the grocery store can really help address some of the nutrition gaps often seen in LIS enrollees, especially those with CVD.

[00:06:09] Another example would be offering reduced cost-sharing for high-value Part D drugs to address CVD risk factors, which might include anti-hypertensives or high-intensity statins. And, as a final example: offering eligible enrollees the opportunity to participate in a care management or digital program to receive the benefit, either additional supplemental benefit or reduction in cost-sharing. And within the model's rewards and incentives programs, MAOs could also, for example, offer a reward for the completion of milestones in a cardiac rehab

program for enrollees who have experienced a heart attack. This can also be coupled with the VBID flexibility for reduction in cost-sharing for cardiac rehab visits. Under the new and existing technologies model component, MAOs may also offer targeted coverage of blood pressure monitors and cuffs to enrollees with hypertension to allow beneficiaries to better track their blood pressure over the course of their treatment. So, you can see that there's a unique opportunity to test a suite of benefits to address some of these disparities in CVD management and outcome.

[00:07:26] With this final slide, we wanted to provide an example of how these complementary flexibilities can help Mark. So, Mark is a 66-year-old black male from Vicksburg, Mississippi. He recently had a heart attack and has unmanaged hypertension. He receives low-income subsides and struggles to afford his medical bills and meet his food and housing needs. He was working full-time, but has recently reduced his hours due to his heart attack. It's worth mentioning that while we're talking about, Mark on the slide here as an example, there are thousands of other Marks that are enrolled in your plan. And while you cover a fair amount of medical spending for Mark currently, his costs will increase dramatically if he has a readmission.

[00:08:12] If you can develop a way to better tailor benefits to help Mark, you'll also be helping to reduce some of the huge disparities seen in CVD outcomes. By tailoring benefits to those beneficiaries that are most in need, either based on low-income subsidy status or chronic conditions, VBID plans are able to offer a suite of benefits tailored towards many of Mark's needs. Similar to what I mentioned on the previous slide, there are a number of opportunities that can be leveraged to help support Mark. The first example is VBID flexibilities to offer a reduction in cost-sharing for Part D drugs associated with CVD, including, as we talked about, high-intensity statins and anti-hypertensive drugs.

[00:08:55] And an MAO might also be interested in coupling that with reduced cost-sharing for cardiac rehab services, as well, to cover both medical intervention and drug intervention. And thinking about cardiac rehab services, you may want to couple that reduced cost-sharing with a reward to incentivize the use of those services. And similarly, we talked about on the last slide, the opportunity to cover a blood pressure monitor to encourage the use of blood pressure monitoring and offer a healthy foods card with additional messaging surrounding dietary changes that would be helpful for Mark to incorporate to prevent a second heart attack.

[00:09:40] So, all of these different VBID model components can really work together to help address some of Mark's social needs and health-related needs. I just want to reiterate that there are thousands of other Marks that these types of interventions would help that are currently enrolled in your plan. Not only do they save money, they also help improve quality of care and address social needs for some of the most vulnerable beneficiaries within MA and are readily available within flexibilities offered under the VBID model. Now, I'll turn things over to Dr. Sperling.

Laurence Sperling:
[00:10:22] Thank you very much, Abigale. I'm Larry Sperling. I serve as the Executive Director of the Million Hearts Initiative, and I'll be speaking about inequities in heart disease and

stroke burden. My comments today reflect my specific comments and not those of the organizations I work for, work with, or serve.

[00:10:48] We know in our country, there's a heavy burden of heart disease and stroke. Almost two million people a year in our country suffer from heart attacks and strokes, and almost a million deaths per year are related to cardiovascular disease. Cardiovascular disease is the greatest contributor to racial disparities in life expectancy, and uncontrolled hypertension is the primary contributor to the morbidity/mortality rate disparities in cardiovascular disease between black people and white people.

[00:11:25] From 1950 and for the 50 years ensuing, we celebrated about a 50% reduction in mortality related to cardiovascular disease, coronary heart disease, and stroke. Over the last 10 years or so, however, these curves have stagnated, and we are concerned that the trends are heading in the wrong direction. I do want to point out that cardiovascular disease has been the leading cause of mortality in our country since 1910, with the exception of two years. Those two years were 1918 to 1920, during the Spanish Flu pandemic, and that racial and ethnic disparities have persisted in cardiovascular disease mortality since 1968.

