



Answers to Questions for the Record Following a Hearing by the House Committee on the Budget on CBO's Estimates of the Budgetary Effects of the Center for Medicare & Medicaid Innovation

On September 7, 2016, the House Committee on the Budget convened a hearing at which Mark Hadley, Deputy Director of the Congressional Budget Office, testified about CBO's estimates of the budgetary effects of the Center for Medicare & Medicaid Innovation's activities. After the hearing, Chairman Price and other Members of the Committee submitted questions for the record. This document provides CBO's answers.

Chairman Price

Question. How often does the Congressional Budget Office (CBO) communicate with the Center for Medicare & Medicaid Innovation (CMMI) about the status of model tests? Do these conversations include regular updates of model savings estimates? What kind of information does CBO receive from CMMI on their work plan to inform scoring of legislative proposals? Is this information also available to Congress on a routine basis? If not, how is it possible for Congress to develop effective legislative proposals outside of areas where CMMI is planning demonstrations? How does CBO consider the likelihood that CMMI's work plan could change, for example, under a new administration?

Answer. CBO relies primarily on information obtained from CMMI's website to monitor the status of demonstrations. The center's website describes the basic features of demonstrations that are under way or that have been announced and gives an update on the status of each. CBO pays particular attention to evaluation reports, which are typically prepared by independent contractors and contain estimates of federal savings. Evaluation reports are not yet available for many demonstrations, however, and results from those that are available reflect only the early experiences of some demonstrations. CBO's ability to monitor CMMI's activities in the future will depend on how much information the center releases about demonstration evaluations and how quickly that information is released. Conversations with CMMI staff concerning the status of particular demonstrations occur infrequently.

CMMI does not share detailed information about its future plans with CBO. To monitor CMMI's plans for future demonstrations, CBO routinely gathers information from publicly available sources such as CMMI's Requests for Information—in which the center solicits input from providers and other stakeholders about the design of demonstrations under consideration—as well as from public statements and presentations by Administration officials. CBO also engages in conversations with staff at CMMI and various stakeholders.

CBO's projection of the budgetary effects of CMMI's activities incorporates the judgment that future Administrations will continue to use the authority granted to CMMI and the Secretary of Health and Human Services under current law. That judgment is shared by most experts whom CBO has consulted, including former Medicare officials serving under Presidents from both political parties. CBO expects the types of demonstrations to change under new Administrations—perhaps dramatically—but it has no basis for assessing whether those different demonstrations would be more or less effective in reducing federal spending. As discussed in the testimony, CBO's projection of the budgetary effects of CMMI's activities is based primarily on judgments about the effectiveness of CMMI's process for conducting demonstrations, not on judgments about the expected results of particular demonstrations.¹

Question. Given that CBO monitors the entire CMMI process, what is the total amount of the \$10 billion appropriation that CMMI has spent to date? What is the amount of total savings that have been achieved to date through the CMMI initiatives?

Answer. Of the \$10 billion provided to CMMI for fiscal years 2011 through 2019, the center has spent about \$4 billion to date on developing, conducting, and evaluating demonstrations. However, it is not possible to determine the total amount of savings that CMMI's initiatives have achieved thus far. Numerous demonstrations are under way and have been in operation for varying lengths of time, and evaluations that include estimated budgetary effects are not yet available for many of them. Results from those evaluations that are available reflect only early experiences of the demonstrations. CBO is therefore unable to assess the accuracy of its projections of the effects of the center's activities on federal spending to date.

CBO will continue monitoring CMMI's activities to learn more about its operations, including its approaches to selecting and testing, evaluating, and expanding demonstration projects. That information will help CBO improve its budget projections. However, unlike CMMI's spending—which is readily observed—reductions in spending on Medicare benefits generated by CMMI's activities will never be observed; instead, those reductions will always be estimated in relation to what overall Medicare spending would have been if CMMI had never been established.

Question. The last full 10-year, year-by-year estimate of CMMI provided by CBO was included in an estimate of the Affordable Care Act and estimated total savings of \$1.3 billion over the 2011–2019 period. In its 2015 blog post, CBO estimated \$27 billion in savings by 2026. Now, CBO estimates \$34 billion in savings by 2026. Please describe in detail the specific CMMI actions that have led CBO to increase its estimate. Which CMMI models does CBO anticipate will account for these savings?

Answer. The three estimates of federal savings that CBO expects will be generated by CMMI's activities differ from one another mostly because different 10-year projection periods were used for each estimate. To a small extent, the estimates differ because the trajectory of CMMI's spending has deviated somewhat from CBO's original projections. In 2010, the agency estimated that CMMI's activities would reduce federal spending by \$1.3 billion from

1. Testimony of Mark Hadley, Deputy Director, Congressional Budget Office, *CBO's Estimates of the Budgetary Effects of the Center for Medicare & Medicaid Innovation* (September 7, 2016), www.cbo.gov/publication/51921.

2010 through 2019.² CBO expected CMMI's activities in its initial years to be devoted largely to the development and design of demonstrations, resulting in an increase in federal spending through 2015. CBO currently estimates that CMMI's activities will reduce federal spending by \$34 billion from 2017 through 2026. CBO projects that CMMI's activities will reduce federal spending for the following reason: After enough demonstrations are implemented, their savings are expected to more than offset the costs of their operation. Both CBO's 2010 estimate and its 2016 baseline showed total federal savings of less than \$500 million for 2017, about \$1 billion in 2018, and about \$1 billion in 2019. For later years, CBO projects that savings will be larger, reaching \$7 billion in 2026 (see Table 2 in the testimony).

