HEALTH MANAGEMENT ASSOCIATES

ISSUE BRIEF #2

Center for Medicare and Medicaid Innovation: Recommendations for Future Direction

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October 2021

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Executive Summary

For more than a decade, the Centers for Medicare & Medicaid Services' (CMS's) Center for Medicare and Medicaid Innovation (CMMI)—the Innovation Center—has been implementing and testing models to determine if new approaches to providing care to beneficiaries could reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) program spending, improve the quality of care, or both. In an earlier issue brief, Health Management Associates (HMA) examined the progress the Innovation Center has made to date in fulfilling this mission specifically for the Medicare program and noted questions raised by our various findings that policymakers may wish to consider as they plan for the next phase of the Innovation Center's work. In this issue brief, we return to these questions and discuss some potential answers.

New CMS leadership has recently announced a review of CMMI's demonstrations that will culminate in the release of information about the Innovation Center's future direction. Experience has shown that the Innovation Center will need to balance competing goals as it continues to test models and design new ones, such as reducing the number of models versus maintaining a broad portfolio. In the hope of assisting CMMI's planning for a new direction, we discuss seven pairs of these competing goals and offer four recommendations that may, in part, help to balance these competing goals, as they are designed increase the transparency of Innovation Center efforts and improve the likelihood that more models succeed in decreasing spending or improving quality. The recommendations include:

- The Department of Health and Human Services (HHS) should establish a National Healthcare Transformation Strategy
- CMMI should articulate a vision for how different models work together
- CMMI should tailor models to test ideas that address the largest areas of spending growth and key areas of quality concerns, including
    - Include Part D in models
    - Include Part C in models
    - Promote primary care as a counterbalance to excessive low-value care
    - Address social determinants of health and other drivers of quality and access disparities
- Congress and HHS should revisit the Physician-Focused Payment Model Technical Advisory Committee (PTAC)

New CMS leadership has also recently announced plans to integrate equity into all models. We applaud this commitment and observe that Congress may wish to consider adding equity to the criteria used to evaluate models and granting the Secretary of the Department of Health and Human Services the authority to approve models that improve quality and equity while minimally increasing spending.

This brief was supported by Arnold Ventures.

Acknowledgements

The authors would like to thank Arnold Ventures for supporting this work and Amber Burkhart, Hunter Kellett, Erica Socker, and Alexandra Spratt for their guidance and support

throughout the project. We also express our appreciation to Jonathan Blum for his contributions to this issue brief; to Samantha Di Paola, Amanda Glickman, Elaine Henry, and Cami McIntire for their assistance with summarizing information about Innovation Center models for the companion catalog; to Matt Hudson for graphic design support; and Karen Brodsky for comments on a draft of this issue brief.

Introduction

Overall, the results from the Innovation Centers' first decade show minimal success in fulfilling its statutorily defined objectives. Despite spending more than $10 billion overall and testing hundreds of models, only four models have met the statutory criteria of lower spending or improved quality and been expanded—or introduced—to the Medicare program nationwide:

- Home Health Value-Based Purchasing (HHVBP) model
- Medicare Diabetes Prevention Program (MDPP)
- Pioneer Accountable Care Organizations (ACOs)
- Repetitive Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior Authorization model

With a new Administration and Innovation Center Director—who have announced they are reviewing demonstrations and plan to share details about future direction soon—combined with the start of the next decade of $10 billion in funding, now is an opportune time to look ahead and consider how to adjust the Innovation Center's approach to improve the chances for model success.

In 2010, CMS's Center for Medicare and Medicaid Innovation (CMMI)—the Innovation Center—was established to test "innovative payment and service delivery models to reduce program expenditures . . .while preserving or enhancing the quality of care" provided to people who receive benefits from Medicare, Medicaid, or the Children's Health Insurance Program (CHIP).[1] The statute provides the Secretary of Health & Human Services (HHS) with authority under section 1115A of the Social Security Act to expand through rulemaking the duration and scope of a model being tested, including implementation on a nationwide basis.[2] To exercise this authority through rulemaking the:

- Secretary must determine that an expansion would either
  - reduce spending without reducing quality of care, or
  - improve quality of care without increasing spending
- CMS Chief Actuary must certify that expansion of the model would reduce (or not increase) net program spending

[1] "H.R. 3590- Patient Protection and Affordable Care Act." 111th Congress (2009-2010), accessed May 28, 2021, https://www.congress.gov/bill/111th-congress/house-bill/3590

[2] "Compilation of the Social Security Laws: Center for Medicare and Medicaid Innovation." Social Security Administration, accessed May 28, 2021, https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm

- Secretary must determine that the expansion would not deny or limit the coverage or provision of benefits under Medicare, Medicaid, or CHIP.[3]

The statute also requires that the Secretary terminate or modify CMMI models before testing is completed if the Secretary determines that the model is not expected to fulfill these spending and quality goals (and CMS's Chief Actuary agrees with the spending expectations).[4] In other words, if initial testing results indicate that a model is **not** expected to improve the quality of care without increasing spending or **not** reduce spending without reducing the quality of care, then CMMI has a responsibility to make changes to the model to improve the likelihood of a successful outcome or cease operating the model.

The statute dedicated funds to CMMI for:

- $5 million for fiscal year 2010,
- $10 billion in total for fiscal years 2011 through 2019, and
- $10 billion for each subsequent 10-year period beginning with fiscal year 2020.[5]

The statute also requires that the Secretary evaluate each CMMI model and "make the results of each evaluation … available to the public in a timely fashion."[6] Additionally, the Secretary must issue a report to Congress every other year that describes CMMI's models including:

- The number of Medicare and Medicaid beneficiaries participating in the respective models
- Payments made by Medicare and Medicaid for services for these participating beneficiaries
- Models chosen for expansion
- Results from model evaluations.[7,8]

The bi-annual report to Congress must also include recommendations that the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.[9] CMMI released the fifth report in August 2021.[10]

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[3] "Compilation of the Social Security Laws: Center for Medicare and Medicaid Innovation." Social Security Administration, accessed May 28, 2021, https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm

[4] "Compilation of the Social Security Laws: Center for Medicare and Medicaid Innovation." Social Security Administration, accessed May 28, 2021, https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm

[5] "Compilation of the Social Security Laws: Center for Medicare and Medicaid Innovation." Social Security Administration, accessed May 28, 2021, https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm

[6] "Compilation of the Social Security Laws: Center for Medicare and Medicaid Innovation." Social Security Administration, accessed May 28, 2021, https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm

[7] "Compilation of the Social Security Laws: Center for Medicare and Medicaid Innovation." Social Security Administration, accessed May 28, 2021, https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm

[8] To date, CMMI has issued reports to Congress for 2012, 2014, 2016, 2018, and 2020.