[00:12:18] We are here with a partnered webinar between CDC and CMS/CMMI focusing on Million Hearts. And Million Hearts sits as a partnership between the Division for Heart Disease and Stroke Prevention and CMS. The Division for Heart Disease and Stroke Prevention has a vision for a heart-healthy and stroke-free world with the goals of reducing the risk for high cholesterol and high blood pressure, improving the management and control of high cholesterol and high blood pressure, and then reducing the burden of heart disease and stroke in the U.S., advancing our goals and objectives by addressing health equity, focusing on priority populations, and strategically engaging partners. The aim of the Million Hearts initiative is to prevent a million heart attacks, strokes, and cardiovascular events within five years.

[00:13:12] This is a slide I refer to as Million Hearts mathematics and it's based upon population-attributable risk. So, as we think about that goal, or aim to prevent a million events in our country over a five-year cycle, the two areas we have to invest our greatest focus on are related to blood pressure control and cholesterol management.

[00:13:43] This is an excellent figure from the Surgeon General's Call to Action to Control Hypertension. And, in this figure, you can see that hypertension impacts many, many different organ systems. It affects our brain. So, brain health, risk for cognitive decline, heart disease, heart attack, heart failure, kidney disease, risk for blindness, as well, and visual loss as well as peripheral arterial disease. Hypertension is common, it's costly, and it's controllable. Nearly one in two adults have hypertension. About 80% of adults with hypertension are recommended prescription medications along with lifestyle modifications but only one in four adults, or one in five African-American people or adults with hypertension have it controlled. And that progress is stalled and we're here today to focus on socially-constructed disparities that are persisting. We know what works and we're working hard to tailor, replicate, and scale strategies.

[00:14:59] Well, we have been immersed over the last 19 months now in a global pandemic. And there have been multiple impacts of the COVID-19 pandemic on health as they relate to

health disparities. Of course, the acute COVID infections, but then the secondary impact and some unintended consequences: delays in urgent care, lack of guideline-directed care, the effect of COVID on chronic conditions. We'll talk today some about cardiac rehabilitation and then the long-lasting potential effect on mental health and the economy.

[00:15:42] This is provisional mortality data from the U.S. in the year 2020 from the CDC National Vital Statistics system. And even in the midst of a global pandemic, heart disease deaths in our country have been the number one cause of death. COVID-19 deaths were number three. Age-adjusted death rates in our country increased by 16% last year with the overall death rates highest in non-Hispanic black people and non-Hispanic American Indian and Alaskan native people. COVID-19 death rates were highest among Hispanics.

[00:16:22] As I begin to close my portion of the presentation, over the past 19 months we've been in the midst of converging syndemics, an epidemic of chronic diseases and the impact of these chronic diseases on the population, certainly a concerning epidemic related to health disparities. And both the chronic disease burden and health disparities have been impacted by an infectious disease, COVID-19, its challenges and consequences.

[00:17:00] So, thanks for letting me lead off the webinar today. I'll hand off to Hilary Wall, our senior scientist at Million Hearts. You can see our website there if you want to learn more about Million Hearts or reach me. Thanks very much, again.

Hilary Wall:

[00:17:18] Great, thanks, Dr. Sperling, and good afternoon, everyone. I am Hilary Wall. I am, as Dr. Sperling said, a Senior Scientist in our Division for Heart Disease and Stroke Prevention at CDC. I serve as the Science Lead and I'm really thrilled to be with you today to talk about a really important topic of medication adherence. So, as you likely know, medication adherence is a complicated topic and it calls for a multifaceted approach for solutions. So, today, I'm going to review with you some evidence-based strategies that have been shown to improve medication adherence; especially for anti-hypertensive medications and statins, but for other medications, as well.

[00:18:02] So, I have no disclosures. Dr. Sperling mentioned our Million Hearts goal of preventing one million heart attacks, strokes, and other acute cardiovascular events in a five-year period. Among other things, we are attempting to meet that goal by optimizing care for people with cardiovascular disease or its risk factors. And getting people on appropriate medications is really key for optimizing care, particularly for anti-hypertensive medications and statins. The effectiveness of both of these medication types is supported by reams of evidence, not only in their ability to improve blood pressure control and cholesterol management, respectively, but also for their ability to prevent major cardiovascular events.

[00:18:47] These two figures, and hopefully you can see them, I apologize that they're a little small, but they're from two studies showing efficacy of medication adherence on cardiovascular outcomes. So, on the left, and I put a little star here so you could see it a little more easily, but the black dotted line shows that people who had greater than or equal to 80% of days covered with pertinent cardiovascular medications were much less likely to have a major cardiovascular

event than people with fewer covered days. And on the right, this is called a forest plot. I kind of like the name, but it's not particularly important. This is from a meta-analysis or aggregation of effectiveness studies on the impact of statin non-adherence in cardiovascular disease outcomes, including acute myocardial infarction, coronary artery disease, heart failure, stroke, and venous thromboembolism. And basically, across the board, what we see here is if you are non-adherent to statin therapy, you are more likely to have one of these major cardiovascular events than someone who regularly takes their statins. So, the bottom line is medication adherence equals fewer cardiovascular events.