CBO's current estimate indicates that CMMI's activities will reduce federal spending by \$34 billion from 2017 through 2026. That estimate is higher than the corresponding 10-year estimate of \$27 billion provided in the agency's 2015 blog post, mostly because the earlier estimate was for a slightly earlier period (2016 through 2025).³ Compared with the estimate in CBO's blog post, the calculations for the agency's current estimate dropped a year (2016) with estimated federal savings of less than \$500 million and added a year (2026) with estimated federal savings of \$7 billion.

CBO's 10-year projections of the federal savings generated by CMMI's activities are not based on judgments about the expected results of particular demonstrations, but instead are based primarily on judgments about the effectiveness of CMMI's process for conducting demonstrations. (CBO's approach to estimating the budgetary effects of CMMI's activities is described in detail below.)

Question. In the blog post, it states that "CBO examines any legislative proposals that seek to enact approaches similar to ones that CMMI is testing, to determine whether HHS would do something different under the proposal from what it would do under current law. That analysis involves some judgment, which CBO must apply on a case-by-case basis. To the extent that legislative proposals overlap with initiatives that CMMI is undertaking (or is expected to undertake), the potential for additional savings is reduced. And if those proposals would delay implementation of promising initiatives or limit CMMI's flexibility, they could increase federal costs."

- How does CBO come to such a determination for a particular proposal? Does a back and forth take place between CBO and CMMI or the Office of the Chief Actuary? If not, how then can CBO determine the scope of work CMMI intends to undertake?
- If CMMI indicates it will pursue a model, but not in the near term and yet the Congress puts forward a legislative proposal to pursue a demonstration with similar scope, how does CBO judge the legislative proposal?
- How does CBO score legislative proposals to delay or prohibit demonstrations proposed by CMMI? Is the impact different for voluntary versus mandatory demonstrations?

2. Congressional Budget Office, letter to the Honorable Nancy Pelosi providing an estimate of the direct spending and revenue effects of an amendment in the nature of a substitute to H.R. 4872, the Reconciliation Act of 2010 (Final Health Care Legislation) (March 20, 2010), Table 5, www.cbo.gov/publication/21351.

3. Congressional Budget Office, "Estimating the Budgetary Effects of Legislation Involving the Center for Medicare & Medicaid Innovation," *CBO Blog* (July 30, 2015), www.cbo.gov/publication/50692.

- Is it correct that CBO may attribute savings to legislation implementing demos and models if CMMI is not pursuing work in that area?
- If so, how is that intellectually consistent over time, since CMMI's funded priorities will evolve?

Answer. CBO relies primarily on information obtained from CMMI's website to identify demonstrations that are under way or have been announced. The center's website describes the basic features of demonstrations and gives updates on the status of each one. As noted above, CBO monitors CMMI's plans for future demonstrations by routinely gathering information from publicly available sources, including CMMI's Requests for Information and statements and presentations by Administration officials, and by engaging in conversations with staff at CMMI and various stakeholders.

In assessing the degree of overlap between a legislative proposal and CMMI's activities, CBO accounts for how much interest the center has shown in testing similar approaches—either in terms of the tools that would be used or in terms of the opportunities for savings that would be targeted. An example of tools would be the management of prescriptions before a hospital discharge, and an example of opportunities targeted for savings would be avoiding hospital readmissions. CBO looks at both tools and targets because, even though multiple tools may address the same problem, the resulting savings can often be realized only once. For instance, many approaches may try to reduce hospital readmissions, but a given readmission can be avoided only one time. If a proposal required CMMI to conduct a demonstration that aimed to reduce hospital readmissions, CBO would have to determine whether other demonstrations were already trying to achieve that goal and, if so, the chances that the resulting savings were already accounted for in the agency's baseline projections.

To evaluate the budgetary effects of a legislative proposal for a demonstration that is similar to a project that CMMI intends to test, but not in the near term, CBO would determine whether it has enough information to estimate the effects of that demonstration. CBO would also consider the amount of overlap between the proposed demonstration and ongoing CMMI demonstrations with respect to the tools that would be used and the opportunities for savings that are targeted. If, after accounting for those potential overlaps, CBO expected the proposed demonstration to reduce federal spending, on average, a legislative proposal that implemented the demonstration faster than CMMI had planned would, in CBO's estimation, reduce spending because the proposal would enable the government to achieve the savings sooner than it would otherwise.

A similar consideration applies to legislative proposals for demonstrations in areas that CMMI has expressed no intention to pursue. If, after accounting for overlaps with ongoing demonstrations in terms of tools and targets for savings, CBO determines that such a demonstration is expected to reduce spending, on average, a legislative proposal to implement that project would achieve federal savings, in CBO's assessment. Although the particular demonstration might be conducted by CMMI under a future Administration, a proposal to conduct it sooner would enable the government to achieve the expected savings sooner.

