United States Government Accountability Office

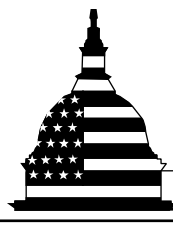
GAO

Report to Congressional Requesters

November 2012

CMS INNOVATION CENTER

Early Implementation Efforts Suggest Need for Additional Actions to Help Ensure Coordination with Other CMS Offices



G A O

Accountability * Integrity * Reliability

GAO-13-12

November 2012

CMS INNOVATION CENTER

Early Implementation Efforts Suggest Need for Additional Actions to Help Ensure Coordination with Other CMS Offices

GAO Accountability * Integrity * Reliability

Highlights

Highlights of GAO-13-12, a report to congressional requesters

Why GAO Did This Study

PPACA created the Innovation Center within CMS. The purpose of the Innovation Center is to test new approaches to health care delivery and payment—known as models—for use in Medicare or Medicaid.

GAO was asked to review the implementation of the Innovation Center. Specifically, GAO: (1) describes the center's activities, funding, organization, and staffing as of March 31, 2012; (2) describes the center's plans for evaluating its models and its own performance; and (3) examines whether efforts of the center overlap with those of other CMS offices and how the center coordinates with other offices. GAO analyzed budget and staffing data; reviewed available documentation, such as Innovation Center policies and procedures and functional statements for CMS offices; and interviewed officials from the Innovation Center and other CMS offices, such as the Center for Medicare. GAO assessed how the Innovation Center coordinates in the context of federal internal control standards and key practices for collaboration from prior GAO work.

What GAO Recommends

GAO is recommending that the Administrator of CMS direct the Innovation Center to expeditiously complete its process to review and eliminate any areas of unnecessary duplication in contracts that have been awarded in one of its models. HHS agreed with this recommendation and described steps it is taking to address unnecessary duplication.

View GAO-13-12. For more information, contact Linda Kohn at (202) 512-7114 or kohnl@gao.gov.

What GAO Found

From the time it became operational in November 2010, through March 31, 2012, the Center for Medicare and Medicaid Innovation (Innovation Center) has focused on implementing 17 new models to test different approaches for delivering or paying for health care in Medicare and Medicaid. The center is still relatively early in the process of implementing these models. Eleven of the models were selected by the Innovation Center under the provision in the Patient Protection and Affordable Care Act (PPACA) that established the center, while the remaining 6 were specifically required by other PPACA provisions. The Innovation Center projects that a total of $3.7 billion will be required to fund testing and evaluation of the 17 models, with the expected funding for individual models ranging from $30 million to $931 million. As of March 2012, the center's 184 staff were organized into four groups responsible for coordinating the implementation of different models and another five groups responsible for key functions that support model implementation. Officials said that, among other things, the center's initial hiring of staff reflected the need for leadership and for specific types of expertise, such as individuals with a background in evaluation.

The Innovation Center's plans for evaluating individual models include identifying measures related to the cost and quality of care. Officials from the Centers for Medicare & Medicaid Services (CMS) told GAO that the Innovation Center had developed preliminary evaluation plans for the 17 models being implemented that, among other things, identified proposed measures. According to CMS officials, these measures will be finalized by contractors responsible for evaluating, on behalf of CMS, each model's impact on cost and quality. As of August 1, 2012, the Innovation Center had contracted for the evaluation of 10 of the 17 models. The center's plans for evaluating its own performance include aggregating data across models by using a set of core measures it has developed. In addition, the Innovation Center has taken steps to monitor its progress in implementing the 17 models through biweekly reviews of standard milestones and related data, such as the number of applications to participate in a model the center has received.

GAO identified three key examples of overlap between the 17 Innovation Center models and the efforts of other CMS offices, meaning that the efforts share similar goals, engage in similar activities or strategies to achieve these goals, or target similar populations. However, these overlapping efforts also have differences, and CMS officials said the efforts are intended to be complementary to each other. GAO also identified a number of mechanisms the Innovation Center uses to coordinate its work in order to avoid unnecessary duplication between its models and other efforts, such as multi-office meetings at the staff, director, and agency level. Further, through using these mechanisms, the Innovation Center has engaged in key practices for collaboration, including leveraging resources across offices. At the same time, the center is still working on ways to make its coordination more systematic. For example, largely because of questions raised during GAO's review, the Innovation Center initiated a process to ensure that CMS does not pay for the same service under the contracts in one of its models and those in another CMS office. However, officials told GAO that the center is still working on implementing this process and may need to take additional steps to eliminate any unnecessary duplication.

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Abbreviations

ACO	Accountable Care Organization
CCSQ	Center for Clinical Standards and Quality
CMCS	Center for Medicaid and CHIP Services
CMS	Centers for Medicare & Medicaid Services
GS	General Schedule
HEN	Hospital Engagement Network
HHS	Department of Health and Human Services
ICIP	Innovation Center Investment Proposal
Innovation Center	Center for Medicare and Medicaid Innovation
OMB	Office of Management and Budget
ORDI	Office for Research, Development and Information
PPACA	Patient Protection and Affordable Care Act
QIO	Quality Improvement Organization

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

November 15, 2012

The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Tom Coburn
Ranking Member
Permanent Subcommittee on Investigations
Committee on Homeland Security and Governmental Affairs
United States Senate

Spending on health care in the United States reached $2.6 trillion in 2010 and is expected to increase, with federal spending—driven primarily by expenditures for Medicare and Medicaid—accounting for a growing percentage of the total.[1] Complicating these trends, recent evidence suggests that higher levels of health care spending do not always lead to enhanced quality of care.[2] As a result, policymakers have sought to both

[1]Medicare is the federal health insurance program for persons aged 65 or over, individuals under the age of 65 with certain disabilities, and individuals with end-stage renal disease. Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals. The State Children's Health Insurance Program is a federal-state program that provides health care coverage to children 18 years of age and younger living in low-income families whose incomes exceed the eligibility requirement for Medicaid. For this report we use the term "Medicaid" to include both Medicaid and the State Children's Health Insurance Program.

[2]See for example, E. S. Fisher and H. G. Welch, "Avoiding the Unintended Consequences of Growth in Medical Care: How Might More Be Worse?" *Journal of the American Medical Association*, vol. 281, no. 5 (1999): 446-453; E. S. Fisher et al., "The Implications of Regional Variations in Medicare Spending; Part 1: The Content, Quality, and Accessibility of Care," *Annals of Internal Medicine*, vol. 138, no. 4 (2003): 273-287; E. S. Fisher et al.,"The Implications of Regional Variations in Medicare Spending; Part 2: Health Outcomes and Satisfaction with Care," *Annals of Internal Medicine*, vol. 138, no. 4 (2003): 288-298; and Joseph P. Newhouse and the Insurance Experiment Group, *Free for All? Lessons from the RAND Health Insurance Experiment* (Cambridge, Mass.: Harvard University Press, 1993).

reduce costs and improve quality by researching ways of changing how health care services are delivered and health care providers are paid. To identify approaches that work, policymakers need credible information on the effects of the approaches on cost and quality. In 2010, the Patient Protection and Affordable Care Act (PPACA) created the Center for Medicare and Medicaid Innovation (Innovation Center) within the Centers for Medicare & Medicaid Services (CMS)—the agency within the Department of Health and Human Services (HHS) that administers Medicare and Medicaid.[3] The purpose of the Innovation Center is to test new approaches to health care delivery and payment—known as models—in order to reduce Medicare and Medicaid expenditures while preserving or enhancing quality of care for beneficiaries of the programs.[4] Although CMS conducted similar testing through demonstrations prior to PPACA, the recent law provides the Innovation Center with additional authority.[5] For example, unlike for demonstrations CMS has frequently conducted in the past, models tested under the provision establishing the Innovation Center can, under certain conditions, be expanded—including on a nationwide basis—through rulemaking instead of requiring legislation.[6] In addition, PPACA significantly increased the funding available to CMS to test new approaches. According to an analysis by the Medicare Payment Advisory Commission, CMS's funding for research, demonstrations, and evaluations has historically been appropriated annually, and was less than $1 billion for the period of fiscal years 2000

[3]Pub. L. No. 111-148, §§ 3021, 10306, 124 Stat. 119, 389, 939 (codified at 42 U.S.C. § 1315a).

[4]Tests of models are initially limited in duration and put into effect through agreements with participants, such as providers, that may be located in several geographic areas or be specific to particular areas. Participants apply and are selected by the Innovation Center generally through a competitive process and may enter into a variety of agreements, such as grants and cooperative agreements.

[5]Historically, CMS's efforts to test new approaches to health care delivery and payment have been referred to as "demonstrations." In this report, we will use the term "models" when discussing approaches initiated by the Innovation Center, and "demonstrations" when discussing approaches that were initiated prior to the establishment of the Center.

[6]Another important difference is that while approval of prior demonstrations has generally been contingent on a determination of budget neutrality—that is, that estimated federal expenditures under the model are expected to be no more than they would have been without the model— PPACA provides that HHS cannot make such a requirement for models tested under the provision establishing the Innovation Center.

through 2010.[7] In contrast, PPACA provided the Innovation Center with a dedicated source of funding, appropriating $10 billion for its activities for the period of fiscal years 2011 through 2019 and $10 billion per decade beginning in fiscal year 2020.[8]

PPACA required CMS to make the Innovation Center operational by January 1, 2011, and the center became operational in November 2010. Since that time, some members of Congress have raised questions about the extent to which models the Innovation Center has selected for testing will lead to reduced costs and improved quality in health care, particularly given the amount appropriated for its work. They have also raised questions about the potential for overlap between efforts of the Innovation Center and those of existing centers and offices within CMS,[9] which, if not effectively coordinated, could result in the inefficient use of federal resources through unnecessary duplication.[10] We were asked to review the implementation of the Innovation Center. In this report, we: (1) describe the Innovation Center's activities, funding, organization, and staffing; (2) describe the Innovation Center's plans for evaluating its models and its own performance; and (3) examine whether efforts of the Innovation Center overlap with those of other CMS offices and assess how the center coordinates with other offices.

To describe the Innovation Center's activities, funding, organization, and staffing, we focused our review on information as of March 31, 2012—about 2 years after the enactment of PPACA. We reviewed documents,

[7]See Medicare Payment Advisory Commission, *Report to Congress: Aligning Incentives in Medicare* (Washington, D.C.: 2010).

[8]PPACA also appropriated $5 million for fiscal year 2010 activities. Amounts appropriated by PPACA are to remain available until expended.

[9]For the purposes of this report, we refer to both centers and offices within CMS as offices.

[10]We have previously defined "overlap" as occurring when two or more agencies or programs have similar goals, engage in similar activities or strategies to achieve them, or target similar beneficiaries, and observed that while some degree of overlap may be warranted due to the nature or magnitude of the federal effort, overlap can also result in unnecessary duplication of efforts. We have previously defined "duplication" as occurring when two or more agencies or programs are engaged in the same activities or provide the same services to the same beneficiaries. See GAO, *2012 Annual Report: Opportunities to Reduce Duplication, Overlap and Fragmentation, Achieve Savings, and Enhance Revenue*, GAO-12-342SP (Washington, D.C.: Feb. 28, 2012).

including information on models the center was implementing as of this date, and planning documents, such as organizational charts.[11] We also reviewed budget and staffing data for the Innovation Center. We interviewed knowledgeable agency officials about their efforts to ensure the quality of the data, checked for anomalies, and determined these data were sufficiently reliable for our purposes. In order to obtain more in-depth information on center activities, we reviewed examples of the types of documents used in implementing models, such as a model's Innovation Center Investment Proposal (ICIP), which is the document developed to obtain approval for models or initiatives. Finally, we interviewed Innovation Center officials and officials in CMS's Office of Financial Management.