[00:20:02] So, all of us, many of us on this call are from CDC and I believe we're contractually-obligated to share surveillance data on every presentation we give. So, these are some data from our nationally-representative survey called the National Health and Nutrition Examination Survey. Right now, over 100 million adults have hypertension. A hundred million. That is almost half of adults in this country. Of them, 87 million are recommended to be on both medications in addition to lifestyle modifications. And of those 87 million people, 61 million do not have their blood pressure controlled, and over half of those are currently on anti-hypertensive medications, but still do not have their blood pressure at safe levels.

[00:20:51] So, let that sink in for just a minute. When we look at cholesterol management, it does get a little bit more complicated. So, we've got about 39 million adults who are not taking statins as indicated by the 2018 clinical guideline for cholesterol management by the American College of Cardiology and the American Heart Association. What that number doesn't include is people who are taken a statin but have not yet achieved their recommended percent LDL [low-density lipoprotein] cholesterol reduction goal. Now, all of these tens of millions of adults that I've just highlighted are floating around at increased risk for having a cardiovascular event. And I want to be clear, like, they may be some of the same people. These are not necessarily mutually exclusive populations. We know many people with chronic conditions have more than one chronic condition. But regardless, these are tens of millions of adults who are at risk for events.

[00:21:47] And the data on the slide really represent a combination problem. And that includes: not having medication initiated, perhaps some therapeutic inertia, lack of medication intensification, wrong medication intensity, and poor medication adherence or persistence. Now, we don't have time to tackle all of those issues today, but let's look at some evidence-based strategies that can help with medication adherence and persistence and possibly therapeutic inertia.

[00:22:20] So, as I started off with, medication adherence is a complicated problem for patients for a whole host of reasons, right, including: cost issues, complex medication regimens, transportation issues that make just getting to a pharmacy difficult, forgetfulness, and not understanding why it's important to take their medications. There's some cultural beliefs that come into play. Or there may just be concerns or misinformation about potential side effects. And each of these challenges has its own potential solutions that I think payers may be well-poised to assist with. So, let's go through a few of these.

[00:23:00] So, no surprise: cost is a big issue for many people, especially those who may be on multiple medications. We've got lots of folks who have multiple chronic conditions, which often warrant multiple medications. So, the CDC-supported Community Preventive Services Task Force (CPSTF) commissioned a systematic review a number of years ago on the impact of reducing or eliminating out-of-pocket costs for anti-hypertensives and statins. And they found strong evidence that reducing or eliminating those out-of-pocket costs improves not only medication adherence but also the result in blood pressure and cholesterol-related outcomes, as well. And that's not really a surprise.

[00:23:46] We all found it very interesting that back in 2020, CMS published a federal registered notice with its VBID blueprint that highlighted high value, underutilized medications and services that qualified health plans were encouraged to cover with no cost sharing. And of, you can see the table on the right inside of the slide, of the 15 high-value medications that CMS called out for zero cost sharing, six are related to cardiovascular disease prevention, including statins and several classes of anti-hypertensives.

[00:24:23] It is important to note that for people at highest risk of having an atherosclerotic cardiovascular disease event, high-intensity statins are indicated - And these are statins that have been shown to be able to lower LDL cholesterol by 50% or more. And there are only two high-intensity statins that exist: Atorvastatin and Rosuvastatin. And in our experience, and it is anecdotal, but what I've heard is that Atorvastatin is often available with no or low out-of-pocket cost by many plans. But it would be really great to have Rosuvastatin available in that same way, as well, so that there are choices that clinicians have for most patients who need a high-intensity statin. So, do think about that.

[00:25:16] The 2017 American Heart Association and American College of Cardiology blood pressure guideline recommended initial combination therapy for most - that is, most people with hypertension should be started on two or more anti-hypertensives. Yet, our surveillance data show us that four out of ten people with hypertension are on monotherapy - so, only one medication. One possible solution is fixed-dose combination pills, where two or more antihypertensive pills are combined, excuse me, where two or more anti-hypertensive medications are combined in one pill. So, there are multiple systematic reviews and metanalyses that have shown fixed-dose combination medications can definitely improve medication adherence, most likely because it just simply reduces pill burden.