When asked to estimate the cost of a legislative proposal that would prohibit or delay a specific demonstration project, CBO assesses how much is known about the potential budgetary effects of that demonstration. For most demonstrations that have not yet been tested, CBO has no basis for judging how conducting or preventing that particular

demonstration would change spending. However, because CBO expects that CMMI's overall process of testing, evaluating, and expanding demonstrations will produce savings, on average, proposals that prevent demonstrations from occurring would tend to reduce those average savings and thus increase spending. Similarly, proposals that would postpone demonstrations would reduce savings by causing CMMI's process to be delayed and somewhat disrupted. When CBO does have a basis for estimating how a specific project would affect federal spending, the agency incorporates that information into its estimate.

In general, the effect of prohibiting or delaying a particular demonstration project does not depend on whether it is mandatory or voluntary. However, in CBO's judgment, legislation that prevented CMMI from conducting any mandatory demonstrations would substantially reduce savings from CMMI's activities, on average. As discussed in response to another question below, CBO believes that mandatory participation is an important tool that enhances CMMI's ability to identify approaches that would achieve federal savings because that tool generally results in a stronger research design for evaluating the effects of demonstrations.

Question. CBO lists several reasons for concluding CMMI will generate such effective demonstrations. What is the correlating budgetary impact for each?

- The ACA provided dedicated resources for CMMI (\$10 billion for fiscal years 2011–2019 and an additional \$10 billion for each subsequent decade).
- It created a mechanism to solicit, screen, and develop ideas for new models to be tested that is much broader and more rigorous than the development process that existed under prior law.
- It gave priority to designing demonstration projects that could be scientifically evaluated using appropriate research methods, including requirements for sample sizes large enough to allow statistical analysis.
- It gave the Secretary of HHS broad authority to modify and refine the models being tested midstream.
- It created an incentive for the Secretary to end unsuccessful models by supplying a finite amount of funds to develop and test models (\$10 billion every 10 years).
- Finally—and most important for CBO's conclusion—the legislation authorized the Secretary to expand models that proved successful.

Answer. A substantial share of the budgetary savings that CBO projects for CMMI's activities is attributable to the expansion of successful models that are expected to reduce federal spending while maintaining or improving quality of care. The Secretary also has the authority to expand models that are expected to improve quality without increasing federal spending, but on balance CBO anticipates that the expansion of those models would have no effect on federal spending. CBO expects that only a small share of the demonstrations tested by CMMI will generate savings, most will have little or no effect on federal spending, and some will increase federal spending. CBO also anticipates that demonstrations that succeed will operate for four to seven years, on average, before HHS decides whether to expand them and that demonstrations that do not succeed will operate for two to five years, on average, before HHS

cancel them. A small share of the budgetary savings that CBO projects for CMMI stems from the continued testing of successful models and the cancellation of unsuccessful models. However, the bulk of the projected savings stems from the expansion of successful models.

In CBO's judgment, the other major aspects of CMMI's process for conducting demonstrations, outlined in the question above, increase the likelihood of finding approaches that achieve federal savings. CBO has not quantified the budgetary effect of each of those aspects of CMMI's process, however.

Question. CMS had the authority to conduct demonstrations prior to the creation of CMMI. How is the new authority different than previous authority that produces the magnitude of savings in CMMI?

Answer. Before CMMI was created, demonstration projects to test new ways to deliver and pay for health care for Medicare beneficiaries were either initiated by the Department of Health and Human Services (acting under its statutory authority) or mandated by legislation. In several ways, the process through which demonstrations were developed and implemented hampered HHS's ability to identify approaches that would reduce spending. Many demonstrations were mandated by legislation, which limited HHS's ability to modify them on the basis of early experience or to terminate them if they proved unsuccessful. In some cases, the legislation imposed constraints on HHS involving the geographic areas or providers that could be included, which did not necessarily improve the chances of identifying successful approaches. HHS also generally lacked the authority to expand demonstrations if they were successful. In addition, funding constraints limited HHS's ability to develop and test demonstrations, according to the Medicare Payment Advisory Commission. Finally, some demonstrations were designed in a way that did not allow robust evaluation—so even in cases in which a demonstration might have achieved savings, it was impossible to attribute those savings to the demonstration.

In CBO's judgment, several aspects of CMMI's process for conducting demonstrations increase the likelihood of finding approaches that achieve federal savings. (That assessment is primarily based on judgments about the effectiveness of the process, not on judgments about the expected results of particular demonstrations.) Those aspects of the process include the following:

- Current law specifies a robust mechanism for CMMI to solicit, screen, and develop new ideas to be tested.
- CMMI prioritizes demonstrations that can be empirically evaluated by means of appropriate data sources, adequate sample sizes, and other rigorous research methods—including valid methods of estimating outcomes in relation to what they would have been in the absence of the demonstration.
- CMMI may modify demonstrations on the basis of early experience to improve the chances of implementing a project in a way that achieves savings.
- The set amount of funds to develop and test demonstrations that is supplied under current law creates an incentive to end unsuccessful demonstrations and redirect funds to other demonstrations.

- The Secretary of Health and Human Services has the authority to expand a demonstration if doing so is expected either to decrease spending without harming quality or to improve quality without increasing spending. Medicare's Chief Actuary must certify the expected effects on spending before the expansion may proceed.

Question. The authority to expand successful models is deemed the most important factor related to CMMI's potential for savings. In more than five years of operation, however, the Secretary has not used the authority to expand a model operated through CMMI. Was this outcome expected? How many models does CBO assume will be deemed successful, eligible for expansion, and actually expanded? How does this impact CBO's baseline for CMMI? If so, how are the savings achieved?