To describe the Innovation Center's plans for evaluating its models and its own performance, we reviewed documents, such as descriptions of the center's model evaluation process and internal tracking documents. We also reviewed examples of more-detailed information, such as documents discussing evaluation plans for individual models the center was implementing as of March 31, 2012, and reviewed information on the center's progress in evaluating models. In addition, we reviewed the statement of work for a contractor to evaluate the Innovation Center's operations. To supplement this information, we interviewed Innovation Center officials and officials from CMS's Office of the Actuary.

To examine whether efforts of the Innovation Center overlap with those of other CMS offices and assess how the center coordinates with other offices, we reviewed the key functions of all offices within CMS, using information that was available on CMS's website to identify areas of potential overlap. We then interviewed Innovation Center officials, as well as officials from other CMS centers and offices, including the Center for Medicare, the Center for Clinical Standards and Quality (CCSQ), and the Center for Medicaid and CHIP Services (CMCS), to obtain more-specific information about the efforts they conduct. On the basis of these interviews and review of related documentation, such as statements of

[11]Model implementation involves a period of planning and development followed by a period of testing and evaluation. Planning and development include a series of steps, such as developing an evaluation approach and obtaining approval from CMS, HHS, and the Office of Management and Budget (OMB). Testing and evaluation also includes a series of steps, such as the collection of cost and quality data and sharing feedback with model participants.

work for program contractors, we assessed whether Innovation Center models being implemented as of March 31, 2012, had similar goals, engaged in similar activities or strategies to achieve these goals, or targeted similar beneficiaries as the efforts of other CMS offices. While efforts identified in this report may not represent the full universe of overlapping efforts between the Innovation Center and other CMS offices, we conducted a systematic examination to identify key examples of where overlap may have occurred. Finally, we interviewed the same officials to obtain information on how the Innovation Center coordinates its efforts with other CMS offices, and reviewed corroborating documentation, such as center policies and procedures, when available. We assessed how the center coordinates within the context of federal internal control standards and key practices for collaboration identified in prior GAO work.[12] According to federal internal control standards, an entity should, among other things, have the policies and procedures necessary to provide reasonable assurance of the effectiveness and efficiency of its operations, including the use of resources, and ensure that these policies and procedures are appropriately documented.[13]

We conducted our performance audit from February 2012 through November 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[12]These collaboration practices are: (1) defining and articulating a common outcome; (2) establishing mutually reinforcing or joint strategies; (3) identifying and addressing needs by leveraging resources; (4) agreeing on roles and responsibilities; (5) establishing compatible policies, procedures, and other means to operate across agency boundaries; (6) developing mechanisms to monitor, evaluate, and report on results; (7) reinforcing agency accountability for collaborative efforts through agency plans and reports; and (8) reinforcing individual accountability for collaborative efforts through performance-management systems. See GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

[13]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

Background

While PPACA gives CMS discretion in how to implement the Innovation Center, such as the composition of its staff, the law also established certain requirements for the center. For example, PPACA requires that, in carrying out its duties described in the law, the Innovation Center consult with representatives of relevant federal agencies and clinical and analytical experts with expertise in medicine or health care management. It also requires that, of amounts appropriated to the center, the center make no less than $25 million available for model implementation each fiscal year starting in 2011. In addition, PPACA requires that the Innovation Center evaluate each model to measure its effects on spending and quality of care, and that these evaluations be made public. Further, PPACA requires the Innovation Center to modify or terminate a model any time after testing and evaluation has begun unless it determines that the model either improves quality of care without increasing spending levels, reduces spending without reducing quality, or both.

In addition to these requirements, when selecting models, PPACA requires the Innovation Center to determine that a model addresses a situation in which deficits in care were leading to poor clinical outcomes or unnecessary spending. The law also describes types of models that the Innovation Center could consider in selecting models to test; however the center is not limited to this list. Examples of model types include changing the way primary care providers are reimbursed for services and improving care for patients recently discharged from the hospital. PPACA also directs that in selecting models, the Innovation Center give preference to those that improve the coordination, quality, and efficiency of health care services and lists additional factors for consideration, such as whether the model uses certain technology to help achieve its goals.

Finally, PPACA also makes certain requirements not applicable to models tested under the provision establishing the Innovation Center that were applicable to demonstrations CMS has frequently conducted in the past. For example, while prior demonstrations generally required legislation in order to be expanded, PPACA allows CMS to expand Innovation Center models more broadly into Medicare or Medicaid—including on a nationwide basis—through the rulemaking process if the following conditions are met: (1) the agency determines that the expansion is expected to reduce spending without reducing the quality of care or improve quality without increasing spending, (2) CMS's Office of the

Actuary certifies that the expansion will reduce or not increase net spending, and (3) the agency determines that the expansion would not deny or limit coverage or benefits for beneficiaries.[14] In addition, PPACA makes inapplicable certain requirements that have previously been cited as administrative barriers to the timely completion of demonstrations.[15] Specifically, PPACA provides the following:

- HHS cannot require that an Innovation Center model be budget neutral, that is, designed so that estimated federal expenditures under the model are expected to be no more than they would have been without the model, prior to approving a model for testing.

- Certain CMS actions in testing and expanding Innovation Center models cannot be subject to administrative or judicial review. For example, the selection of models for testing or expansion is not subject to review by the agency or the courts.

- The Paperwork Reduction Act does not apply to Innovation Center models. Under the Paperwork Reduction Act, agencies generally are required to submit all proposed information collections to the Office of Management and Budget (OMB) for approval and provide a 60-day period for public comment on collections, among other things, when they want to collect data on 10 or more individuals.[16]

[14]In addition, PPACA provides that demonstrations conducted under 42 U.S.C. § 1395cc-3 may also be expanded under the same conditions. 42 U.S.C. § 1315a(c). These demonstrations comprise Medicare's Health Care Quality Demonstration Program.

[15]See for example Medicare Payment Advisory Commission, *Report to Congress: Aligning Incentives in Medicare*, (Washington, D.C.: 2010).

[16]44 U.S.C. §§ 3501-3520.OMB assists the President in overseeing the preparation of the federal budget and in supervising its administration in executive branch agencies. OMB also oversees and coordinates the administration's procurement, financial management, information, and regulatory policies.

The Innovation Center's Activities, Funding, Organization, and Staffing Focused on Implementing 17 New Models

From the time it became operational in November 2010, through March 31, 2012, the Innovation Center's activities and use of funding focused on implementing 17 new models to test different approaches to health care delivery and payment in Medicare and Medicaid. During this period, the Innovation Center hired and organized staff into groups to implement models and to provide for the key functions that support model implementation.

Innovation Center Activities and Funding Have Focused on Implementing 17 New Models

From the time it became operational in November 2010, through March 31, 2012, the Innovation Center announced the implementation of 17 new models[17] designed to test different approaches to health care delivery and payment in Medicare and Medicaid.[18] These models generally fall into three different types on the basis of the delivery and payment approaches tested. The center's "Patient care" models test approaches that are designed around improving care for clinical groups of patients such as patients needing heart bypass surgery. "Seamless care" models test approaches designed to improve coordination of care for a patient population across care settings, such as the coordination of inpatient and outpatient care for all of a provider's Medicare beneficiaries. "Preventive care" models test approaches designed to improve health, such as incentive programs to prevent smoking. The 17 models vary by the program and beneficiaries targeted. For example, some target Medicare or Medicaid beneficiaries specifically, whereas others are open to beneficiaries of either program. In addition, three models have been designed to target individuals who are covered by both Medicare and Medicaid. The models also vary in terms of the types of participants

[17]While there are 17 models, each model may include multiple strategies for achieving changes in health care delivery or payment. For example, Innovation Center models may engage broad segments of the health care delivery system simultaneously, including multiple delivery settings, purchasers, or consumers. In another example, 1 of the 17 models—Strong Start for Mothers and Newborns—tests, among other things, three different ways of providing enhanced prenatal care.

[18]In addition, the Innovation Center launched two other initiatives intended to support innovation. These initiatives are not models because they did not involve a test of a particular payment or delivery approach. For example, the Innovation Advisors Program provides training and support to individuals across the country so that they can help their organizations implement new approaches to care delivery.

involved, ranging, for example, from physician group practices to Federally Qualified Health Centers, to health plans, to state Medicaid programs.[19]

Of these 17 models, 11 were selected by the Innovation Center under the PPACA provision that established the center and, as a result, certain requirements that have applied to demonstrations CMS has frequently conducted in the past are not applicable to these models. The Innovation Center selected the 11 models for implementation by reviewing model types identified in PPACA and ideas submitted by CMS staff as well as through a variety of mechanisms designed to obtain ideas from beneficiaries, providers, payers, state policymakers and others.[20] Selection criteria—which are available to the public on the Innovation Center's website—include focusing on health conditions that offer the greatest opportunity to improve care and reduce costs, and meeting the needs of the high-admission-rate hospitals most vulnerable populations.

The remaining six new models the Innovation Center is implementing were specifically required by other PPACA provisions. For example, the center is implementing a model required by PPACA that tests whether partnerships between and community-based organizations can improve transition care services for Medicare beneficiaries.[21] The degree of flexibility that the Innovation Center has in implementing these six models varies by each model's specific statutory authority.[22]

[19]Federally Qualified Health Centers are health centers that have received a "Federally Qualified Health Center" designation from CMS and provide comprehensive community-based primary and preventive care services in medically underserved areas or to medically underserved populations. Federally Qualified Health Centers must meet certain federal requirements and enjoy certain federal benefits, such as enhanced Medicaid reimbursement rates.

[20]These mechanisms included the Innovation Center's online web program and "listening session" meetings held across the country in 2010.

[21]Pub. L. No. 111-148, § 3026, 124 Stat. at 413 (codified at 42 U.S.C. § 1395b-1 note).

[22]For example, for the Independence at Home model, PPACA provides that the Innovation Center may waive such provisions of titles XVIII and XI of the Social Security Act as is determined necessary to implement the program. 42 U.S.C. § 1395cc-5. In contrast, the Treatment of Certain Complex Diagnostic Tests model does not include this broad waiver authority. 42 U.S.C. § 1395l note. See app. I for more information on these models.

The Innovation Center projects that the total funding required to test and evaluate these 17 models will be $3.7 billion over their lifetime, including $2.7 billion for the 11 models selected by the Innovation Center and $1.0 billion for the 6 models specifically required by other provisions of PPACA.[23] The expected funding for individual models ranges from $30 million to $931 million, depending on model scope and design. Officials said that the period required to test and evaluate an individual model typically ranges from 3 to 5 years. With regard to the Innovation Center's annual expenditures, as of March 31, 2012, the Innovation Center forecast that most of its fiscal year 2012 budget—or 76.8 percent—would be spent implementing the 11 models that were selected for implementation by the Innovation Center.[24] Table 1 provides funding information on the 17 Innovation Center models, including total funding for models over their lifetime, by model type. Appendix I provides additional information about individual models.

[23]These estimates include programmatic costs, such as payment to providers, and acquisition costs, such as contracts to support testing and evaluation of models. They do not include administrative costs, such as CMS staff salaries.

[24]The Innovation Center's total fiscal year 2012 budget was expected to be $1.2 billion. Outside of the money spent implementing the 11 models, 13.8 percent of the budget was expected to be spent on implementing the other 6 PPACA models and on other demonstrations that predated the Innovation Center. An estimated 5.7 percent was expected to be spent on programmatic resources that support all models and 3.7 percent was expected to be spent on administrative costs that are not included in implementation costs. The Innovation Center's annual funding comes primarily from the appropriation in the PPACA provision establishing the center. However, the center also receives funding from amounts specified in other sections of PPACA for the testing of specific models provided for in those sections. Finally, the center receives funding from the annual appropriation for CMS.

Table 1: Number of Models and Total Funding over Lifetime by Model Type, as of March 31, 2012

Model type	Number of models of this type	Total funding in millions of dollars[a]
Models selected by the Innovation Center		
Patient care[b]	4	**$889**
Seamless care[c]	6	**837**
Preventive care[d]	—	**—**
Other[e]	1	**931**
Subtotal	**11**	**2,657**
Models specifically required by PPACA		
Patient care[b]	3	**380**
Seamless care[c]	2	**530**
Preventive care[d]	1	**100**
Subtotal	**6**	**1,010**
Total	**17**	**$3,667**

Source: GAO analysis of CMS data.