[9] "Compilation of the Social Security Laws: Center for Medicare and Medicaid Innovation." Social Security Administration, accessed May 28, 2021, https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm

[10] https://innovation.cms.gov/data-and-reports/2021/rtc-2020

Methodology

This issue brief is the second of two that examine Innovation Center models to date and make recommendations for the future direction of models. In the first issue brief, Health Management Associates (HMA) reviewed information about Innovation Center models that was made publicly available by CMMI through May 11, 2021. We inventoried this information in a model catalog available here. A unique characteristic of our review is the description of the 110 individual Medicare models included under the umbrella of the Round One and Two Health Care Innovation Awards and State Innovation Models, which are typically reported in the aggregate in other studies.

In the first issue brief, along with describing characteristics of Innovation Center models to date, we noted questions raised by our various findings that policy makers may consider as they plan for the next phase of CMMI's work. These questions were included in 12 call-out boxes.[11] In this issue brief, we include each of the 12 call-out boxes and discuss these questions in more depth to lay out the competing goals and tensions that the Innovation Center will have to weigh going forward and offer recommendations on the outlook for new models.

The Innovation Center will need to balance competing goals

The Innovation Center's first decade of experience has illustrated several competing goals that the Director will need to maintain in ongoing balance in the next decade. New CMS leadership has released a brief description of plans for CMMI's next decade in advance of forthcoming detailed information that addresses balancing some of these goals.[12] For example, CMMI plans to reduce the total number of models going forward. We review seven pairs of competing goals below and discuss ideas for refining CMMI's future direction to promote an optimal balance between each pair.

- Reduce the number of models versus maintain a broad portfolio
- Employ a bottom-up versus a top-down approach
- Focus on scalable versus targeted models
- Collaborate with other payers versus focus on Medicare-only models
- Continue to refine unsuccessful models versus move on to new ideas
- Design models to address population health versus avoid incentivizing market consolidation
- Require participants to meet goals sooner versus provide a glide path for new participants

[11] Note that the color of each call-out boxes corresponds to the color of the data point (e.g., pie slice or bar) included in the exhibit figure in the first issue brief.

[12] Chiquita Brooks-LaSure, Elizabeth Folwer, Meena Seshamani, and Daniel Tsai. "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years." Health Affairs, August 2021. https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/

Reduce the number of models versus maintain a broad portfolio

The most common Medicare model category by far is "New Payment and Service Delivery" (76%).

Is this the right portfolio mix for CMMI models?

As we and other observers have noted, the Innovation Center has tested and continues to test more than 170 models that include Medicare across seven categories.[13,14,15] (Others count more than 50 models. Our total counts the Health Care Innovation Awards (HCIA) and State Innovation Models (SIM) individually.) This year, MedPAC voted to recommend that the Innovation Center reduce the total number of models. The Commission posited that "a smaller set of [models]—with better aligned incentives to reduce volume and costs—could increase the degree to which providers change their behavior in response to the models and could lead to reductions in spending over a time frame of longer than five years."[16] In addition, the new CMMI Director has indicated agreement with testing fewer models.[17] This could address several concerns, such as confusion, diluted incentives, and challenges in study design and evaluation caused by overlapping models, and spending significant resources on ideas that do not result in successful reduction of spending or improved quality. Ideally, there would be several promising models for the Innovation Center to focus resources on and several models that are clearly under-performing to be culled.

One idea to consider, if the Innovation Center were to reduce the number of models, is to review the different categories of models and number of models in each category. CMMI currently organizes models into seven categories:

- Accountable Care
- Episode-based Payment Initiatives
- Primary Care Transformation
- Initiatives Focused on the Medicaid and Children's Health Insurance Program (CHIP) Population

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[13] Jennifer Podulka and Yamini Narayan. "Issue Brief #1: Center for Medicare and Medicaid Innovation: Findings from Medicare Models To-Date." *Health Management Associates*, June 2021. https://www.healthmanagement.com/wp-content/uploads/HMA-AV-Issue-Brief-1-CMMI-findings.pdf.

[14] *Report to the Congress: Medicare and the Health Care Delivery System*. Washington, District of Columbia, 2021. http://www.medpac.gov/docs/default-source/default-document-library/jun21_medpac_report_to_congress_sec.pdf?sfvrsn=0

[15] Donald Berwick and Rick Gilfillan. "Reinventing the center for Medicare and Medicaid innovation." *JAMA* 325, no. 13 (2021): 1247-1248.

[16] Report to the Congress: Medicare and the Health Care Delivery System. Washington, District of Columbia, 2021. http://www.medpac.gov/docs/default-source/default-document-library/jun21_medpac_report_to_congress_sec.pdf?sfvrsn=0

[17] Chiquita Brooks-LaSure, Elizabeth Folwer, Meena Seshamani, and Daniel Tsai. "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years." *Health Affairs,* August 2021. https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/

- Initiatives Focused on the Medicare-Medicaid Enrollees
- Initiatives to Accelerate the Development and Testing of New Payment and Service Delivery Models
- Initiatives to Speed the Adoption of Best Practices

To date, three-quarters of models have been implemented under the category "New Payment and Service Delivery." Much of this skew is explained by the numerous HCIA and SIM models that were included in this category. Currently, the Innovation Center is operating 28 models.[18] Nearly half of these (12) fall into the "Initiatives to Accelerate the Development and Testing of New Payment and Service Delivery Models" category.[19] The Innovation Center may wish to reduce the share of models in this category.