[00:26:08] The forest plot - I like saying forest plot; it's fun. The forest plot on this slide is from a meta-analysis that assessed fixed-dose combinations versus their free equivalent combinations. So, that means the medications, if there were two medications in this fixed dose combination pill, then those would have been two separate pills taken in separate pill form - That's a free equivalent combination. And the data from this meta-analysis showed at six and 12 months of follow-up, fixed dose combination pills are much more likely to be associated with medication persistence or long-term adherence. Not totally surprising, but I like to see it.

[00:26:50] As of April 2020, there were 33 FDA-approved anti-hypertensive fixed-dose combination pills available. Now, most of those combinations are of two antihypertensive medications. Only three of the FDA-approved pills are three-medication combinations. So,

hopefully, three-or-more medication combinations or greater will become more readily available through FDA approval in the future. The sprint trial is a really big trial for people who work in hypertension; I'm sure you all have heard of it. Data from this trial suggests that one in three patients will need at least three anti-hypertensives and one in four patients will need at least four antihypertensives to achieve blood pressures of less than 120 over 80 millimeters of mercury.

[00:27:40] And then, interestingly, a study that caught, I know, my eye and some of our colleagues at CDC's eyes in August. Researchers from Australia published findings from the quartet study. That showed ultra-low-dose quadruple combination therapy - so, really low levels of four different anti-hypertensives in one pill was more effective at controlling blood pressure than monotherapy alone. And at both 12 and 52 weeks of follow-up, participants in the intervention group had lower blood pressure and better hypertension control than patients on monotherapy. So, again, I think we're going to see more research in this area and hopefully, a shift in what's been approved by FDA in terms of fixed-dose combination pills.

[00:28:30] So, another strategy that has long been known as a way to improve medication adherence is once-per-day dosing. And this is not rocket science and it's probably not new to any of you on this call. This is just a really easy strategy to help simplify medication regimens, which, again, can be very complex, especially for people with chronic conditions: multiple chronic conditions, multiple pills a day. If you've got to be taking, multiple pills two to three times a day, those can get really complicated. So, we want to try to simplify that as much as possible and once-per-day dosing is definitely an easy way to do that.

[00:29:08] For some people with cardiovascular disease, physically getting to a pharmacy to pick up prescribed medications can be a challenge. This is true for people without ready transportation, as well as for people who live in what I would call a pharmacy desert where they have to travel long distances to try to access a pharmacy. This could be elderly beneficiaries who no longer drive; people with lower incomes who rely on public transportation to get around; people living in rural communities; or, frankly, just single parents who can't easily leave children or take them with them to make a pharmacy trip.

[00:29:49] The pandemic has, of course, just compounded all of this. One way to tackle this challenge is by limiting the number of visits people have to make to a pharmacy by increasing the days supplied per fill. For example, by allowing longer-duration prescriptions, say 90-day versus 30-day fill, you can easily reduce the burden of those monthly refills. And data suggests that this increases medication adherence for a multitude of medications, including statins and anti-hypertensives.

[00:30:21] Another strategy, where the data aren't quite as robust but they're certainly there that can help alleviate, again, that burden of having to access a pharmacy multiple times per month is something called medication synchronization. Now, medication synchronization is simply allowing for all of a beneficiary's medications to be filled at one time. Initially, this may mean that a typical amount of medication that's distributed, you may need more than the typical amount of medication that's normally distributed to allow for those disparate refill rates to be synched. So, if pill A gets filled on this date, I might need 12 extra pills of pill B, 14 extra pills

of pill C, etc. But it would really just be for that first fill until you can synchronize all those refill dates so that only one pickup is needed, whether that's monthly or every three months.

[00:31:20] Another potentially surprising strategy that can help support medication adherence is self-measured blood pressure monitoring. And you heard Abigale mention this earlier. This is also known as home blood pressure monitoring. But self-measured blood pressure monitoring, or SMBP is the measurement of blood pressure by a patient outside of the office, ideally using their own validated automatic upper arm device. So, data aggregations have shown that SMBP can have a small but significant impact on medication adherence. And again, medication adherence challenges are multifaceted and they really warrant a multi-pronged approach. That includes some of the things I've talked about: simplifying medication regimens, lowering associated cost, deploying things like pill reminders, and self-measured blood pressure monitoring.

[00:32:12] So, earlier, I showed you that table of CMS's recommended high-value medications for zero cost-sharing from their suggested VBID blueprint. And it's worth noting that SMBP devices or home blood pressure monitoring devices are also included on their list of recommended high-value services for no cost sharing. I didn't show you that table but they're on there.

[00:32:38] So, obviously, none of the aforementioned strategies work if beneficiaries and their caregivers aren't educated on their availability and purpose. We're hopefully going to have a lot of time for question and answers and some discussion. I would be really interested to hear about ways that you all educate your beneficiaries. I know my family personally has received newsletters of various sorts. We have received offers for incentives to complete things like a personal health assessment, and there's probably lots of other very interesting modes of communication. And I think, when it comes to medication adherence, we need to hit this from public health, from clinicians, from payers, from all sorts of directions to really help support beneficiaries and patients in being able to take their medication regimen as closely as prescribed as possible.