Answer. The Secretary of Health and Human Services has announced plans to expand the Diabetes Prevention Program, which began in 2013 and tries to prevent or delay diabetes among high-risk beneficiaries by encouraging healthier lifestyles. That decision followed a certification by Medicare's Chief Actuary that expanding the demonstration would not increase Medicare spending and a determination by the Secretary that expansion would improve the quality of care. The fact that the Secretary has proposed expanding only one demonstration to date is not inconsistent with CBO's projections. CBO expects that demonstrations deemed successful will operate for four to seven years, on average, before HHS decides whether to expand them. That period of time is generally necessary to conduct a rigorous evaluation using medical claims data to estimate federal savings. CBO will continue to monitor all aspects of CMMI's activities, including decisions by HHS about whether or not to expand some demonstrations and the projected savings from those that are expanded.

CBO does not estimate the number of CMMI models that will be considered successful or the number that will be expanded. CBO anticipates that HHS will expand some models that are expected to reduce federal spending while maintaining or improving quality and other models that are expected to improve quality without increasing spending. However, on the basis of the experience of demonstrations that were conducted before CMMI was established, CBO expects that most models tested by CMMI will not achieve savings. Because the number and scale of new CMMI demonstrations are likely to vary from year to year, CBO's budget projections are based on an estimate of the federal savings that will be achieved from the set of demonstrations that begin each year, not on an estimate of the number of those demonstrations that will be expanded. Specifically, CBO estimates that the total effect of a set of demonstrations started in a given year will be an eventual reduction in gross spending for Part A and Part B Medicare benefits of about 0.1 percent each year, on average. That estimate is based on CBO's assessment of the effects of prior demonstrations that have reduced Medicare spending. For example, the set of demonstrations begun this fiscal year are expected to reduce spending by a total of about \$1 billion in 2026; for each year's set, the percentage reduction in spending could be higher or lower, but unexpectedly high amounts from some sets are anticipated to offset unexpectedly low amounts from others.

Question. CMMI has now operated for nearly six years and has launched over 45 distinct models. Please explain the experience with these demonstrations and how they relate to CBO's estimates of CMMI's savings impact going forward.

Answer. CBO is actively monitoring the demonstrations being conducted by CMMI but does not believe that the information gathered to date provides a basis for assessing the accuracy of the agency's budget projections. The evaluations of the demonstrations are in various stages.

For some demonstrations, no evaluation results have been released, and for many others, results are available for only the initial year of the demonstration. Those initial results are not generally sufficient for drawing conclusions about the likely success of the models being tested.

The savings that CBO expects to result from CMMI's activities would stem largely from the expansion of successful demonstrations. However, CBO anticipates that demonstrations that succeed will operate for four to seven years, on average, before HHS decides whether to expand them. Over the next several years, CBO expects to learn much more about CMMI's activities and will use that information to improve its budget projections. As discussed in the testimony, CBO will continue monitoring all aspects of CMMI's activities, including its approach to selecting, testing, and evaluating demonstrations. CBO will pay particular attention to evaluation reports that are released and decisions by HHS about whether or not to expand some demonstrations—and the projected savings from those that are expanded.

Question. CMMI may only expand demonstrations that maintain or improve quality of care. How does CBO build this into estimates of CMMI savings? Does CBO consider the possibility that a demonstration will be terminated because even though it saves money, it lowers quality of care? How does this impact CBO's estimates of individual CMMI proposals?

Answer. The law that established CMMI specifies that the Secretary of Health and Human Services may expand demonstrations under the following circumstances: when they are expected to decrease federal spending while maintaining or improving quality of care or when they are expected to improve quality without increasing spending. As described in the response to a previous question, CBO's approach to projecting the budgetary effects of CMMI's activities does not involve predicting the outcomes of particular demonstrations or predicting the number of demonstrations that will be expanded. Instead, CBO's projections are based on an estimate of the percentage reduction in federal spending that will be achieved, on average, from the set of demonstrations that begin each year. That projected reduction in federal spending comes mainly from the expansion of demonstrations that save money—which CBO expects will represent a small share of the demonstrations conducted by CMMI. In making those determinations, CBO accounts for the chances that demonstrations that lower the quality of care will not be expanded.

Question. One of the requirements for expansion of a demonstration is certification by the CMS Chief Actuary to certify that a demonstration will either decrease spending or at least maintain current spending levels. Do CBO and the Office of the Chief Actuary use the same information to determine their baselines? What certainty can Congress have that CBO and the Office of the Chief Actuary are likely to estimate similar levels of savings for a model? If the Chief Actuary were to certify a model as cost-saving, and thus it were expanded, is it possible that CBO would find that the same model is cost-increasing? How should Congress consider such disagreements?

Answer. Determining the effects on federal spending of expanding demonstration projects is challenging, and such analyses are often subject to considerable uncertainty. CBO expects that, in making decisions about whether to certify that certain models would not increase spending if expanded, the Office of the Actuary will base its determinations on a combination of the following: the findings of demonstration evaluations, the findings of prior research, and its own analysis. CBO will use the same sources of information as the Chief Actuary in assessing the likely effects of expanding demonstrations. However, it is possible that the two

organizations will disagree about the reliability of the evaluation findings for particular demonstrations. CBO will use its own judgment about the conclusions that should be drawn from demonstration evaluations and will use that judgment in assessing and updating its budget projections. Policymakers considering the effects of demonstrations receive information from a variety of sources. CBO works hard to make its analysis transparent so that policymakers can understand the basis for the agency's findings—enabling them to compare those findings to other information.