Notes: Section 3021 of PPACA established the Innovation Center and authorized the selection of models to test using the funds appropriated to it in that section. Pub. L. No. 111-148, §§ 3021, 10306, 124 Stat. 119, 389, 939 (codified at 42 U.S.C. § 1315a). For models selected by the Innovation Center, the center obtains approval from CMS, HHS, and OMB for the amount it expects will be required to test and evaluate the models. In addition to the models selected by the Innovation Center, there are models specifically required by other PPACA provisions that the Innovation Center is responsible for implementing. For these models, the funding amount is the amount appropriated in each model's PPACA provision.

[a]Includes programmatic costs, such as payment to providers, and acquisition costs, such as contracts to support testing and evaluation of models. Does not include administrative costs, such as CMS staff salaries.

[b]Patient care models test approaches to health care delivery and payment that are designed around improving care for clinical groups of patients such as patients needing heart bypass surgery.

[c]Seamless care models test approaches designed to improve coordination of care for a patient population across care settings.

[d]Preventive care models test approaches designed to improve health, such as incentive programs to prevent smoking.

[e]One model includes grants for multiple types of models.

Innovation Center Model-Implementation Process

Planning and Development

- Solicit ideas and select models to develop (except for models specifically required in PPACA).
- Develop an Innovation Center Investment Proposal that includes the proposed model design and evaluation approach.
- Obtain approval from CMS, HHS, and OMB, and announce model.
- Solicit, select, and establish agreements, such as grants or cooperative agreements, with participants, such as providers or health plans.
- Solicit and select contractors for testing and evaluating model (evaluation contractors are not always hired before testing begins).

Testing and Evaluation

- Conduct test of model in which participants and CMS put specified changes to health care delivery and payment into effect.
- Conduct evaluation of model, which includes evaluation while the test is ongoing, as well as completing a final evaluation of model outcomes.
- Determine whether to terminate, modify, or recommend expanding model, which can occur at any time during the testing and evaluation period depending on evaluation results (models specifically required in PPACA may require different steps in considering expansion).

As of August 1, 2012, the Innovation Center was still relatively early in the process of implementing the 17 models. CMS officials explained that this process includes a series of steps to develop and prepare the model for testing followed by a testing and evaluation period that is typically 3 to 5 years in which, among other things, participants and CMS put specified changes to health care delivery or payment into effect. (See sidebar.) While the Innovation Center had started testing 12 of the 17 models as of August 1, 2012, nearly all of these tests had started within the prior 12 months, and 5 had started within the prior 6 months.[25] Thus, the models still have a significant portion of their testing and evaluation period remaining. In addition, for the 5 models that had not yet started testing, the Innovation Center was still completing the steps necessary to start testing.[26] Appendix II provides additional information about the general process used to implement models.

In addition to the 17 models, the Innovation Center also assumed responsibility for 20 demonstrations that were initiated prior to the Innovation Center's formation. Responsibility for the demonstrations was moved to the Innovation Center in March 2011, when the demonstration and research and evaluation groups of CMS's former Office for Research, Development and Information (ORDI) were brought into the Innovation Center through reorganization.[27] As of August 1, 2012, testing of 9 of these 20 demonstrations had ended, although evaluation activities were still ongoing for 4 of them. The demonstrations were initiated under the Medicare Health Care Quality Demonstration Program which enables CMS to select which demonstrations to conduct,[28] or because they were

[25]Of the 12 models, 7 were selected by the Innovation Center under the PPACA provision that established the center, and the remaining 5 were specifically required by other PPACA provisions.

[26]Of the 5 models, 4 were selected by the Innovation Center under the PPACA provision that established the center, and the remaining 1 was specifically required by another PPACA provision.

[27]The remaining group within ORDI—the data group—was originally merged with CMS's Center for Strategic Planning and later with its Office for Enterprise Management.

Whereas most Medicare demonstrations were consolidated under the Innovation Center when it merged with parts of ORDI, state Medicaid demonstrations are overseen by CMCS. CMS officials said that where Medicare demonstrations are still being conducted outside of the Innovation Center, it is generally because the effort was already ongoing within an office other than ORDI when the Innovation Center was established.

[28]42 U.S.C. § 1395cc-3.

specifically required by various pre-PPACA statutes. Like the Innovation Center's models, the demonstrations test a range of delivery and payment approaches; for example, one demonstration tests the use of care management—a particular approach to coordinating and managing health services—for high-cost Medicare beneficiaries while another tests approaches for preventing and treating cancer among minorities in Medicare.

The Innovation Center's Organization and Staffing Reflect Its Focus on the 17 Models and Other Key Functions That Support Model Implementation

As of March 31, 2012, the Innovation Center's 184 staff were organized into nine groups and the Office of the Director. Four of the nine groups are generally responsible for coordinating the implementation of models. Three of these four groups—the Patient Care Models, Seamless Care Models, and Preventive Care Models Groups—focus on models selected by the Innovation Center under the PPACA provision that established the center.[29] The Medicare Demonstrations group is generally responsible for implementing models specifically required by other PPACA provisions as well as the CMS demonstrations that existed prior to the establishment of the Innovation Center. Staff in these four groups coordinate planning, develop model designs, and obtain approval for their models from CMS and HHS. Once a model is approved, staff in these groups coordinate the remaining implementation steps, including soliciting and selecting participants and overseeing the model during the testing and evaluation period.

The remaining five groups have primary responsibility for key functions that support model implementation. The Policy and Programs Group reviews ideas submitted for consideration as possible models and seeks to ensure a balanced portfolio of different types of models. The Rapid Cycle Evaluation Group is responsible for evaluation of models, including collecting data on and providing feedback to model participants about their performance. The Learning and Diffusion Group facilitates learning within models and disseminates the lessons learned across models so that participants can benefit from the experiences of other models. The

[29]However, as of March 31, 2012, 3 of the 11 models selected by the Innovation Center were targeted at beneficiaries of both Medicare and Medicaid and were coordinated by CMS's Federal Coordinated Health Care Office. Two models were coordinated by two of the other groups within the Innovation Center, the Learning and Diffusion Group and the Policy and Programs Group. One of the models selected by the Innovation Center was coordinated by the Medicare Demonstrations Group.

Stakeholder Engagement Group conducts outreach to potential stakeholders to gain support and solicit ideas for innovative models, as well as outreach to potential participants—such as physician groups and hospitals—to inform them of the opportunity to participate in models. The Business Services Group coordinates with other CMS centers and offices to provide administrative and business support to the Innovation Center in areas such as budgeting, contracting, and project management.

CMS officials explained that the 184 staff hired between the time the Innovation Center became operational in November 2010, and March 31, 2012, were distributed across the Office of the Director and the nine groups in part because of an initial need for expertise with certain model types and certain key functions. For example, because most of the models that the Innovation Center selected for implementation were Patient Care and Seamless Care Models, more staff were hired in those groups than in the Preventive Care Models Group.[30] Similarly, the Rapid Cycle Evaluation Group and the Business Services Group were among the largest groups by staff size because of (1) the Innovation Center's need for evaluation expertise when selecting which models to test as well as its responsibility for evaluating existing demonstrations and (2) the need for staff to carry out key administrative activities right away, including contract solicitation, budget development, and hiring. Because the Innovation Center assumed responsibility for prior CMS demonstrations, staff from ORDI, which was responsible for implementing the demonstrations, were reassigned to the Innovation Center to form the Medicare Demonstrations Group and part of the Rapid Cycle Evaluation Group. Table 2 provides information on the staff size for each group in the Innovation Center as of March 31, 2012.

[30]As of March 31, the Innovation Center had not yet announced a model coordinated by the Preventive Care Models Group; however CMS officials told us that this group is overseeing a number of approaches funded through the Health Care Innovation Awards model.

Table 2: Innovation Center Staff by Group, as of March 31, 2012

Office or group	Purpose	Total staff
Office of the Director	Manage the Innovation Center	**8**
Groups organized by type of model		
Seamless Care models	Develop Seamless Care models and coordinate implementation. Seamless care models test approaches designed to improve coordination of care for a general patient population across care settings.	**18**
Patient Care models	Develop Patient Care models and coordinate implementation. Patient care models test approaches designed around improving care for clinical groups of patients, such as patients needing heart bypass surgery.	**11**
Preventive Care models	Develop Preventive Care models and coordinate implementation. Preventive care models test approaches designed to improve health, such as incentive programs to prevent smoking.	**2**
Medicare Demonstrations	Coordinate implementation for models specifically required by other PPACA provisions and for demonstrations that existed before PPACA and the Innovation Center.	**29**
Groups organized by key function		
Rapid Cycle Evaluation	Coordinate evaluation of models including providing ongoing feedback to participants and final model evaluations.	**38**
Business Services	Coordinate with other CMS centers to provide administrative support for budgeting, contracting and project management.	**33**
Policy and Programs	Manage the intake of ideas, and help ensure balanced portfolio of models.	**9**
Learning and Diffusion	Communicate with model participants about what is working across models.	**27**
Stakeholder Engagement	Communicate with potential stakeholders and the public.	**9**
Total		**184**

Source: GAO analysis of CMS information.

CMS officials explained that initial hiring of staff also reflected other needs such as the need for rapid recruitment, the need to balance the number of staff with expertise in CMS policies and procedures with staff who had experience in the private sector, and the need for leadership to guide the development of the new center's activities.

Rapid recruitment: Approximately 40 percent of the staff working in the Innovation Center as of March 31, 2012, was brought on board within the first 5 months from when it became operational in November 2010.[31] In

[31]Of the staff brought on board within the first 5 months from when the Innovation Center became operational in November 2010, about 82 percent were reassignments from within CMS, and officials told us most of these were from ORDI.

order to help the center get started quickly, CMS gave the Innovation Center authority to hire staff directly until March 31, 2011, after which it followed standard hiring procedures. Of the 184 staff in CMMI as of March 31, 2012, 64 had been hired through the Innovation Center's direct-hire authority.

Balancing the need for CMS expertise with expertise in the private sector: CMS officials said the Innovation Center sought a balance of staff who had expertise with CMS policies and procedures and staff from outside of the agency in the private sector. Of the staff on board as of March 31, 2012, about 54 percent were reassignments from within CMS, while about 46 percent were new hires from outside of the agency, and officials explained that most of these were from the private sector.

Leadership: During its first year, CMS officials said the center sought to build its leadership. When compared with data for CMS as a whole for 2011, the distribution of the center's staff as of March 31, 2012, shows a higher percentage of Innovation Center staff at the General Schedule (GS)-15 employment level,[32] which is one of the higher management levels.[33] Specifically, 23.4 percent of the Innovation Center's staff were in the GS-15 level, compared with 11.5 percent for CMS as a whole. At the same time, the proportion of staff at other upper levels, including the Senior Executive Service level, in the Innovation Center was similar to that of CMS as a whole. Table 3 provides information about Innovation Center staff by employment level as of March 31, 2012.

[32]The General Schedule is a classification and pay system for civilian Federal employees. The General Schedule has 15 grades—GS-1 (lowest) to GS-15 (highest). Senior Executive Service positions are Federal employee positions that are classified above GS-15.

[33]CMS Officials told us that the higher level of staff at the GS-15 level reflects a higher concentration of researchers at the Ph.D. and master's degree level supporting Innovation Center functions.