[00:33:48] So, I just quickly like to review a few resources of potential interest. Very interestingly, last week, as the CDC team was tying the final bow on our slides for today, the American Heart Association published a scientific statement specifically on medication adherence and blood pressure control. So, I've included the reference here on this slide. I've also included one of the key tables that highlights evidence-based strategies for improving adherence for various sectors, and you'll see the last column there is health insurers. And I was very happy to see that it was very aligned with the material our team intended to cover. But I think that scientific statement, if you're interested in this topic, is definitely worth reviewing. It's got a lot of great information in there.

[00:34:35] Our Million Hearts team has developed a quality improvement tool called the Hypertension Control Change Package. This is a little bit tangential to the work that you do, but I think there's some real pearls in here that you can use. So, this document offers a menu of evidence-based ways clinical settings can change hypertension care-related processes.

[00:34:59] And it is organized into four focus areas that you see on the slide and the underlined-notes, the sections that contain medication adherence-related tools and resources that you or the clinicians in your networks may find useful. If you have opportunities to be incentivizing clinicians to work on medication adherence, this is a really nice document that can provide tools and resources for them to use to do that.

[00:35:29] I will be available to answer questions at the end of this presentation but please feel free to email me any time, as well. And with that, I will pass you over to my colleague, Nicole Therrien.

Nicole Therrien:
[00:35:44] Thank you, Hilary. Good afternoon, everyone. My name is Nicole Therrien. I'm a Pharmacist Consultant contractor with the Applied Research and Evaluation Branch within the CDC's Division for Heart Disease and Stroke Prevention. I'm excited to be here today to discuss how pharmacists can be engaged in high-impact strategies to improve medication adherence. Pharmacists are well-equipped and highly accessible, making them an ideal partner in efforts to help patients take their medications consistently as prescribed. With an estimated 86% of the U.S. population living within five miles of a community pharmacy, pharmacists are one of the most accessible healthcare professionals in the U.S. Evidence shows that when pharmacists are included on the healthcare team, be it in the community or in traditional clinical settings, medication adherence and chronic disease outcomes improve.

[00:36:41] As you know, there's many causes and no single solution to medication non-adherence. As Hilary mentioned, barriers that prevent patients from taking their medications can be complex and occur at the patient, provider, or health system levels. Personal and cultural beliefs also play a major role in a patient's medication-taking behavior. As one way to address this, in The Community Guide, the Community Preventive Services Taskforce recommends tailored pharmacy-based interventions on the basis of strong evidence of effectiveness in an increasing patient adherence to medications related to cardiovascular disease prevention. These interventions can be delivered by pharmacists in community and health system pharmacies and can increase the number of patients that report taking their medications as prescribed.

[00:37:33] The taskforce found the interventions to be cost-effective in preventing cardiovascular disease in those with cardiovascular disease risk factors, and also found evidence that the averted healthcare costs exceeded the implementation cost for those with existing cardiovascular disease. Tailored pharmacy-based interventions are a group of services and interventions delivered by pharmacists that aim to help patients take their medications as prescribed by understanding the reason for that specific person's non-adherence and tailoring the intervention to the specific patient needs. The interventions include, first, an assessment. This can be either done through interviews or assessment tools by the pharmacist to identify adherence barriers, which means things that get in the way of patients taking their medications as prescribed. The pharmacists then use the results of these assessments to develop and deliver tailored guidance and services that aim to reduce patients' barriers.

[00:38:42] Tailored pharmacy-based interventions can be set in community or health system pharmacies. They may also include additional components like communication between the

pharmacist and a patient's primary care provider or educational materials given to the patient. They can be used alone or as part of a broader intervention intended to reduce the patient's cardiovascular disease risk. Medication therapy management is one strategy used by pharmacists that supports tailored pharmacy-based interventions to improve medication adherence. On the Division for Heart Disease and Stroke Prevention website, you can also find an implementation resource that provides some supporting information on how to implement this intervention that's recommended by the CPSTF in The Community Guide, including a section on economic considerations for different partner perspectives.

[00:39:40] Medication therapy management or MTM encompasses a broad range of professional activities that are used by pharmacists to ensure that their patients are achieving optimal therapeutic outcomes for the medications that they're taking. An important piece of achieving these outcomes is helping patients to achieve appropriate medication adherence. MTM provides a unique and important strategy to integrate pharmacists into patient care, particularly for patients with chronic disease. It could be provided in various settings, including community pharmacies or other community settings, as well as traditional health settings like clinics.