Question. In its initial 2010 savings estimate of CMMI, did CBO assume that CMMI would perform mandatory demonstrations? What portion of CMMI savings come from mandatory demonstrations?

Answer. In its initial budget projections for CMMI, CBO assumed that the center would conduct demonstrations using a broad array of innovative approaches to the delivery of and payment for health care. CBO was not surprised when CMMI designed a demonstration in which participation was mandatory because that approach offers several important advantages (which were discussed in the testimony). Moreover, the Centers for Medicare & Medicaid Services (CMS) had conducted at least one previous demonstration—involving competitive bidding for durable medical equipment—in which participation was mandatory. All suppliers in two metropolitan areas who wished to furnish durable medical equipment to Medicare beneficiaries were required to receive payment from Medicare under the competitive bidding system that was being tested. In its budget projections, CBO did not identify a specified portion of the savings that would come from mandatory demonstrations.

Question. If Congress were to limit CMMI's ability to pursue mandatory models through legislation that specifically limited the Secretary's authority to include only voluntary participation in demonstrations, what would be the effect on the CMMI baseline?

Answer. In CBO's judgment, legislation that prevented CMMI from conducting demonstrations that required certain beneficiaries or providers to participate would substantially reduce the savings from CMMI's activities. The amount of the reduction in savings would depend on the details of the legislative proposal. CBO believes that mandatory participation is an important tool that helps CMMI identify approaches that achieve federal savings. Prohibiting CMMI from using that tool would lessen its ability to determine the actual effects of many of the models being tested. Such a prohibition would increase the risk that some models that appeared successful in the testing phase might not achieve savings—and might even increase spending—if expanded. It would also increase the risk that CMMI might fail to identify and expand some models that would be successful if implemented on a broader scale.

Evaluating the effects of a demonstration on Medicare spending, for instance, requires using valid methods of estimating what spending would have been in the absence of the demonstration. Such estimates require comparing spending for two similar groups of beneficiaries—one that experiences a new model of health care under the demonstration and one that does not. When participation by health care providers or beneficiaries is voluntary, they are often able to determine how a demonstration might affect them before deciding whether or not to participate. Consequently, analysts must determine whether those who opted to participate are similar enough to the others to make comparisons between the two groups yield reliable estimates of the demonstration's effects.

If participation is voluntary, one way to compare outcomes is to assign participants randomly either to a treatment group (which experiences a new model for health care) or to a control group (which does not). Because participants in the two groups are expected to be similar, analysts can compare their outcomes. A less powerful approach is to use statistical methods to compare the outcomes of beneficiaries who choose to participate with the outcomes of those who choose not to—but again, it can be hard to draw valid conclusions if the two groups are substantially different.

An approach that is more powerful than either of those is to require some beneficiaries or providers to participate in the demonstration and to compare their outcomes with those of similar beneficiaries or providers who were excluded. That approach, which CMMI has used, is very effective at determining whether a demonstration reduced spending and, if it did, how it could be expanded to a larger group that the participating population is representative of. (In contrast, those who participate voluntarily in demonstrations are generally not representative of larger groups, and voluntary demonstrations are therefore less useful in predicting effects on spending and identifying challenges in implementation.) According to most of the experts that CBO consulted, requiring participation in demonstrations helps CMMI conduct rigorous evaluations that are capable of identifying successful approaches.

Question. In the updated estimate of CMMI provided in the written testimony, it states that the program is anticipated to achieve net savings of \$34 billion over the 2017–2026 period, up from \$27 billion over the 2016–2025 period. Are savings anticipated to continue to grow at the current pace in future decades?

Answer. Next year, CBO’s baseline projection—covering the 2018–2027 period—will exclude an early year in CMMI’s development (2017) and add a year by which more demonstrations will be completed (2027). That change in the period analyzed will tend to increase projected savings. However, CBO has not developed projections for the budgetary effects of CMMI’s activities beyond 2026, and other factors affect the projections. CBO’s assessment of those budgetary effects involves judgments that are inherently uncertain. Over the next several years, CBO expects to learn much more about CMMI’s activities and will use that information to improve its budget projections. CBO will pay particular attention to estimates of federal savings presented in newly released evaluation reports and to decisions by HHS about whether or not to expand demonstrations. CBO expects that HHS will expand some demonstrations that are expected to reduce federal spending while maintaining or improving quality and others that are expected to improve quality without increasing federal spending. The projected savings from demonstrations that are expanded will therefore be of particular interest to CBO in assessing its budget projections. CBO will also continue monitoring all aspects of CMMI’s activities, including its approach to selecting, testing, and evaluating demonstrations.

Question. In the case of the Part B demonstration proposed by CMMI, the evidence shows that this will likely lead to further consolidation among providers and serve to increase costs as patients move from a clinical to a hospital setting to receive cancer care, specifically chemotherapy. One study said this phenomenon, which is already occurring due to other factors, cost the Medicare program \$2 billion in 2014 alone. Does CBO take into account this real world economic impact that occurs as a result of mandatory demonstrations like the Part B demonstration?