After more than a decade, only 4 models have proven successful enough to be expanded into traditional Medicare through CMMI authorities.

How can CMMI increase the likelihood that models succeed?
Should some current models that have yet to succeed cease operations?

Reducing the number of models may prove to be easier said than done. The numerous Innovation Center models are intended to test various hypotheses about how care can be improved, and a decade of experience has shown that we do not yet have a clear, narrow path to guide us to which models that are currently being tested or that spring from new ideas in the future will succeed. Only four models have met the statutory criteria of lower spending or improved quality and were expanded to the Medicare program nationwide. These models cross provider type and category. All seven categories currently include select models that are testing exciting new approaches for improving healthcare delivery. Even models that may be contenders for discontinuation, like models that have been in place for multiple years without producing successful results, include unique characteristics that the Innovation Center may not want to retire before fully testing.

Employ a bottom-up versus a top-down approach

The Innovation Center solicits ongoing input from stakeholders on ideas for individual models, modifications to existing models, and the overall direction for the various categories that it pursues. This bottom-up approach allows CMMI to benefit from methods developed and sometimes tested by innovative providers in the community. The largest trial of this approach has been the HCIA and SIM models that the Innovation Center tested from 2012 through

[18] Chiquita Brooks-LaSure, Elizabeth Folwer, Meena Seshamani, and Daniel Tsai. "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years." *Health Affairs,* August 2021. https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/

[19] Health Management Associates. *Center for Medicare and Medicaid Innovation—Innovation Center Model Overview*. (May 11, 2021). Distributed by Health Management Associates.

2020.[20] About three thousand "clinicians, entrepreneurs, health centers, hospitals, and community-based organizations" submitted applications for the first round alone.[21] In total, the Innovation Center awarded grants to more than one hundred individual models focused on Medicare.[22] One model—the Medicare Diabetes Prevention Program (MDPP)—was successful and has since been introduced to the Medicare program nationwide. An additional six models implemented under the HCIA had especially promising independent evaluation results in that they were shown to decrease spending while improving quality.[23] Despite these findings, none of these six models have been expanded under the Medicare program. The Innovation Center may want to revisit these models to determine if they could be expanded or built upon for additional testing. Continuing to seek stakeholder input on ideas for models and refinements to existing models has the advantages of tying models to provider engagement. Effective implementation of models requires a significant level of effort in making real change to provider practice patterns. Providers who have a voice in designing models may be more likely to succeed in them.

Conversely, there are advantages to a top-down approach that focuses on Innovation Center staff development and refinement of models. Soliciting stakeholder input on models is resource-intensive and may experience provider dissatisfaction centered exclusively on payment changes; it is possible that these resources would be better spent elsewhere. Even though stakeholder-recommended models may have greater provider engagement, they are still not guaranteed success. Despite the seven successful HCIA models, nearly 100 models did not achieve similar results. These stakeholder-recommended models also included far fewer ambitious goals that have been included in some more recent models, such as two-sided risk and mandatory participation. Innovation Center staff may be in the best position to determine how to structure models to achieve desired outcomes while incorporating lessons learned from past models, avoiding unnecessary overlap with other models, and more efficiently deploying Innovation Center resources.

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[20] Jennifer Podulka and Yamini Narayan. "Issue Brief #1: Center for Medicare and Medicaid Innovation: Findings from Medicare Models To-Date." *Health Management Associates*, June 2021. https://www.healthmanagement.com/wp-content/uploads/HMA-AV-Issue-Brief-1-CMMI-findings.pdf.

[21] Rocco Perla, Hoangmai Pham, Richard Gilfillan, Donald M. Berwick, Richard J. Baron, Peter Lee, C. Joseph McCannon, Kevin Progar, and William H. Shrank. "Government as innovation catalyst: lessons from the early Center for Medicare and Medicaid Innovation models." *Health Affairs* 37, no. 2 (2018): 213-221.

[22] Health Management Associates. *Center for Medicare and Medicaid Innovation—Innovation Center Model Overview*. (May 11, 2021). Distributed by Health Management Associates.

[23] Jennifer Podulka and Yamini Narayan. "Issue Brief #1: Center for Medicare and Medicaid Innovation: Findings from Medicare Models To-Date." *Health Management Associates,* June 2021. https://www.healthmanagement.com/wp-content/uploads/HMA-AV-Issue-Brief-1-CMMI-findings.pdf.

Focus on scalable versus targeted models

47% of Medicare models operate in a single state.
75% of Medicare models operate in 10 or fewer states.

Should more Medicare models be tested in larger geographic areas to improve the chances that models are generalizable and can be scaled up?

CMMI's mission is to test ideas that could be expanded beyond the model to the traditional Medicare program nationwide. Yet nearly half of Medicare models to date are limited to a single state and three-quarters are limited to 10 or fewer states.[24] This narrow geographic focus of many models calls into question whether successful results will be generalizable to the Medicare program as a whole. Reducing or eliminating models with limited geographic reach offers one way to follow through on MedPAC's recommendation to reduce the total number of Innovation Center models.

Only 13% of Medicare models specifically target rural areas.

Should rural models and others designed for populations of interest be a greater focus for CMMI?

On the other hand, the United States is a large, diverse country with heterogeneous geographic areas. If the adage *all health care is local* holds true, it makes sense for the Innovation Center to test ideas in individual markets. For instance, models that succeed in rural areas, but that are unlikely to be as effective in urban areas could still be of tremendous benefit to all Medicare beneficiaries in rural markets. Existing Medicare program features and providers are tailored to specific geographic areas, such as Health Professional Shortage Areas and critical access hospitals.[25,26] Implementing successful program elements into the Medicare program with geographic boundaries could be another a logical way to address the variation in markets across the country.

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[24] Jennifer Podulka and Yamini Narayan. "Issue Brief #1: Center for Medicare and Medicaid Innovation: Findings from Medicare Models To-Date." *Health Management Associates,* June 2021. https://www.healthmanagement.com/wp-content/uploads/HMA-AV-Issue-Brief-1-CMMI-findings.pdf.