[00:40:22] The core elements of MTM services include medication therapy review, a personal medication record, and medication-related action plan for the patient, as well as an intervention or referral and documentation and follow-up by the pharmacist. You may be most familiar with the Medicare Part D medication therapy management program or the MTMP, which I will touch on next. That is one MTM program model which is often implemented in community pharmacies or by plan sponsor pharmacists. Various studies demonstrate that MTM programs can save thousands of dollars per individual in costs related to healthcare each year. Additionally, research conducted across a variety of payers and patient populations indicate that MTM can be effective in improving clinical outcomes, including medication adherence, reducing blood pressure, and A1C, and reducing the side effects of medications. MTM can be incorporated in team-based care or other coordinated care models that involve pharmacists providing recommendations to prescribers and pharmacists managing medication therapy.

[00:41:39] As you know, the MTMP is designed to ensure that covered drugs in Part D are prescribed to targeted beneficiaries and are appropriately used, and to optimize outcomes through improved medication use. There's some flexibilities in who is eligible to receive MTM services. Eligibility is typically based on patients having a certain number of chronic diseases with sponsors setting the number and which specific chronic diseases to include, patients taking a certain number of medications, and those that are likely to incur the annual cost for covered drugs greater than or equal to a specified threshold for each plan year.

[00:42:24] The scope of MTM services provided by this program includes an annual comprehensive medication review, which is designed to reconcile the medications being taken with what is on record as being prescribed, and then to identify and resolve any medication-related problems. From this review, beneficiaries receive a personal medication list and a medication action plan. Beneficiaries are also eligible to receive a targeted medication review quarterly. This benefit is intended to monitor and optimize the use of a specific medication. MTM providers are expected to document and communicate their actions, interventions, and referrals. Of note, medication non-adherence is a medication-related problem identified and

addressed pretty commonly during CMRs [Comprehensive Medication Review] or TMRs [Targeted Medication Review]. Despite the availability of this program, not all eligible beneficiaries receive the services, and many are unaware that they're eligible for these services. Additionally, since barriers to adherence are complex and may not be fully addressed through program eligibility criteria, some who benefit may not be eligible for the program.

[00:43:45] As I close and hand it back to Haley, I want to highlight that pharmacists are trained to identify and resolve issues related to medications, including barriers that a patient maybe experienced to taking their medications as prescribed, making them an excellent partner in initiatives to improve medication adherence. The Division for Heart Disease and Stroke Prevention has a number of guides that describe the evidence supporting the inclusion of pharmacists in team-based care and provide resources and tools for implementation for different partners. And with that, I'll hand it back to Haley.

Haley Stolp:
[00:44:20] Thank you, Nicole. My name's Haley Stolp. I'm a contracted Public Health Analyst on the Million Hearts team for the Division of Heart Disease and Stroke Prevention at CDC. I'll be moderating our Q&A portion, but first I wanted to take a moment to highlight a few additional resources. You heard about the Hypertension Control Change Package, a valuable resource with change ideas and tools. I hope you all check that out. Additional resources specific for medication adherence is our Million Hearts Medication Adherence Webpage. There's a Cardiovascular Health Medication Adherence Action Steps for Health Benefit Managers resource and a webpage, Tailored Pharmacy-Based Interventions to Improve Medication Adherence that's also in the chat, so feel free to explore those resources.

[00:45:00] They also have a Million Hearts Learning Lab. This is in partnership with the colleagues at National Association of Community Health Centers and the American Medical Association that offers CME-accredited trainings on cardiovascular disease prevention. I'll put the link in the chat for folks that might want to join. It is a clinician-focused training session. And the one that we have highlighted here is the one most recently from cholesterol management and statin use. There's also a cholesterol management Million Hearts webpage. And then, finally, another resource is the February 2017 - a bit old but still very much relevant that will help amplify some of the key strategies we shared in today's presentation from the CDC Public Health Grand Rounds.

[00:45:39] So, we do have a couple questions in the Q&A box. And we're going to go ahead and get into the Q&A. So, I'll ask our panelists to please put themselves on video. And the first question we have is for Dr. Sperling.

LS:
[00:46:02] I think I see the one you're referring to. Is that the great study information about statin adherence?

HS:
[00:46:07] It is, yes, please.

LS:
[00:46:09] Yeah, there's a question about great study information about statin adherence is there a level of adherence that serves as a break point for improvement in outcomes? So, first of all, really important question. I think here it's relevant. And Hilary had mentioned high-intensity statins. You know, this is taking a little bit of a deeper dive but the two high-intensity statins, one of the advantages of them, besides that they're the most potent statins is they both have the longest half-life. And so, if you were to miss a dose, these medications likely would still be effective.