Table 3: Innovation Center Staff and CMS Staff by Employment Level

Federal General Schedule (GS) employment level[a]	Innovation Center (as of 3/31/12)		CMS (as of 9/30/11)	
	Number	Percentage	Number	Percentage
GS Grades 1–8	4	2.2%	134	3.1%
GS-9	16	8.7	194	4.5
GS-10	0	0.0	1	< 0.1
GS-11	19	10.3	221	5.1
GS-12	12	6.5	723	16.7
GS-13	60	32.6	1899	43.8
GS-14	22	12.0	586	13.5
GS-15	43	23.4	499	11.5
Senior Executive Service	2	1.1	74	1.7
Other	6	3.3	0	0.0
Total	**184**	**100%**	**4331**	**100%**

Source: GAO analysis of CMS data.

Notes: Percentages do not add to 100 due to rounding.

[a]The General Schedule is a classification and pay system for civilian federal employees. The General Schedule has 15 grades—GS-1 (lowest) to GS-15 (highest). Senior Executive Service positions are federal employee positions that are classified above GS-15.

CMS officials said that the Innovation Center plans to hire additional staff with an emphasis on hiring into the three groups—the Seamless Care, Patient Care, and Preventive Care Models groups—that focus on models selected by the Innovation Center. Officials told us that the center's goal is to have a total of 338 staff and noted that, compared to initial hiring, which focused on staff at leadership levels, future hiring will emphasize lower GS levels.[34]

[34]Officials said that the Innovation Center had received approval from OMB for funding to hire 125 staff in addition to the 154 staff it had on board as of January 1, 2012.

The Innovation Center's Evaluation Plans Include Identifying Measures, Hiring Contractors, and Aggregating Data across Models

The Innovation Center's plans for evaluating its models include identifying measures related to the cost and quality of care and hiring contractors to evaluate the models. The Innovation Center's plans for evaluating its own performance include aggregating data on cost and quality measures to determine the overall impact of the center and monitoring its progress implementing models.

The Innovation Center's Plans for Evaluating Models Include Identifying Measures Related to the Cost and Quality of Care and Hiring Contractors

As part of its evaluation of individual models, the Innovation Center plans to identify measures related to the cost and quality of care. CMS officials said that, as of August 1, 2012, the Innovation Center had developed preliminary evaluation plans for each of the 17 models being implemented. In these plans, the center has identified preliminary cost and quality measures to be used to evaluate the 17 models.[35] According to CMS officials, in identifying the preliminary measures, they generally selected cost and quality measures that were well accepted in the health care industry, including those developed or endorsed by national organizations, such as the National Quality Forum and the Agency for Healthcare Research and Quality.[36] Officials said that they also identified measures for which data sources were readily available, such as claims data and standard patient surveys conducted by providers.

The preliminary cost and quality measures the Innovation Center identified vary for different models. For example, preliminary cost measures include the average total cost of care per Medicare beneficiary per year and the cost per hospitalization and related outpatient care and subsequent hospitalizations for certain types of conditions. In the case of quality, preliminary measures identified by the Innovation Center vary by the type of care involved, such as the percentage of patients whose blood

[35]The evaluation plans also include information on the types of research questions the Innovation Center wants answered, possible analytic approaches to be taken when conducting the evaluations, and reporting guidelines.

[36]The National Quality Forum is a nonprofit organization that fosters agreement on national standards for measurement of health care performance data. The Agency for Healthcare Research and Quality is an agency within HHS that supports research and dissemination of information about health care safety and quality.

pressure exceeds a certain level (primary care); newborn birth-weight (prenatal care); and the number of adverse events, such as hospital-acquired infections (hospital care). See table 4 for examples of preliminary measures identified by the Innovation Center and intended for use for different types of care.

Table 4: Examples of Preliminary Measures for Innovation Center Models Involving Different Types of Care

Model name	Model purpose and type of care	Cost measures	Quality measures
Federally Qualified Health Center Advanced Primary Care Practice[a]	Test the effect of an advanced primary care practice model	• Average annual cost of care per beneficiary (Medicare Parts A and B costs)[b]	• Patient rating of care experience • Inappropriate medication use • Rate of provision of preventive services
Partnership for Patients	Test the effect of multiple strategies to improve patient safety in hospitals, including reducing preventable hospital-acquired conditions and reducing 30-day readmissions[c]	• Cost for initial hospitalization, for outpatient services, and for subsequent hospitalizations, for cases of preventable hospital-acquired conditions	• Rate of certain hospital-acquired conditions • Rate of 30-day readmissions
Strong Start for Mothers and Newborns	Test, among other things, the effect of three different approaches to providing enhanced prenatal care	• Total cost of care for pregnancy, for the delivery, and for care provided to infant in first year	• Gestational age at delivery • Rate of low birth weight births • Timeliness of prenatal care

Source: GAO analysis of CMS information.

[a]Federally Qualified Health Centers are health centers that have received a "Federally Qualified Health Center" designation from CMS and provide comprehensive community-based primary and preventive care services in medically underserved areas or to medically underserved populations. Federally Qualified Health Centers must meet certain federal requirements and enjoy certain federal benefits, such as enhanced Medicaid reimbursement rates.

[b]Medicare is the federal health insurance program for persons aged 65 or over, individuals under the age of 65 with certain disabilities, and individuals with end-stage renal disease. Medicare Part A covers hospital services and Medicare Part B covers physician and other outpatient services.

[c]Hospital-acquired conditions are conditions that a patient acquires while an inpatient in the hospital, such as catheter-associated urinary tract infections or injuries from falls. The 30-day hospital readmission rate is the rate at which patients discharged from the hospital return within 30 days. While some readmissions are unavoidable, such as those not related to the initial diagnosis, others can be prevented through the use of best practices of care.

Preliminary measures the Innovation Center identifies will be finalized with contractors responsible for evaluating models on behalf of CMS. According to CMS officials, the Innovation Center plans on hiring

contractors to evaluate its models.[37] The Innovation Center uses its preliminary evaluation plans as the basis for developing solicitations for and selecting contractors, who will be asked to propose specific evaluation approaches. Officials said that after contracts are awarded, the Innovation Center goes through a "design phase" with the contractor where they reach agreement on the final evaluation plan, including the measures of cost and quality of care that will be used. As of August 1, 2012, the Innovation Center had contracted with evaluators for 10 of the 17 models and had finalized measures for 2 models.[38] The center anticipated awarding contracts for 6 of the remaining models by the end of fiscal year 2012 and for the other remaining model—the Strong Start for Mothers and Newborns model—by March 2013.

In addition to finalizing the selection of a model's measures, each contractor will be responsible for collecting data for the measures, and assessing the model's impact on cost and quality. To make this assessment, CMS officials said the evaluation contractors will generally compare the model's cost and quality outcomes to the outcomes for a comparison group of beneficiaries or providers that did not participate in the model by using a variety of statistical techniques.[39] Officials also said that to ensure that any differences observed between model participants and the comparison group are due to the model's approach as opposed to other factors, they have set a threshold of statistical significance that they will use for all models. While a model's testing and evaluation period is typically set at 3 to 5 years, officials noted that in some cases it may be clear from the data within 1 or 2 years whether a model has had a positive impact on the cost and quality of care and should be recommended for implementation more broadly in Medicare or Medicaid,

[37]Hiring contractors to conduct evaluations of models is consistent with how CMS conducted evaluations of demonstrations initiated prior to the Innovation Center's formation.

[38]Officials said that before measures are finalized with contractors, evaluation activities may still be conducted using preliminary measures.

[39]Officials told us that comparison groups will be matched to model participants along a variety of measurable dimensions, such as provider and market-specific characteristics, and that particular care will be taken to identify the impact of each reform in the context of other models or interventions. Officials also told us that in certain cases, it may not be possible to develop comparison groups for models. In these cases, the center will compare cost and quality outcomes for model participants before and after the start of the model.

or that it has increased costs and should be discontinued. Alternatively, there may also be cases where the results at the end of the testing and evaluation period show that a model saves money but not at the threshold of statistical significance set by the Innovation Center.[40] CMS officials told us that impact assessments will be ongoing, but will not begin until a model has been under way for the amount of time expected for the change in health care delivery or payment to start producing results.[41] Officials said that they received data for their first impact assessment on August 31, 2012, although they emphasized that early impact assessments may not show clear results.

As a complement to assessing the impact of models on the cost and quality of care, evaluation contractors will be asked to conduct site visits and interviews to obtain qualitative information about the different strategies participants may use to deliver care under each model. For example, for models that seek to incentivize better coordination of care, participants may implement different strategies to support care coordination, such as increasing staffing or investing in technology. Contractors will analyze whether different strategies are associated with particular cost and quality outcomes.

Innovation Center officials told us that information collected by contractors will also be shared on a regular basis with model participants. The purpose of what the center refers to as "rapid cycle" feedback is to provide timely information so that participants can make improvements during the testing period of the model. For example, CMS officials explained that under the Federally Qualified Health Center Advanced Primary Care Practice model, participating health centers will be provided with feedback reports on a quarterly basis. According to officials, these reports will describe how each participant is performing relative to others

[40]CMS plans to establish a working group to address cases where the impact of a model is unclear, for example where the cost or quality measures are not statistically significant. In certain cases they may request additional time to test the model.

[41]Officials noted, for example, that with the Comprehensive Primary Care Initiative—which tests the effectiveness of enhanced primary care services—they would not expect participating providers to have an impact on cost and quality right away. Therefore, the assessment of cost and quality measures relative to a comparison group would not be started until approximately 9 months after the start date. Considering the time required to capture claims data and the time it takes to evaluate the data, it would be over a year before they would expect to see results. Officials noted that this time frame will vary by model as some may produce results faster than others.

with respect to the model's measures. The reports, officials say, will also include information on differences among participants in how they are delivering care under the model in order to encourage the adoption of more-successful strategies. Officials told us that rapid cycle feedback will generally begin within the first year after testing of a model has started. As of August 1, 2012, the Innovation Center had started rapid cycle feedback for 1 of the 17 models—the Partnership for Patients model.

The Innovation Center's Plans for Evaluating Its Own Performance Include Aggregating Data across Models and Monitoring Implementation of Models

The Innovation Center's plans for evaluating its own performance include aggregating data on cost and quality measures to determine the overall impact of the center. To do this, the Innovation Center will use a set of core measures. The center has identified about 70 core measures, including some of the preliminary cost and quality measures related to the 17 models it was implementing as of March 31, 2012.[42] Because not all core measures will apply to all models, data will be aggregated for groups of models. To conduct this aggregation, the Innovation Center will use statistical techniques, such as meta-analysis. Aggregation will not occur until individual models have been evaluated, but officials said that the Innovation Center has started asking evaluation contractors to consider using the 70 measures when possible.

The Innovation Center's plans for evaluating its performance also include monitoring its progress in implementing models. The Innovation Center has established a project management approach for its models that includes standard milestones—such as "completion of OMB clearance" and "issuance of participant solicitation and application"—that it uses to track the progress of models against target deadlines. In addition, certain data are monitored for each model against specified targets, such as the number of applications submitted and the number of participants selected. Individual milestones and data are summarized across all of the Innovation Center models every 2 weeks. The intended purpose is to allow the center's management to monitor progress across models and to identify and promptly address potential delays. According to CMS officials, the Innovation Center was monitoring the progress of each of the 17 models it was implementing as of March 31, 2012.

[42]While the core measures will be used to determine the Innovation Center's overall performance, their primary purpose is to compare outcomes between models to determine whether some models had more of an impact on a specific measure than others.

Finally, in order to help evaluate its performance, in June 2012, the Innovation Center contracted with a firm to review the Innovation Center's internal operations and how the center operates within the context of CMS's programs overall. The statement of work for this contract identified a number of objectives, including recommending ways to improve the center's organizational structure, revising the center's management policies and procedures, and identifying additional ways to evaluate the Innovation Center's performance on an ongoing basis. To support these objectives, the contract requires the firm to, for example, identify best practices for expanding innovative models of care into ongoing programs such as Medicare and Medicaid. The contract also requires the firm to identify policies and procedures that are missing within the Innovation Center that would improve its performance. The evaluation under this contract is expected to be completed in November 2012.