[25] Health Professional Shortage Areas are geographic areas of populations that lack enough health care providers to meet the health care needs to that population. See information on the Health Professional Shortage Area Physician Bonus Program: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HPSAfctsht.pdf

[26] Eligible rural hospitals are granted Critical Access Hospital status by CMS. The designation is meant to reduce financial vulnerability of rural hospitals and improve access to health care. See more information about critical access hospitals designations, payments, and admissions: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CritAccessHospfctsht.pdf

Collaborate with other payers versus focus on Medicare-only models

To date, about half of Innovation Center models that include Medicare include no other payers (52%), about one-third include Medicare and Medicaid (34%), and the rest include some additional payers (13%), such as Medicare Advantage and commercial insurance.[27] Some stakeholders have encouraged the Innovation Center to employ multi-payer initiatives.[28,29] [30] Including other payers offers the advantage of setting clear, consistent expectations for participating providers about how the model would like them to change their practice patterns, which is more realistic than expecting providers to manage and comply with different sets of health care delivery rules for the patients affected. Including other payers during the model testing phase may also help to gather ideas about how models should be designed and increase payer buy-in for adopting any models that succeed.

However, CMS and CMMI are tasked with improving care for Medicare, Medicaid, and CHIP; and there are reasons to focus on that statutory mission. First, including other payers increases administrative complexity and may extend the start-up phase of some new models. Second, Medicare may not need other payers to participate to get buy-in later. Where Medicare leads, other payers tend to follow, such as adopting fee schedules and prospective payment systems. Third and perhaps most importantly, Medicare has a unique advantage – once beneficiaries join Medicare they stay in the program – that fact may be diluted or even lost when other payers participate in models. This advantage could allow the program to test and adopt some features that make use of this long-term outlook that would not appeal to other payers, for example offering shared-decision making programs that include alternatives to low-value orthopedic surgeries by offering more generous physical therapy, palliative care, and other services.

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[27] Jennifer Podulka and Yamini Narayan. "Issue Brief #1: Center for Medicare and Medicaid Innovation: Findings from Medicare Models To-Date." *Health Management Associates,* June 2021. https://www.healthmanagement.com/wp-content/uploads/HMA-AV-Issue-Brief-1-CMMI-findings.pdf.

[28] Amol S. Navathe, Ezekiel J. Emanual, Sherry Glied, Farzad Mostashari, Bob Kocher. "Medicare Payment Reform's Next Decade: A Strategic Plan for the Center for Medicare and Medicaid Innovation." *Health Affairs,* December 2020.

[29] Rachel M. Werner, Ezekiel J. Emanuel, Hoangmai H. Pham, and Amol S. Navathe. The Future of Value-Based Payment: A Road Map to 2030. University of Pennsylvania Leonard Davis Institute of Health Economics. February 17, 2021

[30] Hannah L. Crook, Robert S. Saunders, Rachel Roiland, Aparna Higgins, Mark B. McClellan. "A Decade of Value-Based Payment: Lessons Learned and Implications for the Center for Medicare and Medicaid Innovation, Part 1." *Health Affairs,* June 2021.

Continue to refine unsuccessful models versus move on to new ideas

Most Medicare models are tested for 3 to 5 years.
Some Medicare models are tested for 7 or more years.

Are Medicare models being tested for the best length of time?
Should some long-running Medicare models be ended?

Most Innovation Center models focused on Medicare operate for five years or less. It may be challenging to complete tests of models in less time, as numerous independent evaluations have noted that models face ramp-up issues in the first one, two, or three years, such as setting up demonstration sites and data sharing infrastructure, educating and getting buy-in from participant providers, engaging beneficiaries, and addressing the early departure of some demonstration sites and participants.[31,32] When models are not shown to decrease spending or improve quality within their allotted testing period, the Innovation Center often extends the model or carries over some of the model characteristics into a new demonstration. Almost one-third of models that include Medicare (31%) have been extended to allow additional time for testing.[33] Many current models that include Medicare build on prior models (see Exhibit 1). Continuing to test ideas for longer periods of time, either by extending models or incorporating them in new iterations of models, allows the Innovation Center to continue to refine and test these characteristics, which may have not yet achieved success for exogenous reasons, such as demonstration site ramp-up delays or small sample sizes. Some models such as ACOs have had mixed initial results; CMMI has used second-generation versions of models to test ideas for refining approaches to hopefully get more consistent positive results.

8 Medicare models have been shown to both decrease spending and improve quality but have not been expanded nationwide.

Should CMMI review and expand or build on past models that show promise?

[31] Deborah Peikes, et al. "Independent Evaluation of Comprehensive Primary Care Plus (CPC+): Third Annual Report." Mathematica, January 2021. https://innovation.cms.gov/data-and-reports/2021/cpc-plus-third-anual-eval-report

[32] Kristy Piccinini, et al. "Evaluation of the Shared Decision Making (SDM) Health Care Innovation Awardees: Third Annual Report." Acumen, LLC, February 7, 2017. https://downloads.cms.gov/files/cmmi/hcia-shareddecisionmaking-thirdannualrpt.pdf

[33] Jennifer Podulka, and Yamini Narayan. "Issue Brief #1: Center for Medicare and Medicaid Innovation: Findings from Medicare Models To-Date." *Health Management Associates,* June 2021. https://www.healthmanagement.com/wp-content/uploads/HMA-AV-Issue-Brief-1-CMMI-findings.pdf.