[00:46:59] Now, there are usages of statins in some individuals who have statin-associated muscle symptoms or statin-associated side effects. These would not be, FDA [Food and Drug Administration]-approved. But using them every other day, for instance, and getting significant benefit. Now, there is no randomized control clinical data to support that use but that's one of the other benefits of high-intensity statins. I'll give you a clinical pearl: just a very simple question that I ask my patients when I see that their LDL cholesterol, for instance, isn't where it should be, taking a high-intensity statin, just how many times a week or month do you miss taking your cholesterol medication? And if you start asking that question, you will get unbelievable answers that - it's also a lot of insight to what's happening on the ground.

[00:47:57] Now, I will mention we talked today about medication adherence and strategies to improve medication adherence. On the flip side of the coin is therapeutic inertia. And so, our clinicians, must think about optimizing care and optimizing therapy at each and every clinical encounter. And Hilary and Nicole, mentioned some of those strategies that we should be thinking about from a partnered-care situation. So, with that, I know there are other questions and comments. Thanks, Haley.

HS:
[00:48:37] Great, thank you. Another question from the chat, a bit out of context, but, oh, I think this is for Hilary regarding self-measured blood pressure monitoring. Is the data showing home deliveries more prevalent? And if that person that asked the question cares to put their audio on and – there might be a little more clarification. But the question, again: is the data showing home delivery is more prevalent?

HW:
[00:49:00] I think they mean pharmacy medication home delivery.

HS:
[00:49:05] Gotcha, okay.

HW:
[00:49:07] So, I don't know that I have seen studies looking at that. But we can try to see if we can dig that up and get back to you. I don't know if - Nicole, you're nodding your head. Do you know the answer?

NT:

[00:49:26] We don't have specific numbers, but I'm thinking there is a pretty recent article that's looking at home delivery and adherence. It's positively correlated with people who received home delivery services had better adherence.

HW:
[00:49:47] I mean, it makes sense, for sure. I mean, if you think about some of those things I laid out: people not being able to get to pharmacies, the longer - a lot of those mail-order meds or 90-day supplies, like, all of those things clearly contribute to getting those evidence-based strategies in place. So, that makes a lot of sense to me.

NT:
[00:50:09] Yes, and I think it can be home delivery through mail order sort of situations as well as pharmacies, community pharmacies that offer delivery services.

HS:
[00:50:25] Another question, I think, for you, Nicole: what is the role of a pharmacy benefit manager in medical adherence?

NT:
[00:50:33] I think it can have varied roles. Some of the tailored pharmacy-based intervention studies, they take place with a pharmacist - it was the minority of the studies. But a pharmacist in a PBM office, there's definitely a role in providing the services, though sometimes there can be some additional benefits to the services being provided by a community pharmacy where the patient may be more familiar with the person delivering the service. But that may not be possible for all situations.

HS:
[00:51:18] Great, thank you. A question for Abigale: challenge with incentives, is it managed care plans, there are limits and restrictions for incentives? Any comments on the challenges and incentives work with managed care plans, for the VBID model?

AS:
[00:51:36] Yes. So, under the VBID model, some plans are allowed to offer both Part C and Part D RI [Rewards and Incentives]. So, Part D RI can be focused on something like completion of medication therapy management consultation, or something of that nature. But then, even in the Part C RI, the programs that are allowed under the VBID model are a little bit more expensive than are allowed in the Part C program because the reward that's given can reflect a value that is based on the benefit of the service rather than just the cost of the service, and that can be up to $600 annually per enrollee. So, there's really a big opportunity in the VBID model to kind of address those incentives, yes.

HS:
[00:52:24] Great, thank you. A question for the group at large: are there certain interventions that are most impactful to improve medical adherence, e.g., pharmacist counsel, text messaging, refill reminder calls, I think a prioritization of those that would be most impactful?

HW:
[00:52:40] You know, I was trying to think. I saw that question come in and I was trying to think if I've seen a comparative effectiveness review - that would really tell us because it would pit the interventions against each other to really see which were most effective. So, I don't know that I've seen that. And truthfully, I think we really need to take a combination approach, because it's not like patients have one barrier that they need help overcoming. So, I think we all need to think of this as what collective group of solutions could be deployed to help all patients with medication adherence. Larry, I see you were going to add something.