The Innovation Center Uses a Number of Mechanisms to Coordinate Efforts That Overlap with Other Offices, but Is Still Working on Ways to Make Coordination More Systematic

In our review of models the Innovation Center was implementing as of March 31, 2012, we identified three key examples of overlap with efforts of other CMS offices. While the center uses a number of mechanisms to coordinate with other CMS offices, it is still working on ways to make coordination more systematic.

Some Innovation Center Models Overlap with Efforts of Other CMS Offices

We identified three key examples of Innovation Center models being implemented as of March 31, 2012, that overlap with efforts of other CMS offices, meaning that the efforts share similar goals, engage in similar activities or strategies to achieve these goals, or target similar populations. However, these overlapping efforts also have differences, and CMS officials said they are intended to be complementary to each other. The three key examples we identified are the following:

- *The Innovation Center's Two Accountable Care Organization (ACO) Models and the Center for Medicare's Shared Savings Program*.[43] The Innovation Center is implementing two models—the Pioneer ACO model and the Advance Payment ACO model—that share similar goals with those of the Shared Savings Program, which is required by PPACA and administered nationally by CMS through its Center for Medicare.[44] All three efforts aim to encourage Medicare providers that participate in ACOs to improve the quality of care among the patients they serve, while at the same time reducing Medicare expenditures. In order to achieve these goals, the efforts provide financial incentives for ACOs that meet specified quality of care and cost savings thresholds by allowing them to share in a certain amount of the savings they achieve for the Medicare program.[45] However, the Innovation Center's models and the Shared Savings Program each adopt a different approach to sharing any realized savings.[46] Further, while the Shared Savings Program is open to all eligible ACOs, the models target specific subgroups of ACOs.[47] According to CMS officials, the Innovation Center's ACO models are intended to be complementary to the Shared Savings Program, because they allow CMS to test alternative approaches to the national effort. If these

[43]An ACO refers to a group of providers and suppliers of services, such as hospitals and physicians, that will work together to coordinate care for the patients they serve.

[44]As required by PPACA, the Center for Medicare is implementing the Shared Savings Program to encourage the use of ACOs in Medicare. Pub. L. No. 111-148, §§ 3022, 10307, 124 Stat. 119, 395-399, 940-941. While the Shared Savings Program is a national program within Medicare, a provider's decision to participate in an ACO is voluntary, and Medicare beneficiaries are still able to choose the providers they would like to see regardless of whether they are in an ACO.

[45]In certain cases, ACOs must also agree to share a certain amount of risk for any losses incurred. See 42 C.F.R. § 425.606 (2011).

[46]For example, whereas the Shared Savings Program pays an ACO—and correspondingly its membership of providers and suppliers—after specified quality of care and savings thresholds are met, the Advance Payment model prepays a portion of expected shared savings.

[47]In the case of the Advance Payment model, it targets ACOs that lack the necessary capital to make investments in care coordination, such as hiring new staff or improving information technology systems.

alternative approaches are proven effective, officials explained, they could be incorporated into the Shared Savings Program.[48]

- *The Innovation Center's Medicaid Models and CMCS's State Medicaid Demonstrations*. As of March 31, 2012, the Innovation Center was implementing nine models that share the same broad goal as the state Medicaid section 1115 demonstrations overseen by CMCS[49]—testing new ways of delivering and paying for health care in Medicaid.[50] Despite this similarity, the Innovation Center's models can test delivery and payment approaches across geographic areas and with different types of participants, including directly with providers, while Medicaid demonstrations under CMCS are agreements between CMS and state Medicaid agencies to test approaches within a particular state. According to CMS officials, the Medicaid models and demonstrations are intended to be complementary: the models allow CMS to test the effectiveness of approaches it selects, while the demonstrations are initiated by states on the basis of their own priorities and needs. Further, officials said that while evaluations of Innovation Center models may be able to more-rigorously test effectiveness,[51] state Medicaid demonstrations allow for a larger number of tests to be conducted—according to CMS, there were

[48]According to CMS officials, it is more difficult to implement changes within the Shared Savings Program because, unlike models, the Shared Savings Program must go through the federal rulemaking process. Among other things, the rulemaking process requires CMS to propose changes and a rationale for the changes, seek and consider stakeholder input, review comments, and make final policy decisions.

[49]Of the nine models, three specifically target Medicaid beneficiaries (Incentives for Prevention of Chronic Disease in Medicaid, Strong Start for Mothers and Newborns, and the Medicaid Emergency Psychiatric Demonstration), three target individuals eligible for both Medicare and Medicaid (State Demonstrations to Integrate Care for Medicare-Medicaid Beneficiaries, Initiative to Reduce Hospitalizations Among Nursing Facility Residents, and the Financial Alignment Initiative), and three include Medicaid beneficiaries in addition to other beneficiary types (Partnership for Patients: Hospital Engagement Networks and Other Strategies, Health Care Innovation Awards, and the Comprehensive Primary Care Initiative). See app. I for more information on these models.

[50]While each state administers its Medicaid program within federal requirements established in statute and regulations, section 1115 of the Social Security Act allows the Secretary of HHS to waive certain federal requirements for demonstrations that the Secretary deems likely to promote Medicaid objectives. 42 U.S.C. § 1315.

[51]For example, according to CMS officials, the Innovation Center is able to define necessary sample sizes and comparison groups for its models, which officials said has historically been difficult within the framework of state Medicaid demonstrations for a number of reasons, including that evaluations have generally been state-specific.

approximately 70 active section 1115 demonstrations as of August 2012—and can point to promising approaches that should be considered for further testing.[52]

- *The Innovation Center's Partnership for Patients Model and CCSQ's Quality Improvement Organization (QIO) Program*. The goals of the Innovation Center's Partnership for Patients model—namely reducing the rate of preventable hospital-acquired conditions and 30-day hospital readmissions[53]—are also currently among the many goals of CCSQ's QIO program.[54] In order to achieve these goals, both the Partnership for Patients model and the QIO program contract with organizations—Hospital Engagement Networks (HEN)[55] and QIOs, respectively—to disseminate successful patient safety interventions in hospitals through training and technical assistance.[56] While the two efforts are very similar in this respect, compared to QIOs, the activities of HENs target more hospital-acquired conditions and focus on a

[52]While there were approximately 70 active section 1115 demonstrations as of August 2012, states use these demonstrations for more than testing specific approaches to health care delivery or payment, such as expanding Medicaid coverage to additional individuals in their state.

[53]According to CMS officials, for the purposes of the Partnership for Patients model, hospital-acquired conditions are conditions that a patient acquires while an inpatient in a hospital, such as catheter-associated urinary tract infections or injuries from falls and immobility. The 30-day hospital readmission rate is the rate at which patients discharged from the hospital return within 30 days. While some readmissions are unavoidable, such as those not related to the initial diagnosis, others can be prevented through the use of best practices of care.

[54]The mission of the QIO Program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. The QIO Program is required by the Social Security Act. 42 U.S.C. §§ 1320c-1320c-4, 1395y(g). While QIOs currently work on reducing hospital-acquired conditions and readmissions, they also conduct other activities, such as the promotion of immunizations and screenings, and work in more settings than hospitals, such as nursing homes and physicians' offices. There is one QIO for every state as well as the District of Columbia, Puerto Rico, and the U.S. Virgin Islands.

[55]HENs are state, regional, and national hospital system organizations, such as the Health Care Association of New York State and Intermountain Healthcare.

[56]Contracting with HENs is one of multiple strategies the Partnership for Patients model uses to achieve its goals. Other strategies include engaging in other activities within the federal government and developing relationships with external stakeholders.

broader population that includes non-Medicare patients.[57] CMS officials also told us that the work of HENs and QIOs is intended to be complementary and that HENs reinforce and expand on work already being done by QIOs in order to reduce hospital-acquired conditions and 30-day hospital readmissions at a faster rate. While QIOs may have established relationships with certain hospitals in their states, as of September 2012, CMS officials said that HENs had engaged a much wider network of hospitals in patient safety interventions when compared with QIOs—about 4,000 versus just over 800 respectively. Officials said that one reason for this is that HENs focus exclusively on hospitals whereas QIOs are responsible for implementing improvement projects across all settings of care. Additionally, officials said that because hospital system organizations serve as HENs, they can leverage their member hospitals to encourage these hospitals to adopt patient safety interventions.

The Innovation Center Uses a Number of Mechanisms to Coordinate with Other Offices, but Is Still Working on Ways to Make Coordination More Systematic

Over the period of our review, we identified a number of mechanisms the Innovation Center uses to coordinate its work in order to avoid unnecessary duplication in models that overlap with efforts of other CMS offices. In using these mechanisms, the center has engaged in key practices that we identified in prior work as helping enhance and sustain collaboration,[58] such as leveraging resources, establishing compatible policies and procedures, and developing ways to report on results across offices. The mechanisms the Innovation Center uses are the following:

[57]According to CMS, HENs and QIOs target four of the same conditions: catheter-associated urinary tract infections, central line-associated blood stream infections, surgical site infections, and venous thromboembolism (refers to pulmonary embolisms resulting from deep vein thrombosis). However, HENs target an additional five conditions: injuries from falls and immobility, obstetrical adverse events, pressure ulcers, adverse drug events, and ventilator-associated pneumonia. Conversely, QIOs target one additional condition, clostridium difficile infections (refers to infections from a bacterium that can cause symptoms ranging from diarrhea to life-threatening inflammation of the colon).

[58]These collaboration practices are: (1) defining and articulating a common outcome; (2) establishing mutually reinforcing or joint strategies; (3) identifying and addressing needs by leveraging resources; (4) agreeing on roles and responsibilities; (5) establishing compatible policies, procedures, and other means to operate across agency boundaries; (6) developing mechanisms to monitor, evaluate, and report on results; (7) reinforcing agency accountability for collaborative efforts through agency plans and reports; and (8) reinforcing individual accountability for collaborative efforts through performance management systems. See GAO-06-15.

- *Committees and boards*. The Innovation Center uses a number of committees and boards to coordinate with other offices. For example, CMS officials told us that in deciding whether to select a model for testing, the Innovation Center's Portfolio Management Committee considers other efforts within CMS—as well as more broadly across HHS—that may overlap with the model in order to avoid unnecessary duplication. Officials said that when overlap is identified, the decision to continue with the model is made on a case-by-case basis and involves a determination of whether the model is significantly different from existing efforts. Additionally, members of the Portfolio Management Committee are able to help identify staff in other offices that the Innovation Center might want to invite to work on a model in order to leverage existing agency expertise.[59] In another example, CMS's Enterprise Management Board brings together relevant offices across the agency, such as the Chief Operating Officer, the Office of Acquisition and Grants Management, and the Center for Medicare, early in a model's implementation to determine what needs to be done operationally. To avoid unnecessary duplication, the board considers whether there are existing CMS resources that could be leveraged for the model's infrastructure needs or whether a resource being developed for an Innovation Center model could be shared with other CMS efforts.

- *Model approval process*. According to CMS officials, the process CMS uses to approve Innovation Center models for implementation also allows the center to coordinate with other CMS offices. Officials explained that as part of this process, all CMS offices must have the opportunity to review and comment on the ICIP—a document that contains key information on a proposed model, such as design parameters and cost estimates—before the model is approved by the CMS administrator. Officials said that under CMS policy, the Innovation Center must address these comments. The ICIP contains sections that specifically address issues related to overlap, such as a section on "Synergy with Existing or Planned Initiatives" and a section on "Uniqueness/Innovation." CMS officials said that, as a result, when the ICIP is circulated, if the Innovation Center did not sufficiently

[59]CMS officials told us that staff from other offices are invited to participate on teams for Innovation Center models and initiatives to provide technical support on aspects of models that require specific programmatic knowledge. In certain cases, the idea for a model has originated as much from another office as from the Innovation Center, and in these cases the center jointly sponsors the model with that office.

coordinate with other CMS centers or offices during the initial selection of a model, these offices would have the opportunity to raise any concerns related to unnecessary duplication. After a model is approved by CMS, HHS and OMB also review and approve the ICIP.