Exhibit 1. Current Innovation Center models that include Medicare and their earlier iterations

Current model	Built on these earlier models
Bundled Payments for Care Improvement (BPCI) Advanced	Bundled Payments for Care Improvement (BPCI)
Comprehensive Primary Care Plus (CPC+)	Comprehensive Primary Care (CPC)
Global and Professional Direct Contracting (GPDC)	Next Generation Accountable Care Organization (ACO)
Kidney Care Choices (KCC)	Comprehensive ESRD Care
Maryland Total Cost of Care (TCOC)	Maryland All-Payer
Medicare Diabetes Prevention Program (MDPP) Expanded	Medicare Diabetes Prevention Program (MDPP)
Pennsylvania Rural Health	• Maryland All-Payer • Vermont All-Payer Accountable Care Organization (ACO)
Primary Care First	Comprehensive Primary Care Plus (CPC+)
Vermont All-Payer Accountable Care Organization (ACO)	• Maryland All-Payer • Next Generation ACO Model

Note: ESRD (end-stage renal disease). Among the earlier models, only the Medicare Diabetes Prevention Program (MDPP) was successful and introduced to the Medicare program nationwide.
Source: HMA analysis of publicly available information from the Center for Medicare and Medicaid Innovation.

Many more Medicare models (30%) are currently operating than are planned to begin (5%).

What share of CMMI's resources will ongoing and new models consume? Will there be sufficient resources to initiate new model priorities?

Continuing to test models for extended periods raises a question about the Innovation Center's mission – should it be a source of ongoing funding across many years to allow programs as much chance to succeed as possible? Or should it be winnowing out unsuccessful models and moving successful ones to the full Medicare program so that testing resources are freed up to move on to other ideas? A few models that include Medicare have been in operation for about a decade or longer. For example:

- the Medicare Intravenous Immune Globulin (IVIG) demonstration is scheduled to have more than nine performance years.
- The Medicare Coordinated Care model had more than 12 performance years.
- The Independence at Home model is scheduled to have more than 11 performance years.

- The Rural Community Hospital demonstration is scheduled to have 18 performance years.

None of these long-running models have yet been found to be successful enough in reducing spending or improving quality to be expanded into the Medicare program nationwide.

Design models to address population health versus avoid incentivizing market consolidation

The Innovation Center has introduced several models that embrace calls for participants to focus broadly on maintaining and improving the overall health of a population, such as Comprehensive Primary Care Plus (CPC+), Global and Professional Direct Contracting (GPDC), Maryland Total Cost of Care (TCOC) model, and the currently under review Geographic Direct Contracting model. These models are designed to foster collaboration among participant providers and organizations in improving how care is delivered to beneficiaries. They include regulatory relief and additional flexibilities that, if the models prove to be successful, could transform how some aspects of the Medicare program operate.

However, in encouraging greater collaboration among participants for the goal of improved patient care, these models may be inadvertently, if incrementally, further increasing market consolidation pressures. Hospitals and physician groups have increasingly consolidated, in part to gain leverage in negotiating higher payment rates with private insurers (which, themselves, have become more concentrated).[34] Most studies indicate that increased market consolidation increases prices and does not improve quality. The Innovation Center may wish to seek ways to balance model design that encourages greater collaboration while seeking to mitigate or avoid model characteristics that drive providers towards increased market consolidation.

Require participants to meet goals sooner versus provide a glide path for new participants

Few Medicare models have been shown to decrease spending (15%) or improve quality (22%).

Are lessons being learned from less successful models that can improve future models?

Over time, the Innovation Center has shifted to include greater expectations of some model participants, such as mandatory participation and two-sided risk arrangements. We discuss each of these two expectations below. Both of these greater expectations may improve the likelihood that models result in savings and quality improvement sooner and to a greater extent than models that have reduced expectations. However, many participants, especially

[34] Medicare Payment Advisory Commission. "Context for Medicare payment Policy." In Washington, DC: Report to the Congress: Medicare Payment Policy. (March 2021).

participants who are new to Innovation Center models, are not prepared to meet these goals at the outset because they do not have prior experience with similar models and need time to adjust their practice patterns. Lowering expectations for these participants may allow a greater number and variety of providers to join Innovation Center models and reduce the likelihood of participants ceasing participation in models early.

Mandatory versus voluntary participation

Only 6% of Medicare models require mandatory participation.

Is it time for CMMI to require mandatory participation for more models?

Mandatory participation has been required for very few Innovation Center models over the past decade and remains rare among current models that include Medicare.[35] Currently the Comprehensive Care for Joint Replacement (CJR), ESRD Treatment Choices (ETC), Maryland All-Payer, and Maryland Total Cost of Care (TCOC) models each require some degree of mandatory participation.[36] Including mandatory participation as a characteristic of models during testing may better reflect how the models' features would play out if they were to be introduced into the Medicare program nationwide. For example, if in the future the CJR model is successful and thus Medicare begins to pay for hip and knee replacement surgeries and after-care using bundled payments rather than current prospective-payment-system and fee-for-service payments, the new payment landscape would mimic the mandatory nature of the model test. Making demonstrations mandatory also forces participants to adjust their practice patterns if they wish to benefit from the model's rewards, such as sharing in savings, and avoid the model's penalties, such as sharing in losses. Whereas in voluntary models, unsuccessful participants can and do opt to leave demonstrations when faced with penalties.

However, there are potential drawbacks to requiring mandatory participation, such as the risk of provider pushback; the need to employ notice-and-comment rulemaking, which extends timelines; and the possibility of a reduced likelihood of success based on the performance of a group of providers that includes unwilling participants. Some degree of provider pushback is inherent in most CMS decisions that affect payments, and agency decisions can be received by groups of providers differently, so pushback alone is not sufficient reason to avoid mandatory participation for all models. However, models that are designed to shift most or all providers within a group that is currently benefiting from the status quo into a new mandatory model are likely to spur significant, organized pushback from providers who can turn not just to CMS but to Congress and the courts for support. Furthermore, once these broad, mandatory models proceed, the models' payment, reward, and penalty mechanisms become the new status quo, in

[35] Jennifer Podulka and Yamini Narayan. "Issue Brief #1: Center for Medicare and Medicaid Innovation: Findings from Medicare Models To-Date." *Health Management Associates*, June 2021. https://www.healthmanagement.com/wp-content/uploads/HMA-AV-Issue-Brief-1-CMMI-findings.pdf.