Answer. In evaluating the effects of such proposals, CBO strives to account for such responses by market participants to the fullest extent possible. To inform its judgment about such responses, CBO reviews available research and other relevant information and engages in discussions with experts in the field. As for the specific issue of the consolidation of physicians' practices with hospitals, that development has increased Medicare spending because Medicare pays the same amount for services delivered in a hospital-owned physician's practice as it pays for services provided in the hospital's outpatient department; those payment rates are higher than the amounts paid for services delivered in an independent physician's practice. However, a provision of the Bipartisan Budget Act of 2015 (Public Law 114-74) eliminated that disparity for physicians' practices acquired by hospitals after the legislation was enacted. Although CBO anticipates that the consolidation of physicians' practices and hospitals will continue regardless of the incentives created under the proposed Part B demonstration, that development will not lead to higher Medicare spending as it has in the past.

Question. CMS designed Phase I to be budget neutral, but anticipates savings from provider behavior change. Does CBO agree? What changes do you expect and how quickly do you believe these changes will occur? Do your estimates include the potential for the new reimbursement structure to shift care to more expensive settings? What behavioral change does CBO anticipate for expensive drugs that have no generic substitute, which is the case for many last-in-line therapeutic products?

Answer. In Phase I of the demonstration that is testing new approaches to paying for prescription drugs under Medicare Part B, providers will be divided into two groups. The control group will receive payment at the current level—that is, the drug's average sales price (ASP), plus a 6 percent markup (about 4.3 percent after accounting for the effect of mandatory sequestration). The demonstration group will receive payment equal to the ASP plus 2.5 percent, plus a flat fee of \$16.80 for each day the drug is administered. CMS calculated the add-on percentage and flat fee so that aggregate spending on Part B drugs would be the same as it would have been without the demonstration, assuming there were no changes in prescribing patterns.

CBO expects that Phase I of the demonstration will reduce spending on Part B drugs.⁴ CBO's estimate of those savings is based on an analysis of how the change in the formula for paying for Part B drugs will affect the incentives providers face when prescribing those drugs. The change in the payment formula will reduce the difference in payments for drugs with different prices. CBO expects that, as a result, some providers will choose lower-cost therapeutic alternatives for some of their patients, which will reduce spending. CBO anticipates that those changes in prescribing patterns will begin to occur in the first year of the demonstration and will grow over the next several years as providers become more familiar with the new payment approach. CBO does not anticipate any change in prescribing patterns for drugs that have no lower-cost therapeutic alternatives.

Several physicians' organizations have raised concerns that the changes in payment rates for Part B drugs under the demonstration would shift care to higher cost settings by accelerating the acquisition of physicians' practices by hospitals. CBO met with several stakeholders to explore those concerns. CBO concluded that, even if the pace at which physicians' practices

4. See Congressional Budget Office, cost estimate for H.R. 5122, a bill to prohibit further action on the proposed rule regarding testing of Medicare Part B prescription drug models (October 4, 2016), www.cbo.gov/publication/52087.

are acquired by hospitals was affected by the demonstration, there would be no significant effect on Medicare spending. As discussed in response to a previous question, the higher Medicare payment rates that hospital-owned physicians' practices receive relative to those received by independent physicians' practices were eliminated by a provision of the Bipartisan Budget Act of 2015 for physicians' practices acquired by hospitals after the legislation was enacted. (The difference in payment rates remains in effect for physicians' practices acquired by hospitals before the legislation was enacted.)

Question. In the proposed rule for the Part B proposal, CMS notes the “possibilities of overlap between the Part B Drug Payment Model and the Medicare Shared Savings Program, the Medicare Intravenous Immune Globulin (IVIG) Demonstration, and other Innovation Center payment models, such as the Oncology Care Model (OCM) and the Bundled Payments for Care Improvement (BPCI) initiative.”⁵ Does CBO consider this potential for significant overlap of demonstrations in its estimate of CMMI?

Answer. The demonstration to test new payment methods for Part B drugs could differ significantly from what has been proposed—for example, in its scope or duration. CBO will carefully review the final rule for the demonstration to assess the potential for overlap with other CMMI demonstrations and will consider potential interactions between those demonstrations when updating its budget projections for CMMI.

Question. In the Comprehensive Care for Joint Replacement proposed rule, CMS provided an estimated savings of \$153 million over the five-year demonstration period of the model.⁶ Is this the type of information CBO considers in developing the CMMI baseline?

Answer. CBO does not rely on such projections from CMS when assessing the budgetary effects of CMMI's activities. As discussed in the testimony, CBO's analysis of the budgetary effects of CMMI's activities is primarily based on judgments about the effectiveness of CMMI's process for conducting demonstrations, not on judgments about the expected results of particular demonstrations.

Question. Many CMMI demonstrations, such as the Bundled Payments for Care Improvement Initiative, hold hospitals accountable to a spending benchmark that is based on historical expenditures. Under this type of model, there is a hard limit to the savings that any one hospital may reasonably achieve without harming patient care. How does CBO consider the potential for models to have diminishing or finite returns?