- *Multi-office meetings at the staff, director, and agency level*. First, CMS officials said that staff from the Innovation Center meet with staff from other offices to work on efforts that overlap. For example, during planning for its ACO models, the Innovation Center met with the Center for Medicare to establish compatible policies and procedures with the Shared Savings Program, such as developing common scripts for 1-800-MEDICARE call centers and rules for elevating beneficiary or provider questions to these centers for additional review.[60] Additionally, in March 2012, the Innovation Center started meeting with CCSQ every week to discuss coordination between HENs and QIOs in order to prevent unnecessary duplication of effort. Second, CMS officials told us that there is regular coordination between the director of the Innovation Center and certain other CMS centers and offices, through meetings that happen on a weekly, biweekly, or monthly basis.[61] Officials said that, among other things, these meetings are intended to share the results of ongoing efforts and address such issues as making sure policies are compatible across similar efforts. Officials also told us that all CMS offices have weekly issues meetings with the CMS Administrator that other offices involved in an issue being discussed are encouraged to attend.[62] Officials told us that if staff from other CMS offices thought an issue related to overlapping efforts had not been adequately addressed through other coordination mechanisms, these meetings serve as an opportunity for them to raise it.

[60]1-800-MEDICARE is a nationwide toll-free telephone help line that beneficiaries, their families, and other members of the public can call to ask questions about Medicare.

[61]The Innovation Center's director has one-on-one meetings with, among others, the director of the Center for Medicare, CMCS, the Federal Coordinated Health Care Office, CCSQ, the Office of Information Services, and the Chief Operating Officer. Directors also meet together regularly as a group.

[62]Examples of items discussed during the Innovation Center's meetings include documents that need the Administrator's approval, such as ICIPs, as well as general questions for the administrator regarding model design or implementation. CMS officials said that the Innovation Center's weekly meeting with the Administrator is held jointly with the Federal Coordinated Health Care Office.

- *Liaisons*. Officials told us that staff members in other CMS offices serve as liaisons to the Innovation Center, though they are not formally designated as such.[63] Officials said that these staff members primarily serve as a central point of contact so that there is a systematic way to keep track of coordination across offices. For example, CMCS has a staff member serving as a liaison to the Innovation Center who, among other things, ensures that the Innovation Center's models employ policies and procedures that are compatible with Medicaid program rules.

- *Targeted reviews*. CMS officials said that as part of selecting participants for the Innovation Center's Medicaid models, the Innovation Center works with CMCS, CMS regional offices, and OMB to ensure that the models do not duplicate funding for states that are already being funded to engage in the same activity through a CMCS demonstration. For example, the application for the Strong Start for Mothers and Newborns model—which tests, among other things, the effectiveness of three different approaches to providing enhanced prenatal care to Medicaid beneficiaries—specified that states that were already paying for enhanced prenatal services were not allowed to participate in the model.

While the Innovation Center uses these mechanisms, it is also still working on ways to make its coordination with other offices more systematic. Specifically, CMS officials said that while some of the Innovation Center's coordination mechanisms are formalized through documented policies and procedures, the center is considering the extent to which additional policies and procedures are needed. For example, officials said that while the Enterprise Management Board, which is responsible for addressing how models are coordinated with other CMS efforts operationally, is formally established through a written charter, they have considered whether a similar group that deals with coordination at the policy level needs a more formal structure in place. In another example, the Innovation Center has directed the outside firm that began an evaluation of Innovation Center operations in June 2012 to consider, as part of its statement of work, whether there are any gaps in current

[63]Officials said that directors have assigned staff within their office to serve as liaisons to the Innovation Center when it was determined that their offices were going to have ongoing coordination with the center.

center policies and procedures—including those related to coordination with other offices—and to propose solutions to those gaps.

The Innovation Center is also currently developing a process to ensure that CMS does not pay for the same service under both HEN and QIO contracts. Officials said that CMS recognizes there are areas of overlap between HENs and QIOs and that they made an explicit decision to include overlapping activities in HEN and QIO statements of work, because, among other things, the nature of trying to reduce hospital-acquired conditions and readmissions requires multiple entities working from different perspectives in a reinforcing manner. Although the HEN and QIO contractors were originally told to work out areas of overlap locally, largely because of questions asked during our review, officials recognized the need for a more-formal process to ensure coordination was working in practice. CMS officials said that a review of the 26 HEN contracts is under way to identify if any unnecessary duplication of effort has occurred—that is, whether HENs and QIOs are conducting the same activities in the same hospital.[64] Officials noted that the review process has evolved and may continue to evolve over time, in part because of the size of the review—which includes reviewing HENs' activities in approximately 4,000 hospitals—and in part because the Innovation Center has not conducted this type of review previously. CMS officials said that they will take steps, including potentially modifying HEN or QIO contract language, to eliminate any unnecessary duplication of effort that the review identifies and to document how this duplication was addressed.

Finally, officials noted that CMS is in the process of developing a centralized database, which may also help the Innovation Center make its coordination more systematic. Among other things, officials said that the database is intended to help prevent duplicative payments to providers that participate in CMS efforts involving incentive payments for meeting specified quality of care and cost savings thresholds, such as the Innovation Center's ACO models and the Center for Medicare's Shared Savings Program. Specifically, officials said that the database is intended to track which beneficiaries are participating in different efforts across

[64]For example, officials said that because both have been asked to work on reducing central line-associated blood stream infections, it is conceivable that HENs and QIOs could be providing the same technical assistance on reducing this type of infection in the same hospitals.

CMS to help ensure that beneficiaries are not counted twice for the purposes of calculating incentive payments. While officials reported that the database initially became operational in June 2012, they also said that they are currently working on significant system upgrades that are expected in September 2012.

Conclusions

The Innovation Center became operational in November 2010 and is still in the early stages of implementing its first models, with much work—particularly evaluation activities—to be done in coming years. As of March 31, 2012, the Innovation Center had announced 17 models, covering a variety of topics, to test new approaches in health care delivery and payment. In addition, the Innovation Center has developed preliminary evaluation plans for each of the 17 models, although at the time of our review, most still needed to be finalized, and it may take as long as 3-5 years until the evaluations begin to produce results. With spending on health care in the United States continuing to increase, and an appropriation of $10 billion every 10 years, it is important that the Innovation Center continue the testing of its models and conduct evaluations as planned in order for CMS to determine the extent to which the new approaches are able to reduce costs and improve quality of care.

At the time of our review, we identified three key examples of Innovation Center models that overlap with efforts being conducted by other offices within CMS. As the Innovation Center and other CMS offices work in similar areas—namely paying for and delivering health care to Medicare and Medicaid beneficiaries—there likely will be additional efforts that overlap as the center continues to build its portfolio of models and initiatives. We encourage these efforts to the extent that they are complementary, well coordinated, and do not result in unnecessary duplication. However, our review also suggests that while the Innovation Center has taken steps to coordinate with other offices, it still has work to do in making this coordination more systematic. For example, the Innovation Center is considering whether additional policies and procedures are needed to coordinate its efforts with other offices, and it will be important for the center to continue to determine the extent to which this is necessary, particularly as it considers the results of the evaluation by an outside firm. In addition, the Innovation Center is still implementing a process to ensure that CMS does not make payments for duplicative services under HEN contracts in its Partnership for Patients model—one of its first and most expensive models to date—and QIO contracts. Given the significance of the Innovation Center's work, and the amount of money involved in its operation, having appropriate and well-

documented coordination mechanisms in place will be an important step going forward to help ensure that resources are used most efficiently and any overlapping efforts do not become unnecessarily duplicative.

Recommendations for Executive Action

In order to ensure the efficient use of federal resources, we recommend that the Administrator of CMS direct the Innovation Center to expeditiously complete implementation of its process to review and eliminate any areas of unnecessary duplication in the services being provided by HENs and QIOs in hospitals.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review and comment. In its written comments, reproduced in appendix III, HHS agreed with our recommendation and provided general comments. In addition, on October 26, 2012, the Innovation Center's Deputy Director for Operations provided oral technical comments that were incorporated, as appropriate.

In its written comments, HHS stated that it concurred with our recommendation to expeditiously complete implementation of its process to review and eliminate any areas of unnecessary duplication in the services being provided by HENs and QIOs. HHS described the steps underway to identify and eliminate any duplication of effort, including (1) having Contracting Officer Representatives assess whether there are areas of duplication that require further review and recommend appropriate actions for each contract and (2) if appropriate, putting in place acceptable mitigation strategies, issuing technical direction, or modifying the appropriate contract to eliminate the duplication of effort. HHS stated that it anticipates completing these steps by December 31, 2012, and has monitoring plans in place to assess future changes in the work plans of QIOs and HENs to avoid future duplication.

In its written comments, HHS also stated that only one of the three key examples of overlap cited in the report—the HEN and QIO example—poses a risk of duplicative effort. We agree, and the recommendation we make focuses on this example. The other two key examples we described in our report are overlapping in that they share similar goals, engage in similar activities or strategies to achieve these goals, or target similar populations. We noted that these efforts have important differences and that CMS officials said the efforts were intended to be complementary to each other. Because the Innovation Center and other CMS offices work in similar areas—namely paying for and delivering health care to Medicare and Medicaid beneficiaries—we observed that there will likely be efforts

that overlap. As we reported, we encourage these efforts to the extent that they are complementary, well coordinated, and do not result in unnecessary duplication.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of HHS, the Administrator of CMS, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or at kohnl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Linda T. Kohn
Director, Health Care

Appendix I: Models Initiated by the Innovation Center as of March 31, 2012, in Order of Start Date

Title and description					
Type of participants	**Estimated number and type of beneficiaries affected[a]**	**Start date of testing and evaluation period**	**Length of testing and evaluation period**	**Authorizing section of PPACA[b]**	**Total funding in millions of dollars (lifetime of model)[c]**
State Demonstrations to Integrate Care for Medicare-Medicaid Beneficiaries—Supports state Medicaid programs in designing new approaches to service delivery and financing in order to integrate care for Medicare-Medicaid beneficiaries. This program will enable states to participate in the Financial Alignment Model (see below), which will enroll beneficiaries in 2013.					
State Medicaid programs	Not applicable	4/14/11	18 months for design	3021	$131
Incentives for Prevention of Chronic Diseases in Medicaid—Tests the impact of providing incentives to Medicaid beneficiaries to participate in prevention programs such as those that address tobacco cessation, controlling or reducing weight, lowering cholesterol, lowering blood pressure, and avoiding the onset of diabetes.					
State Medicaid programs	Not available at the time of our review	9/13/11	5 years	4108[d]	100[e]
Federally Qualified Health Center Advanced Primary Care Practice—Tests the effect of the advanced primary care practice model—commonly referred to as the patient-centered medical home—in improving care, promoting health, and reducing the cost of care provided to Medicare beneficiaries by Federally Qualified Health Centers. Federally Qualified Health Centers are health centers that have received a "Federally Qualified Health Center" designation from the Centers for Medicare & Medicaid Services (CMS) and provide comprehensive community-based primary and preventive care services in medically underserved areas or to medically underserved populations.					
Federally Qualified Health Centers (must have at least 200 Medicare fee-for-service beneficiaries)	202,000 Medicare beneficiaries	11/1/11	3 years	3021	57.2
Partnership for Patients: Community Based Care Transitions—Tests approaches to reduce unnecessary hospital readmissions by improving the transition of Medicare beneficiaries from the inpatient hospital setting to home or other care settings.					
Hospitals with high readmission rates that partner with community-based organizations that provide care transition services	275,000 Medicare beneficiaries	11/18/11	5 years	3026[f]	500[g]
Partnership for Patients: Hospital Engagement Networks and Other Strategies—Tests the effectiveness of multiple strategies to reduce preventable hospital-acquired conditions—conditions that a patient acquires while an inpatient in the hospital, such as catheter-associated urinary tract infections or injuries from falls—and 30-day hospital readmissions. One example of a strategy used by the Partnership for Patients is contracting with Hospital Engagement Networks—which are state, regional, and national hospital system organizations—to disseminate successful patient safety interventions in hospitals through training and technical assistance.					
Networks of hospitals and their hospital members	While Medicare and Medicaid beneficiaries will be affected, this model targets all patients receiving related services in participating hospitals	12/9/11	2 years with 1 option year	3021	513