[36] CJR participation is mandatory for participants in certain markets, ETC is mandatory for selected providers, and the Maryland All-Payer and TCOC models are mandatory within the state.

which affected providers will continue to advocate for their interests. This tension may result in CMMI designing mandatory models that ask less of participants in terms of changes that significantly reduce spending or improve quality, for example settling for payment reductions of one or two percent, rather than working with motivated participants who are eager to shift away from the status quo and try more ambitious, innovative approaches. Granted that four models is too small of a sample to lead to conclusions, it should be noted that to date including mandatory participation in Innovation Center models has not correlated with a greater chance of success. Of the four models that have been found to be successful enough to be introduced into the Medicare program nationwide, only the Home Health Value-Based Purchasing (HHVBP) model included mandatory participation. Voluntary participation may make sense for models testing features that might, if successful, be introduced alongside existing payment mechanisms. For example, the successful MDPP model resulted in the Medicare program adopting a new provider type and establishing bundled payments for the service, while existing providers could continue to bill for some similar services under the existing physician fee schedule.

Two-sided risk versus one-side risk

Only 28% of Medicare models that began in 2017 or later exclusively require two-sided risk.

Is it time for CMMI to require two-sided risk for more models?

Two-sided risk—arrangements where providers are eligible to receive some portion of shared savings and must pay back some portion of shared losses—has been added to an increasing number of Innovation Center models over time so that more than a quarter of models that include Medicare that began in 2017 or later require two-sided risk of all participants.[37] Requiring two-sided risk presents negative financial consequences for participants and thus may increase their commitment to implementing the practice changes needed to achieve decreased spending or improved quality and thus may increase the likelihood that models are successful enough to be introduced to the Medicare program nationwide.

However, two-sided risk may present an obstacle to model participation for providers and organizations with fewer financial resources, including smaller ones and those that provide services to underserved populations. Hybrid model options, that are those that allow one-side (such as upside-only) risk for the first year or two of model participation for new entrants, may

[37] Jennifer Podulka and Yamini Narayan. "Issue Brief #1: Center for Medicare and Medicaid Innovation: Findings from Medicare Models To-Date." *Health Management Associates,* June 2021. https://www.healthmanagement.com/wp-content/uploads/HMA-AV-Issue-Brief-1-CMMI-findings.pdf.

offer an appropriate glidepath in these situations. Since 2017, mixed-risk models are slightly more common (29% of models) than those that exclusively require two-sided risk.[38]

Recommendations

New CMS leadership has recently offered their reflections on lessons learned from the Innovation Center's first decade, laid out their vision for the next decade, and indicated that additional information about that outlook will soon be forthcoming.[39] We anticipate that the competing goals we have described here will touch on themes that will be included in that information and that the Innovation Center will be called upon throughout the next decade to continually balance each of the goals when designing and refining models. We offer four recommendations designed increase the transparency of Innovation Center efforts and improve the likelihood that more models prove to be successful in decreasing spending and/or improving quality. Adopting these recommendations may, to some degree, aid the Innovation Center in balancing competing goals. In addition, adopting the recommendations focused on greater transparency would provide information to stakeholders about how the Innovation Center plans to balance competing goals, which can help them prepare for and make more informed choices about participation.

- HHS should establish a National Healthcare Transformation Strategy
- CMMI should articulate a vision for how different models work together
- CMMI should tailor models to test ideas that address the largest areas of spending growth and key areas of quality concerns, including
    - Include Part D in models
    - Include Part C in models
    - Promote primary care as a counterbalance to excessive low-value care
    - Address social determinants of health and other drivers of quality and access disparities
- Congress and HHS should revisit the Physician-Focused Payment Model Technical Advisory Committee (PTAC)

HHS should establish a National Healthcare Transformation Strategy

Incoming CMS leadership recently "concluded that we need a shared vision of the health system that we are collectively striving toward."[40] While former CMS Administrator Don Berwick and former Innovation Center Director Rick Gilfillan have called to "[c]onnect the CMMI agenda more explicitly to a broad HHS and CMS and a strategic plan and aims for

[38] Jennifer Podulka and Yamini Narayan. "Issue Brief #1: Center for Medicare and Medicaid Innovation: Findings from Medicare Models To-Date." *Health Management Associates,* June 2021. https://www.healthmanagement.com/wp-content/uploads/HMA-AV-Issue-Brief-1-CMMI-findings.pdf.

[39] Chiquita Brooks-LaSure, Elizabeth Folwer, Meena Seshamani, and Daniel Tsai. "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years." *Health Affairs,* August 2021. https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/

[40] Chiquita Brooks-LaSure, Elizabeth Folwer, Meena Seshamani, and Daniel Tsai. "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years." *Health Affairs,* August 2021. https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/

improving health and healthcare delivery."[41] We enthusiastically agree and note that the National Quality Strategy, which provides direction for improving the quality of health and healthcare in the United States, could serve as an example of how to develop a new National Healthcare Transformation Strategy . The National Quality Strategy was developed with input from more than 300 groups, organizations, and individuals led by the Agency for Healthcare Research and Quality (AHRQ) on behalf of the U.S. Department of Health and Human Services (HHS).[42]

Like the National Quality Strategy, a National Healthcare Transformation Strategy (National Strategy) could lay out a unifying vision for where HHS and other stakeholders want healthcare to go, along with goals for how programs, including Medicare, would get there. A nationwide strategy could guide CMMI on model design choices in a way that helps to balance the competing goals described above. The Innovation Center could lead the development of the new National Strategy, but all HHS agencies and other stakeholders, especially those focused on improving equity, should have a meaningful role. . The new National Strategy should be transparently communicated to, and receive feedback, from all stakeholders. .