Answer. In considering the potential for the models being tested by CMMI to reduce federal spending, CBO will examine the details of the payment mechanisms, including whether those mechanisms could lead to increasing or diminishing savings over time. For the specific case of the Bundled Payments for Care Improvement Initiative, a target price for each type of episode (such as treatment for heart attack or stroke) is based on the historical experience of the providers participating in the demonstration. However, the target price for the first year of the demonstration and all subsequent years is updated annually to reflect the national growth in

5. Medicare Program; Part B Drug Payment Model, 81 Fed. Reg. 13230 (proposed March 11, 2016) (to be codified at 42 C.F.R. Part 511).

6. Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, 80 Fed. Reg. 41198 (proposed July 14, 2015) (to be codified at 42 C.F.R. Part 510).

the average Medicare payment for the episode. That feature of the payment mechanism is designed to enable providers to continue to achieve savings relative to the target price over time. Moreover, for most of the bundled payment models being tested, the episode includes services delivered by a range of different providers, not just hospitals. For example, in Model 2, the episode includes all services delivered by the hospital and physicians during the hospital stay as well as post-acute care and related services (including readmissions) during a period of time following discharge that varies from 30 days for some conditions to 90 days for others. Providers can therefore achieve savings relative to the target price in a number of ways, such as by reducing the use of post-acute care, by shifting to less expensive types of post-acute care, or by reducing the number of readmissions and emergency-department visits in the period following discharge.

Question. CMMI has announced ambitious programs whose targets appear not to have been met. For instance, beneficiary enrollment in the Financial Alignment Initiative was much lower than first projected, due to higher than expected opt-out rates and lower than expected plan participation.⁷ Similarly, participants in CMMI's Bundled Payments for Care Improvement program have been slow to move to the risk bearing track of the initiative. How has CBO taken these developments into account in the evaluations of CMMI's impact? Have they changed CBO's assessment?

Answer. CBO has not modified its budget projections for CMMI on the basis of the experience to date for those two demonstrations. Many demonstrations are under way, and limited information is currently available on the likely success of most of them. Consequently, CBO believes that it is too soon to assess the accuracy of its projections. CBO expects that only a small share of the demonstrations tested by CMMI will reduce federal spending, most will have little or no effect on federal spending, and some will increase federal spending. The estimates of savings that CBO expects to result from CMMI's activities are based largely on the judgment that successful demonstrations will be expanded and achieve savings. However, CBO expects that demonstrations that succeed will operate for four to seven years, on average, before HHS decides whether to expand them. As discussed in response to a previous question, CBO will continue to monitor all aspects of CMMI's operations—including the evaluation results for each demonstration and decisions by the Secretary to expand demonstrations—and will use that information to improve its budget projections.

Question. CMS determined that CMMI models will qualify as APMs for the purposes of the Medicare Access and CHIP Reauthorization Act and be eligible for a 5 percent payment bump? How does that affect the projected CMMI savings over the 10-year window if models in the program are going to be receiving an additional 5 percent bonus payment?

Answer. CMS released the final rule for the new Quality Payment Program in Medicare on October 14, 2016. That program includes the Merit-Based Incentive Payment System and Alternative Payment Models. CBO has not completed its assessment of how this new program affects its budget projections for CMMI. The agency will review the final rule and continue to monitor developments in this area, and will incorporate additional information into its estimates.

7. Edith G. Walsh and others, *Report on Early Implementation of the Demonstrations Under the Financial Alignment Initiative* (submitted by RTI International to the Centers for Medicare & Medicaid Services, October 15, 2015), <http://go.usa.gov/xkYTN> (PDF, 555 KB).

Congressman Pascrell

Question. In 2012, George Washington University received a Health Care Innovation Award from the Center for Medicare & Medicaid Innovation to study the impact of providing telehealth to home dialysis patients. The Award completed in June of 2015, but we have not seen the results of this study yet, which could be hugely helpful in designing interventions to improve the care and reduce health care costs for patients with End Stage Renal Disease. Are studies like these important to the way that CBO approaches the scoring of telehealth? What other data is important to understand how telehealth might produce cost savings?

Answer. Results from the George Washington University study were included in a report that presented findings for projects—funded by Health Care Innovation Awards—that tested approaches targeted to patients with specific diseases.⁸ The report presented estimates of average Medicare spending and rates of hospital admissions and emergency department visits among participants before and after the program began. The findings do not provide reliable information about whether the intervention reduced Medicare spending, however, because the evaluation did not include a control group of Medicare beneficiaries who did not participate in the program; such a control group is necessary to estimate how spending for program participants would have changed without the intervention. Moreover, even if the study had included a control group, the estimates of program effects would have been imprecise because fewer than 300 patients participated in the program. On the basis of interviews with nurses and patients, the evaluation results suggest that the intended changes in health care processes occurred unevenly (although the number of nurses interviewed was not reported and only 15 patients were interviewed).

CBO analyzes proposals to expand Medicare coverage of telemedicine on a case-by-case basis. The agency considers the design of those proposals—including what services would be covered and under what circumstances and how payments would be determined—as well as any relevant evidence. CBO would also consider how any legislative proposals to expand Medicare coverage of telemedicine would overlap with CMMI's activities. Having more evidence about how telemedicine coverage affects spending would be useful. The results of an additional demonstration project conducted within the fee-for-service Medicare program would be particularly useful, but such a project should be designed to include a valid comparison methodology and adequate sample sizes to estimate its effects on Medicare spending.