LS:
[00:53:16] And I was going to add on about the combination approach because another question here said there's a lot of emphasis on medication: I noted obesity was not mentioned as a driver for disease. And essentially, here, our focus of this webinar, specifically, was on medication adherence and, strategies to impact that from a healthcare team and health system approach using VBID-type implementation. Now, when we think about combination therapy, clearly combination therapy is not just combinations of medications. The foundation for cardiovascular disease prevention is, for all, a lifestyle and behavioral approach. So, we should always use that in combination with appropriate medical strategies. And then, for obesity, we need population health approaches, as well, to address that from an upstream perspective.

HW:
[00:54:22] And also, Larry, we talked about self-measured blood pressure monitoring. While, yes, there's some evidence that it supports medication adherence, there is good evidence that it supports lowering of blood pressure and hypertension control. So, I totally agree with you - I think that's an excellent comment.

[00:54:39] And Haley, I see one question - I'm taking liberties here. There was a question about did we find that COVID-19 impacted patents' adherence? I think maybe anecdotally we can have Larry talk about that? I know the surveillance data I don't think are in yet to help us answer that specific question but anecdotally, I would imagine that we have seen that across the board; Larry, do you have specific experience?

LS:
[00:55:05] Yeah, so certainly my own experiences, absolutely. There have been huge gaps in care, as all of you are quite aware, from wherever you sit in the delivery of healthcare right now. Huge gaps in care. Many people not seeing their clinicians or clinical teams for two years or more. Nicole highlighted something really important: 86% of the U.S. population lives within five miles of a pharmacy. And really, if you said early on during the pandemic, people who were sequestered, the only places they would, wander out of their home for was a pharmacy or sometimes a grocery store. We also have to recognize, the measurement, for instance, of blood pressure and measurement of cholesterol has suffered greatly, even though there's been adaptive

responses to telehealth and telemedicine - So, a lot of holes in care. Hard to manage blood pressure and treat cholesterol problems when you don't even know what those values are.

NT:
[00:56:13] I will add that, like Larry said, pharmacies did continue to be open, and people did often continue to go to them. An interesting thing that some found specific to some of the Part D MTMP: in 2020, some plans found that there were higher completion rates of those services than in other years and kind of thought about how folks maybe weren't able to see their providers. So, they were more interested in speaking to someone in the ways that still were available. So, I think there's complexity here depending on how people get their medications. But if they were able to have an active prescription for their medication, and were able to get to the pharmacy, many pharmacies were still open and accessible capacities.

HS:
[00:57:15] And I see a question for the VBID team: is the health and wellness care planning a requirement for this model? And Sibel, you might be on to answer that one.

SO:
[00:57:27] Yeah, no, that's a great question. So, that's right. MAOs that apply to participate in the VBID model must have a strategy around the delivery of wellness and healthcare planning or what we call WHP services, including advanced care planning services [ACP] to all enrollees. And examples vary depending on the plan and their membership and their relationship with providers. So, we have plans meeting this requirement, doing activities such as working with providers, incentivizing providers to educate around WHP and ACP, advanced care planning, focusing on members and member initiatives and communicating the evidence base around WHP and getting the word out about advanced care planning within their evidence of coverage, and other outreach and education opportunities. So, it really does vary depending on the plan. So, for the model itself, you only need to include what your strategy is around the delivery of WHP services, really get the word out, and educate your membership and providers, for example, about advanced care planning.

HS:
[00:58:37] Thank you. I'll encourage our panelists to have other comments in the Q&A or with the chat. But looking at the time, I'll pass it back to Abigale Sanft to close us out. Thank you.

AS:
[00:58:48] Yeah, thank you, Haley, and thank you, everyone for taking the time to answer these questions. It's been a really great dialogue. So, I know we're reaching the end of our time but as we're moving through the fall and winter, we hope you'll continue to stay engaged with us and reach out with any questions or to discuss ideas for future VBID interventions. You can reach the CMMI VBID model team at VBID@cms.hhs.gov and we would be really happy to brainstorm with you in the cardiovascular disease space or otherwise.

[00:59:25] We did have one additional ask for all of you today and that is: would you be able to take a moment to complete the brief five-question survey following this event? It should take no more than a minute or two, and it will really help us offer additional VBID-focused content that

meets your needs moving forward. We'll also be reviewing the responses to identify topics for future webinars. I want to close by thanking the Million Hearts team for their continued collaboration and providing all of this incredible, detailed information and sharing it all with you today. I want to thank the VBID model team, especially our director, Jason Petroski and the co-model leads, Sibel Ozcelik and Sheila Hanley, as well as our wonderful intern, Michael DeLaGuardia for all of their hard work in bringing this webinar together. And finally, thank you to all of you for joining us today. We look forward to working with you to implement strategies to even more effectively address cardiovascular disease moving forward. Thank you again.