CMMI should articulate a vision for how different models work together

Over time, the number of models has grown so that providers and beneficiaries are more likely to participate in more than one model. CMMI has released numerous documents that include detailed methodology guidance describing how various aspects of models function when models overlap, for example, how shared savings work across models in a hierarchy, but has not yet issued a document describing an overarching vision or goals for how the Innovation Center sees models working together. Incoming CMS leadership has acknowledged this challenge and shared their intention "to focus on launching fewer models."[43] Even with fewer models, some overlap will continue both during testing and eventually within the Medicare program once model features are found to be successful and introduced nationwide. For example, ACOs could potentially exist alongside:

- Episodic payment, such as is being tested in the CJR and BPCI models
- Provider-specific value-based purchasing programs, as was found successful under the HHVBP model
- Disease-specific prevention and treatment programs, such as was found successful under the MDPP model
- Additional programs and payments available once additional models are found to be successful

[41] Donald Berwick and Rick Gilfillan. "Reinventing the center for Medicare and Medicaid innovation." *JAMA* 325, no. 13 (2021): 1247-1248

[42] Agency for Healthcare Research and Quality. "About the National Quality Strategy." March 2017. https://www.ahrq.gov/workingforquality/about/index.html

[43] Chiquita Brooks-LaSure, Elizabeth Folwer, Meena Seshamani, and Daniel Tsai. "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years." *Health Affairs,* August 2021. https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/

Striving for greater clarity and transparency about how models should ideally work together during testing could serve as a foundation for a better understanding of how successful features will be expected to co-exist in the Medicare program under a new National Healthcare Transformation Strategy. A focus on how models, and eventually features of Medicare, are expected to work together is essential to providing clear, aligned signals to providers about which aspects of their practice patterns the program would like them to change and how these revised practice patterns mesh together across different types of providers.

CMMI should tailor models to test ideas that address the largest areas of spending growth and key areas of quality concerns

It would be ideal to target models to the greatest areas of spending growth and quality concerns given that CMMI's:

- Statutory charge is to test models to determine if they reduce spending or improve quality
- Resources, while generous, are not infinite
- New Director has indicated an intention to test fewer models.

As CMMI allows current models to conclude and pares back the number of new models that are undertaken, it will be even more important than before that the smaller slate of models are targeted to address the biggest Medicare concerns, especially those that have not yet featured prominently in model design: Part C and Part D operations and spending, excessive provision of low-value care, and social determinants of health.

Only 6% of Medicare models include Part C, and 12% include Part D.

Should models that address Part C and Part D be a greater focus for CMMI?

Include Part D in models

In recent years, CMMI has introduced models focused on Part D, including the Part D Enhanced Medication Therapy Management model, the Part D Payment Modernization model, and the Part D Senior Savings model.[44] The models are welcome developments, but there remains untapped potential to incorporate Part D in additional models. Ideally, models that focus on caring for the whole person, use population-health based quality measures, and include Part A and Part B would also include Part D. Effectively managing prescription drug use, especially polypharmacy, is a critical element of high-quality, person-centered care for

[44] Health Management Associates. *Center for Medicare and Medicaid Innovation—Innovation Center Model Overview*. (May 11, 2021). Distributed by Health Management Associates.

Medicare. There are challenges to including Part D in models as not all beneficiaries are enrolled in a Part D plan and those that are enrolled in Part D are increasingly enrolled in Medicare Advantage prescription drug plans (MA-PD) that integrate Part C and Part D, and Part C enrollees are typically excluded from model attribution.[45] However, Part D is integral to high-quality care, while pharmacy benefit spending growth is of major concern for the Medicare program and to beneficiaries experiencing high out-of-pocket costs, that it is imperative to find ways to address these challenges.

Include Part C in models

A large and growing share of Medicare beneficiaries are enrolled in Part C managed care plans. Currently, there is one model focused on Part C, the Medicare Advantage Value-Based Insurance Design model.[46] Most other models exclude Medicare beneficiaries who are enrolled in Part C, which may unduly separate Medicare Part C and Medicare fee-for-service (FFS) testing of ideas, limit the size of the population included in model sample sizes, and limit the potential impact of any successful models if their features are introduced into the FFS Medicare program while making them optional for Medicare Advantage (MA) plans. One solution may be to design more models as multi-payer and include as many MA plans in these models as possible. When MA plans participate, it would be helpful to highlight the experience of these beneficiaries versus those in FFS in independent evaluation reports and the Innovation Center's bi-annual reports to Congress.

Promote primary care as a counterbalance to excessive low-value care

Primary care is vital to a high-quality healthcare system that effectively coordinates patient care. Having a regular source of primary care is associated with high-value care, better access, and better care experience.[47] The Innovation Center has implemented 11 models that include Medicare in the category "primary care transformation."[48] (Note that ACOs are included in a separate category "accountable care," which may or may not include efforts to promote primary care relative to other services.) The three most recent ones: CPC+, Global and Professional Direct Contracting (GPDC), and Primary Care First include the most flexibility

[45] Medicare Payment Advisory Commission. " The Medicare prescription drug program (Part D): Status report." In Washington, DC: Report to the Congress: Medicare Payment Policy. (March 2021).

[46] Health Management Associates. *Center for Medicare and Medicaid Innovation—Innovation Center Model Overview*. (May 11, 2021). Distributed by Health Management Associates.

[47] David M. Levine, Bruce E. Landon, and Jeffrey A. Linder. "Quality and experience of outpatient care in the United States for adults with or without primary care." *JAMA internal medicine* 179, no. 3 (2019): 363-372.

[48] Jennifer Podulka and Yamini Narayan. "Issue Brief #1: Center for Medicare and Medicaid Innovation: Findings from Medicare Models To-Date." *Health Management Associates,* June 2021. https://www.healthmanagement.com/wp-content/uploads/HMA-AV-Issue-Brief-1-CMMI-findings.pdf.

and support for providers to date.[49,50,51] The Innovation Center may wish to further accelerate and expand the testing of these models or future models focused on primary care. The COVID-19 public health emergency has underscored the importance of robust primary care. Yet Medicare struggles to promote primary care relative to specialty care, and as a result, beneficiaries report greater difficulty finding a primary care provider (38% of those who sought an appointment) than a specialist (20%).[52] Studies suggest that a stronger primary care system could help to address the problem of excessive delivery of low-value care—services that "have been found to provide little to no clinical benefit on average, either in general or in specific clinical scenarios."[53] Overuse of low-value care harms patients and contributes to waste in the healthcare system by as much as 25%.[54,55] Low-value care

Address social determinants of health and other drivers of quality and access disparities

Incoming CMS leadership recently "acknowledge[d] health equity as a central goal…of the health system that we are collectively striving toward."[56] They listed as the first of six key takeaways of the Center's first decade of experience "The Innovation Center should make equity a centerpiece of every model." They committed to "embed equity in every aspect of [Innovation Center] models by seeking to include more providers serving low- and modest-income, racially diverse, and/or rural populations." We applaud this pledge and encourage the Innovation Center to seek additional opportunities to embed equity in every aspect of models, such as ensuring that these same populations are adequately represented among the beneficiaries attributed to models and requiring independent evaluators to report all performance measures in the aggregate as well as with details for various populations.