It is difficult to predict whether expanding Medicare coverage for telemedicine services would increase or decrease federal spending, but doing so depends on two main considerations:

- The payment rates that would be established for those services, and
- Whether those services would substitute for, or reduce the use of, other Medicare-covered services or whether they would be used in addition to currently covered services.

8. Center for Medicare & Medicaid Innovation, *Second Annual Report: HCIA Disease-Specific Evaluation* (prepared by NORC at the University of Chicago, revised March 2016), pp. 79–86, <http://go.usa.gov/xkyF4> (PDF, 7 MB).

If all or most telemedicine services substituted for or prevented the use of more expensive services, expanding coverage of telemedicine could reduce federal spending. If, instead, telemedicine services were mostly used in addition to currently covered services, expanding coverage of telemedicine would tend to increase Medicare spending. Many proposals to expand coverage of telemedicine strive to facilitate enrollees' access to health care. Therefore, such proposals could increase spending by adding payments for new services instead of substituting for existing services.

Congressman Johnson

Question. CBO strongly believes in the savings that CMMI is supposed to be generating for the Medicare and Medicaid programs, but there must also be loss built into the baseline.

- Please explain how loss assumptions factor into scoring the center.
- What are the distribution assumptions that led to these savings? Is there curvature over time?
- Do Medicaid assumptions differ from those regarding the Medicare program?
- Does the methodology reflect savings/losses experienced by previous demos proposed by HHS before the advent of CMMI?
- Do your assumptions change as demos progress and experience success or failure?

Answer. CBO's projections of the budgetary effects of CMMI's activities take into account the experience of demonstration projects conducted before CMMI was established. Specifically, CBO expects that a small share of the demonstrations conducted by CMMI will achieve savings, most will have little or no effect on federal spending, and some will increase federal spending. Estimates of the federal savings that CBO expects to result from CMMI's activities are based largely on the judgment that HHS will expand some of the demonstrations that are found to reduce spending and that those models will achieve savings once expanded. CBO expects that HHS will also expand some demonstrations that are expected to improve the quality of care without increasing spending, but on balance, CBO expects those models will have no effect on federal spending. CBO expects that CMMI will cancel demonstrations that increase federal spending. Thus, CBO's budget projections account for CMMI's costs of conducting demonstrations and the increased spending expected from the testing of demonstrations that are found to raise spending. Estimates of budgetary savings stem primarily from the expected expansion of demonstrations that will reduce spending.

CBO's assessment of the budgetary effects of CMMI's activities involves judgments that are inherently uncertain. Over time, however, CBO will learn more about CMMI's operations, including its approaches to selecting and testing, evaluating, and expanding demonstration projects. That information will help CBO improve its budget projections. Also, as CMMI evaluates more demonstrations, CBO hopes to gain a greater understanding of the characteristics of those that successfully reduce spending and of those that do not.

On the basis of past experience (both before and since the establishment of CMMI), CBO expects that CMMI will undertake some projects in Medicaid, but that most will focus on Medicare.

Question. CMMI operates within a set of guardrails—observance of those guardrails surely factors into CBO’s budgetary assumptions.

- Who ultimately determines if CMMI is operating within its boundaries—Congress? The Secretary?
- Similarly, who reviews and certifies the demos that are proposed and acted upon by the Center?
- Say a demo is not in compliance with those guardrails and Congress acts to scale back or stop the demo. What’s the result from CBO’s perspective? What’s the result if a demo outside of those guardrails is expanded?
- If additional money is appropriated to a demo, what is the budgetary effect?

Answer. CBO bases its projections of the budgetary effects of CMMI’s activities on the anticipated budgetary effects of how the Administration will use the authorities available in current law, not on analyses of how the legislative or judicial branches of government might view that use. Therefore, CBO’s baseline projections incorporate the expected effects of the Administration’s actions. If the Congress acts to modify those actions, CBO will estimate the budgetary effect of that modification. That estimate would depend on the specifics of the proposed change.

It is CBO’s understanding that the process of designing and reviewing proposed demonstrations involves outside experts, including experts in experimental design and evaluation, and analysts from many parts of the Department of Health and Human Services (including CMMI, the Office of the Actuary, and other offices) and other agencies. The Office of the Actuary conducts the analysis to determine whether a demonstration model being considered for expansion will be certified by the Chief Actuary as meeting the requirement that expansion would either reduce or not affect spending.

If additional money is appropriated for a demonstration, the estimated budgetary effect would depend on the specifics of the proposed change.

Question. Please explain the differences in budgetary assumptions for demos proposed by Congress versus those proposed by CMMI versus those proposed by the Secretary.

- Do assumptions differ based on who tests an idea and how?
- Do those assumptions change when factoring in the ability to turn off the demo at any time?

Answer. CBO incorporates in its baseline projections the expected budgetary effects of activities undertaken by the Administration (including those undertaken by the Secretary of HHS or by CMMI) using authorities the Administration claims under current law. If the Congress acts to modify those authorities, CBO will estimate the budgetary effect of enacting that modification. Because CBO projects that CMMI’s activities will reduce federal spending, there is potential overlap between those activities and legislative proposals for demonstrations. CBO would assess that overlap on a case-by-case basis. For a legislative proposal, CBO would consider the features of the proposed demonstration as well as the process by which it would be evaluated and expanded if found to be successful (or canceled if found to be unsuccessful) and the ways in which that process might differ from the process used by CMMI.