Title and description					
Type of participants	**Estimated number and type of beneficiaries affected**[a]	**Start date of testing and evaluation period**	**Length of testing and evaluation period**	**Authorizing section of PPACA**[b]	**Total funding in millions of dollars (lifetime of model)**[c]
Pioneer Accountable Care Organization (ACO) Model—Tests the effectiveness of allowing experienced ACOs to take on financial risk in improving quality and lowering costs for all of their Medicare patients. An ACO refers to a group of providers and suppliers of services, such as hospitals and physicians, that work together to coordinate care for the patients they serve.					
ACOs with at least 15,000 Medicare fee-for-service beneficiaries (or at least 5,000 Medicare beneficiaries in the case of rural areas)	750,000 Medicare beneficiaries	1/1/12	3 years with optional 2-year extension	3021	77.3
Treatment of Certain Complex Diagnostic Laboratory Tests—Tests the effect of making separate payments for certain complex diagnostic laboratory tests on access to care, quality of care, health outcomes, and expenditures.					
Clinical laboratories performing certain complex tests	Not applicable	1/1/12	2 years	3113[h]	105[i]
Strong Start for Mothers and Newborns—Tests two strategies to improve outcomes for newborns and pregnant women: (1) shared learning and diffusion activities to reduce the rate of early elective deliveries among pregnant women and (2) enhanced prenatal care to reduce preterm births (less than 37 weeks) in women covered by Medicaid. Each of these strategies addresses three different approaches to achieving these goals.					
Providers of obstetric care, hospitals, state Medicaid programs, Medicaid managed care organizations	Strategy 1: This model targets all patients receiving related services Strategy 2: 90,000 Medicaid beneficiaries	2/8/12	Strategy 1: 2 years; Strategy 2: 4 years	3021	99.2
Advance Payment ACO Model—Tests the effect of prepayment of shared savings to support ACO infrastructure development and care coordination on quality and costs of care for Medicare beneficiaries.					
Small physician-led or rural organizations participating in the Medicare Shared Savings Program	650,000 Medicare beneficiaries	4/1/12	3 years	3021	177.1
Independence at Home Demonstration—Tests the effectiveness of delivering an expanded scope of primary care services in a home setting on improving care for Medicare beneficiaries with multiple chronic conditions.					
Physician practices with at least 200 high-need beneficiaries	10,000 Medicare beneficiaries	6/1/12	3 years	3024[j]	30[k]
Health Care Innovation Awards—Tests a variety of innovative approaches to paying for and delivering care that have a focus on those that will train and deploy the health care workforce to support these innovations.					
Diverse set of participants	Not available at the time of our review	7/1/12	3 years	3021	931.2
Medicaid Emergency Psychiatric Demonstration—Tests whether Medicaid can support higher quality care at lower cost by reimbursing private psychiatric hospitals for certain services for which Medicaid reimbursement has historically been unavailable.					
State Medicaid programs	Not available at the time of our review	7/1/12	3 years	2707[l]	75[m]

Title and description					
Type of participants	**Estimated number and type of beneficiaries affected[a]**	**Start date of testing and evaluation period**	**Length of testing and evaluation period**	**Authorizing section of PPACA[b]**	**Total funding in millions of dollars (lifetime of model)[c]**
Graduate Nurse Education Demonstration—Tests the effect of offsetting the costs of clinical training for Advanced Practice Registered Nurses on the availability of graduate nursing students enrolled in APRN training programs.					
Hospitals, schools of nursing, and non-hospital-based community-based care settings	Not applicable	9/1/12	4 years	5509[n]	200[o]
Comprehensive Primary Care Initiative—Tests the impact of enhanced primary care services, including care coordination, prevention, and 24-hour access for Medicare and Medicaid beneficiaries.					
Commercial and state health plans and primary care physician practices in seven selected localities across the country.	Up to 315,000 Medicare and 16,000 Medicaid beneficiaries	10/1/12	4 years	3021	322.1
Initiative to Reduce Avoidable Hospitalizations Among Nursing Facility Residents—Tests partnerships between independent organizations and long-stay nursing facilities to enhance on-site services to reduce inpatient hospitalizations for Medicare-Medicaid beneficiaries.					
Organizations that partner with states and nursing facilities to provide enhanced care coordination	Not available at the time of our review	Fall 2012	4 years	3021	158
Bundled Payment for Care Improvement—Tests the effect of different payment approaches that link payments for multiple services received by patients during an episode of care, including hospitalization and posthospital services, on the coordination of patient care. Four different models of bundling will be tested, but information on models 2 through 4 was not available at the time of our review.					
Providers such as hospitals, physician group practices, and health systems	Model 1: 389,000 Medicare fee-for-service beneficiaries	12/1/12	3 years with possible 2-year extension	3021	119.4
Financial Alignment Initiative—Tests two approaches to integrating the service delivery and financing of the Medicare and Medicaid programs to better coordinate care for Medicare-Medicaid beneficiaries: a capitated approach where a state, CMS, and a health plan enter into a three-way contract to provide comprehensive coordinated care; and a managed fee-for-service approach where a state and CMS enter into an agreement where the state would be eligible to benefit from savings resulting from its initiatives designed to improve quality and reduce costs.					
State Medicaid programs	Up to 2 million Medicare-Medicaid beneficiaries	2013	3 years	3021	73

Source: GAO analysis of CMS data.

Notes: While this report generally uses the term "models" when discussing the Center for Medicare and Medicaid Innovation's (Innovation Center) efforts to test new approaches to health care delivery and payment, in some cases the Innovation Center's title for a model may include the words "demonstration" or "initiative."

[a]Beneficiaries affected may include individuals enrolled in Medicare, Medicaid, or both programs simultaneously, in which case they are referred to as Medicare-Medicaid beneficiaries. Medicare is the federal health insurance program for persons aged 65 or over, individuals under the age of 65 with certain disabilities, and individuals with end-stage renal disease. Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals. The State Children's Health Insurance Program is a federal-state program that provides health care coverage to children 18 years of age and younger living in low-income families whose incomes exceed the

eligibility requirement for Medicaid. For this report we use the term "Medicaid" to include both Medicaid and the State Children's Health Insurance Program.

[b]Section 3021 of the Patient Protection and Affordable Care Act (PPACA) established the Innovation Center and authorized the selection of models to test using the funds appropriated to it in that section. Pub. L. No. 111-148, §§ 3021, 10306, 124 Stat. 119, 389-395, 939-940 (codified at 42 U.S.C. § 1315a). There are also models specifically required in other PPACA provisions that the Innovation Center is responsible for implementing.

[c]Section 3021 appropriated $10 billion for Innovation Center activities for the period of fiscal years 2011 through 2019 and $10 billion per 10-year fiscal period beginning in 2020. These amounts are to remain available until expended. For models selected by the Innovation Center, the center obtains approval from CMS, the Department of Health and Human Services, and the Office of Management and Budget for the amount it expects will be required to test and evaluate the models, and this funding comes from the Innovation Center's PPACA appropriation. For models specifically required by other PPACA provisions, the funding amount is the amount appropriated in each PPACA provision.

[d]Section 4108 requires the award of grants to states to test approaches that may encourage behavior modification and determine scalable solutions by providing incentives to Medicaid beneficiaries. § 4108, 124 Stat. at 561-564 (codified at 42 U.S.C. §1396a note).

[e]Section 4108 appropriated $100 million for a 5-year period beginning on January 1, 2011. The amount appropriated is to remain available until expended.

[f]Section 3026 requires the implementation of a model that tests whether partnerships between high-admission-rate hospitals and community-based service organizations can improve transition care services for high-risk Medicare beneficiaries § 3026, 124 Stat. at 413 - 415 (codified at 42 U.S.C. § 1395b-1 note).

[g]Section 3026 requires the transfer of $500 million from Medicare trust funds for the period of fiscal years 2011 through 2015. The amount transferred is to remain available until expended.

[h]Section 3113 requires CMS to develop appropriate payment rates for the tests included in this demonstration. § 3113, 124 Stat. at 422-423 (codified at 42 U.S.C. § 1395l note).

[i]Section 3113 requires the transfer of $5 million from the Medicare Part B trust fund for administering the demonstration. The amount transferred is to remain available until expended. Payments under the demonstration are to be made from Medicare Part B funds and may not exceed $100 million.

[j]Section 3024 requires CMS to conduct a demonstration to test a payment and service-delivery model that utilizes physician- and nurse practitioner–directed home-based primary care teams for reducing expenditures and improving the health outcomes of certain Medicare beneficiaries. §§ 3204, 10308(b)(2). 124 Stat. at 404-408, 942 (codified at 42 U.S.C. § 1395cc-5).

[k]Section 3024 requires the transfer of $5 million from Medicare trust funds for each of fiscal years 2010 through 2015. The amounts transferred are to remain available until expended.

[l]Section 2707 requires CMS to select states to participate in the demonstration project on a competitive basis. §2707, 124 Stat. at 326-328 (codified at 42 U.S.C. § 1396a note).

[m]Section 2707 appropriated $75 million for fiscal year 2011. The amount appropriated is to remain available through December 31, 2015.

[n]Section 5509 requires CMS to conduct a demonstration under which eligible hospitals receive payment for their reasonable costs for the provision of qualified clinical training to advanced practice nurses. § 5509, 124 Stat. at 674-676 (codified at 42 U.S.C § 1395ww note).

[o]Section 5509 appropriated $50 million for each of fiscal years 2012 through 2015. The amount appropriated is to remain available until expended.

Appendix II: Innovation Center: Steps in Process for Implementing Models

Planning and development	
Solicit ideas for new models and select which models to develop[a]	• The Center for Medicare and Medicaid Innovation (Innovation Center) solicits and receives ideas for different payment and care delivery approaches through "Listening Sessions" and through its web-based idea-submission tool.[b] • The Innovation Center reviews ideas that have been submitted and evaluates them with respect to their potential to meet its primary goals of better health care, better health, and reduced costs. It reviews ideas against "Portfolio Criteria" that were created to guide the Innovation Center in developing a portfolio of models that address a range of populations, issues, problems, and solutions. • Examples of these criteria include: having the greatest potential impact on Medicare and Medicaid beneficiaries and improving how care is delivered nationally; focusing on health conditions that offer the greatest opportunity to improve care and reduce costs; and meeting the needs of the most vulnerable and addressing disparities in care.[c,d] • As part of this selection process, the Innovation Center reviews model types suggested in the Patient Protection and Affordable Care Act (PPACA) provision that established the center, and seeks input from across the Centers for Medicare & Medicaid Services (CMS), the Department of Health and Human Services (HHS), and other federal partners and from an array of external stakeholders.

Develop an Innovation Center Investment Proposal (ICIP)	• Once the Innovation Center identifies a payment and care delivery model that shows promise, it develops an ICIP, which typically includes
	  • a proposed design for the model including the size and scope of testing, the population and programs involved, and duration;
	  • a summary of prior evidence and supporting research;
	  • a preliminary evaluation plan including research questions, proposed measures related to cost and quality, and discussion of the model's expected impact; and
	  • an implementation plan, including the application and selection process, an analysis of whether the model overlaps or complements other initiatives, and an analysis of the potential for expansion of the model.
	• The Innovation Center prepares separate documents for approval that are related to funding requests and solicitations associated with the model.

Obtain approval from CMS, HHS, and the Office of Management and Budget (OMB) and announce model	• The Innovation Center seeks approval for the model. This includes separate approval processes for the ICIP, for model funding, and for any solicitations that would be issued to potential participants. • The approval process includes a sequence of reviews within CMS, within HHS, and finally with OMB. During these reviews, modifications may be made on the basis of input from individuals in other CMS centers and offices, in other related HHS programs, and from OMB. • Once the ICIP is approved, the Innovation Center issues an announcement and other information about the model to the public.

Planning and development	
Solicit, select, and establish agreements with participants	• The Innovation Center issues information about how to apply for participation in the model, including information about which types of providers or organizations are eligible to participate, the process for submitting applications, and the selection process. The Innovation Center may also organize webinars or learning sessions open to the public and interested participants to share information and answer questions. • Innovation Center models vary by the type of participant that is involved—for example, physician group practices, health plans, and state Medicaid programs. • Models also vary in terms of the type of agreement that is established with participants, for example, whether it is a grant, a cooperative agreement, a contract, or a provider agreement. • The selection process for participants is generally competitive. The criteria used in the selection process may vary by model. For example, selection criteria may include such factors as organizational capabilities and plans for ensuring quality of care. In other cases, eligible participants may be selected in order to achieve a mix and balance of certain characteristics for evaluation purposes, for example geographic location (urban, rural) and whether the participant uses electronic health records.
Solicit and select contractors for testing and evaluating model	• The Innovation Center solicits and hires contractors to evaluate the model. Applicants are asked to propose specific evaluation approaches to the preliminary evaluation plans that the Innovation Center has identified. Contractors are selected through a competitive process. Once a contractor is selected, it works with the Innovation Center to complete a design phase and reach agreement on the final evaluation plan for the model. • The Innovation Center also engages contractors for other purposes that are part of implementation, such as data collection and provider recruitment.
Testing and evaluation	
Conduct test of model	• The changes that the model is testing—for example, changes to health care delivery or payment—are put into effect by CMS and by participants. • The testing period for Innovation Center models is typically set for 3 to 5 years. However, evaluation monitoring may indicate that the model should be modified, terminated, or expanded before this period ends (see below). The Innovation Center may choose to shorten the test period for a model for such reasons.
Conduct evaluation of model to assess its impact on cost and quality	• Data are collected for cost and quality measures. Using a variety of statistical techniques, these data are generally compared to data for a comparison group representing patients or providers that are not participating in the model to determine the model's impact on cost and quality. When comparison groups are not possible, data for model participants are compared to "baseline" data that represent a period prior to the test period. Qualitative information on the different strategies participants may use to deliver care under each model is also collected and analyzed. • During the testing period information collected is shared on a regular basis with participants. The purpose of this "rapid cycle" feedback is to provide timely information so that participants can make improvements during the testing period.

Testing and evaluation	
Determine whether to terminate, modify, or recommend expanding model	• The Innovation Center plans to regularly review each model's impact on the quality and cost of care to determine whether the payment or delivery approach is successful and should be recommended for expansion into the Medicare or Medicaid program. • If the Innovation Center seeks to expand a program, the CMS Office of the Actuary must certify that the model would either (1) result in cost savings or (2) not result in any increase in costs if implemented on a broader scale within Medicare or Medicaid, or both.

Source: GAO analysis of CMS information.

Notes: The Innovation Center's process for implementing models includes interaction with several government organizations, including HHS, which oversees a wide range of federal health programs; CMS, which is the agency within HHS that administers Medicare and Medicaid; and OMB, which assists the President in overseeing the preparation of the federal budget and in supervising its administration in executive agencies.

[a]The step of soliciting ideas applies to those models selected by the Innovation Center under the PPACA provision establishing the center. Generally, it does not apply to models the center implements that are specifically required by other provisions of law.

[b]A series of Listening Sessions was held in 2010, and transcripts of these sessions are available at http://www.innovations.cms.gov/community/webinars-and-forums/2010/index.html (accessed Sept. 13, 2012).

[c]Medicare is the federal health insurance program for persons aged 65 or over, individuals under the age of 65 with certain disabilities, and individuals with end-stage renal disease. Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals. The State Children's Health Insurance Program is a federal-state program that provides health care coverage to children 18 years of age and younger living in low-income families whose incomes exceed the eligibility requirement for Medicaid. For this report we use the term "Medicaid" to include both Medicaid and the State Children's Health Insurance Program.

[d]The Innovation Center's criteria can be found at: http://www.innovations.cms.gov/about/our-portfolio-criteria/index.html (accessed Sept. 13, 2012).

Appendix III: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 2 2012

Linda T. Kohn
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Kohn:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "CMS INNOVATION CENTER: Early Implementation Efforts Suggest Need for Additional Actions to Help Ensure Coordination With Other CMS Offices" (GAO-13-12).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "CMS INNOVATION CENTER: EARLY IMPLEMENTATION EFFORTS SUGGEST NEED FOR ADDITIONAL ACTIONS TO HELP ENSURE COORDINATION WITH OTHER CMS OFFICES (GAO-13-12)

The Department appreciates the opportunity to comment on this report. The Patient Protection and Affordable Care Act (PPACA) created the Center for Medicare and Medicaid Innovation (Innovation Center). The purpose of the Innovation Center is to test innovative payment and service delivery models to reduce expenditures in Medicare, Medicaid and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care. GAO was asked to review the implementation of the Innovation Center. In this report, GAO:

- Describes the Center's activities, funding, organization, and staffing as of March 31, 2012;
- Describes the Center's plans for evaluating its models and its own performance; and
- Examines whether efforts of the Center overlap with those of other Centers for Medicare & Medicaid Services (CMS) offices and how the Center coordinates with other offices.

GAO found that the Innovation Center is in the early stages of implementing its first models with much work, particularly on evaluations, to be done in the coming years. GAO noted it is important that the Innovation Center continue testing its models and conduct evaluations to determine the extent to which new approaches are able to reduce costs and improve quality of care. GAO identified a few examples of Innovation Center models that overlap with efforts being conducted in other offices within CMS and the mechanisms the Innovation Center uses to coordinate its work in order to avoid unnecessary duplication.

GAO issued one recommendation for executive action. HHS concurs with this recommendation and are taking steps to address it, as described further below.

GAO Recommendation

The Administrator of CMS should direct the Innovation Center to expeditiously complete implementation of its process to review and eliminate any areas of unnecessary duplication in the services being provided by Hospital Engagement Networks (HENs) and Quality Improvement Organizations (QIOs) in hospitals.

HHS Response

HHS concurs with GAO's recommendation and is committed to identifying and eliminating duplication of effort. However, HHS believes that only one of the three examples cited poses a genuine risk of duplicative effort and we are working to address that concern. Our view on each example of potential overlap is described in detail below.

- CMMI ACO Models / MSSP: The draft GAO report expresses concern about duplication between the Medicare Shared Savings Program (MSSP) and CMMI's two ACO models. We do not believe this concern is justified. The two models (Pioneer ACOs and Advance Payment ACOs) were carefully and explicitly designed to be complementary to MSSP.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "CMS INNOVATION CENTER: EARLY IMPLEMENTATION EFFORTS SUGGEST NEED FOR ADDITIONAL ACTIONS TO HELP ENSURE COORDINATION WITH OTHER CMS OFFICES (GAO-13-12)

The Pioneer ACO model is a discrete initiative; as such, providers who participate in a Pioneer ACO are not permitted to also participate in MSSP. Therefore, there is no potential for overlap. Conversely, the Advance Payment model is a tool to allow certain ACOs to be successful, within the context of the MSSP program. Accordingly, all participants in the Advance Payment ACO initiative are also required to participate in MSSP. As such, the two programs are fully aligned and work in conjunction with each other.

- Innovation Center Medicaid Models and CMCS State Medicaid Demonstrations: The draft GAO report expresses concern about duplication between Innovation Center Models and §1115 State Medicaid Waivers. Here too, we believe this concern is not justified. We note that the coexistence of these two authorities is simply a statutory fact, and in no sense the consequence of CMMI policy decisions or other actions. Moreover, there are very fundamental differences between the two authorities: §1115A (CMMI) models are initiated by CMS, are focused on payment and delivery reforms, are not required to be budget neutral during the testing phase, and can span multiple States and payer types, although their ability to waive Medicaid provisions is limited. By contrast, §1115 (CMCS) waivers are initiated by States, can go beyond payment/delivery reforms to include coverage/service expansions, must be budget neutral, and are limited in scope to Medicaid within a single State, although within this limited context they have broad latitude. Given these fairly fundamental differences, we think the likelihood of overlap is extremely low, although a §1115 waiver and an Innovation Center model may sometimes work in a complementary fashion. We believe it is telling that, of the nine CMMI models cited as potentially overlapping with §1115 authority, all either include other (non-Medicaid) payers or are national in scope (and most are both). As such, none of these models could reasonably have been pursued through §1115 authority. Additionally, two of these models (Incentives for Prevention of Chronic Disease in Medicaid and the Medicaid Emergency Psychiatric Demonstration) were specifically authorized and appropriated through the ACA, so we note that any potential for duplication with existing CMCS efforts would be purely the result of statutory requirements.
- Partnership for Patients Model and QIOs: The Partnership for Patients within the Innovation Center and the Center for Clinical Standards and Quality (CCSQ) are both charged to work collaboratively to reduce hospital acquired conditions and readmissions. CMS designed the Partnership for Patients initiative to maximize the respective strengths of the HENs and the QIOs. For example, QIOs have highly specialized expertise in data collection and analysis, while HENs (which are mostly hospital systems and state or national hospital associations) have strong relationships with hospital administrators and can capitalize on these relationships. It is CMS's intention that QIOs and HENs capitalize on these and other distinct strengths in supporting the quality improvement work of hospitals.

  When the Partnership for Patients awarded the HEN contracts in December 2011, the Secretary specifically charged QIOs and HENs, and their accountable CMS program offices, to collaborate to maximize the teamwork and synergy among these programs. To

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ensure appropriate management and oversight of both initiatives, the Innovation Center and CCSQ have been analyzing the activities of the HENs and QIOs as they relate to one another in the areas of hospital acquired conditions and hospital readmissions.

CMS has put steps into place to identify and eliminate any duplication of effort between the HENs and the QIOs. Both the steps that have previously been implemented and those that are underway within CMS are as follows:

1. Teams were formed in March 2012 in the Innovation Center, CCSQ, and the CMS Office of Acquisition and Grants Management (OAGM) to collaborate, prevent duplication, and continuously monitor the effort. Regular weekly team meetings were established to ensure clear communication and teamwork.
2. QIOs and HENs have been instructed by their accountable CMS Contracting Officer Representatives (CORs) to develop clear plans that delineate their accountabilities and arrangements they may have worked out locally to ensure there is no duplication of effort. In addition, the CORs have collected information from the QIOs and HENs and are conducting an independent assessment of whether there are areas of duplication that require further review. If duplication is identified, the CORs make recommendations to OAGM on the appropriate action for each contract.
3. OAGM assesses the CORs' recommendations to make final determinations whether to accept or modify any recommended actions for each contract. If any potential duplication is identified, CMS will work with the contractors to implement the following actions, as appropriate: (1) Put in place an acceptable mitigation strategy; (2) Issue the appropriate technical direction; or (3) Modify the appropriate contract (either the HEN or QIO, or both) to eliminate the duplication of effort.

CMS anticipates completing the work described above by December 31, 2012. In addition, monitoring plans are in place for the CORs to regularly assess future changes in the work plans of QIOs and HENs and the relationships of QIOs and HENs in the field to avoid future duplication.

Testing new payment and service delivery models for Medicare, Medicaid and CHIP is one of CMS's key priorities. Through such testing we can identify ways to improve health and health care and reduce costs through improvement.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Linda T. Kohn, (202) 512-7114 or kohnl@gao.gov

Staff Acknowledgments

In addition to the contact named above, Kristi Peterson, Assistant Director; Krister Friday; Mary Giffin; Samantha Poppe; Rachel Svoboda; and Jennifer Whitworth made key contributions to this report.