[49] Centers for Medicare and Medicaid Innovation Center. "Comprehensive Primary Care Plus. "July 2021. https://innovation.cms.gov/innovation-models/comprehensive-primary-care-plus

[50] Centers for Medicare and Medicaid Innovation Center. "Global and Professional Contracting (GPDC) Model." May 2021. https://innovation.cms.gov/innovation-models/gpdc-model

[51] Centers for Medicare and Medicaid Innovation Center. "Primary Care First Model Options." July 2021. https://innovation.cms.gov/innovation-models/primary-care-first-model-options

[52] Medicare Payment Advisory Commission. "Physician and other professional services." In Washington, DC: Report to the Congress: Medicare and the Health Care Delivery System. (2021).

[53] Aaron Schwartz, Bruce Landon, Adam Elshaug, Michael Chernew, and J. Michael McWilliams. Measuring low-value care in Medicare. JAMA Intern Med. 2014;174(7):1067-1076. doi:10.1001/jamainternmed.2014.1541

[54] Aaron Baum, Andrew Bazemore, et al. "Primary Care Physicians and Spending on Low-Value Care," *Annals of Internal Medicine* Vol 174, issue 6 (June 2021) 875-878. https://www.acpjournals.org/doi/10.7326/M20-6257

[55] William Shrank, Teresa Rogstad, and Natasha Parekh. "Waste in the US Health Care System Estimated Costs and Potential for Savings," *JAMA* (October 7, 2019) 322(15):1501-1509. doi:10.1001/jama.2019.13978 https://jamanetwork.com/journals/jama/article-abstract/2752664?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jama.2019.13978

[56] Chiquita Brooks-LaSure, Elizabeth Folwer, Meena Seshamani, and Daniel Tsai. "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years." *Health Affairs,* August 2021. https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/

Congress and HHS Should Revisit the Physician-Focused Payment Model Technical Advisory Committee (PTAC)

In 2015, Congress created the Physician-Focused Payment Model Technical Advisory Committee (PTAC) through the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015.[57] PTAC is charged with issuing comments and recommendations to the Secretary of HHS on proposals for physician-focused payment models submitted to it by individuals and stakeholder entities. MACRA requires the Secretary to review PTAC's comments and recommendations on submitted proposals and post a detailed response on the CMS website. The Secretary has posted reviews but has yet to implement any of PTAC's recommendations.[58] Given the resources devoted to the PTAC process, it would be preferrable if some recommendations helped to inform future Innovation Center models. To improve the likelihood of PTAC's recommendations' success in the future, Congress and the Secretary may wish to review and modify the Committee's role and processes. If a more effective approach does not prove possible, it may not make sense to continue the PTAC.

CMMI authority

The CMMI statute requires that the Secretary terminate or modify CMMI models before testing is completed if the Secretary determines that a model is not expected to fulfill spending and quality goals (and CMS's Chief Actuary agrees with the spending expectations).[59] This process has been implemented multiple times, and recently the Innovation Center has also paused several models for review. Given the number of long-running models and the share of CMMI resources that are devoted to existing models versus new ones, the Secretary should consider if there are additional opportunities to terminate or modify CMMI models. Modifying models could be the preferred option for promising new models. Model participants and CMMI tend to experience an adjustment period during the first year or two and learn lessons that could inform modifications to the model design that may increase the likelihood of a successful outcome.

CMMI's statutory authority is clearly delineated to include determining that expanding a model would either:

- Reduce spending without reducing quality of care, or
- Improve quality of care without increasing spending.[60]

[57] Medicare Access and CHIP Reauthorization Act of 2015. "Public Law 114–10" In 114th Congress. (2015) https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf

[58] "Physician-Focused Payment Models (PFPMs): Secretary's Response to Proposals," Centers for Medicare & Medicaid Services, last updated on: 06/09/2021, https://innovation.cms.gov/innovation-models/pfpms

[59] "Compilation of the Social Security Laws: Center for Medicare and Medicaid Innovation." Social Security Administration, accessed May 28, 2021, https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm

[60] "Compilation of the Social Security Laws: Center for Medicare and Medicaid Innovation." Social Security Administration, accessed May 28, 2021, https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm

Furthermore, the Secretary must determine that the expansion would not deny or limit the coverage or provision of benefits under Medicare, Medicaid, or CHIP.[61] We note that various groups of Medicare beneficiaries, such as those who are racially or ethnically diverse or live in rural areas, currently do not generally experience the same benefits of Medicare as other beneficiaries. Congress may wish to consider legislation to include equity as a third criterion in CMMI's mandate and include an option to allow the Secretary to approve models that improve quality and equity while minimally increasing spending.

Looking Forward

Despite the relatively small number of models that were found to be successful during the first decade of CMMI operations, much has been learned about what works and what does not. Hopefully these lessons will serve to inform the design of models over the next decade so that even more of them achieve cost savings and quality improvement and can be introduced into the Medicare program nationwide. We eagerly await release of additional information about CMS's vision for the future of the Innovation Center to improve care for all Medicare beneficiaries. We acknowledge the challenge of balancing competing goals for the Innovation Center's work and hope that the recommendations we offer here may contribute to an even more successful second decade.

[61] "Compilation of the Social Security Laws: Center for Medicare and Medicaid Innovation." Social Security Administration, accessed May 28, 2021, https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm