CHAPTER 1

Enhancing Medicare's ability to innovate

CHAPTER 1

Enhancing Medicare's ability to innovate

Chapter summary

Current statutory provisions limit the flexibility of the Secretary of Health and Human Services and the Administrator of CMS to implement innovative payment, coverage, and delivery system reform policies in Medicare. A range of innovative purchasing policies exists that could be used to improve the delivery of health care services, but Medicare has legislative limits that constrain it from adopting such policies expeditiously. Furthermore, with broader authority to demonstrate (when necessary) and implement policy innovations, Medicare may be able to increase its potential to improve quality and efficiency in the delivery of health care services to beneficiaries.

First, we discuss three innovative policies that Medicare lacks clear authority to implement and that have the potential to increase the value of the program for beneficiaries and taxpayers:

- Reference pricing policies, including least costly alternative determinations, under which a single payment is set for clinically comparable services. The uncertain legal foundation and two recent court decisions limit Medicare to setting the same payment rate for products and services that are clinically comparable.

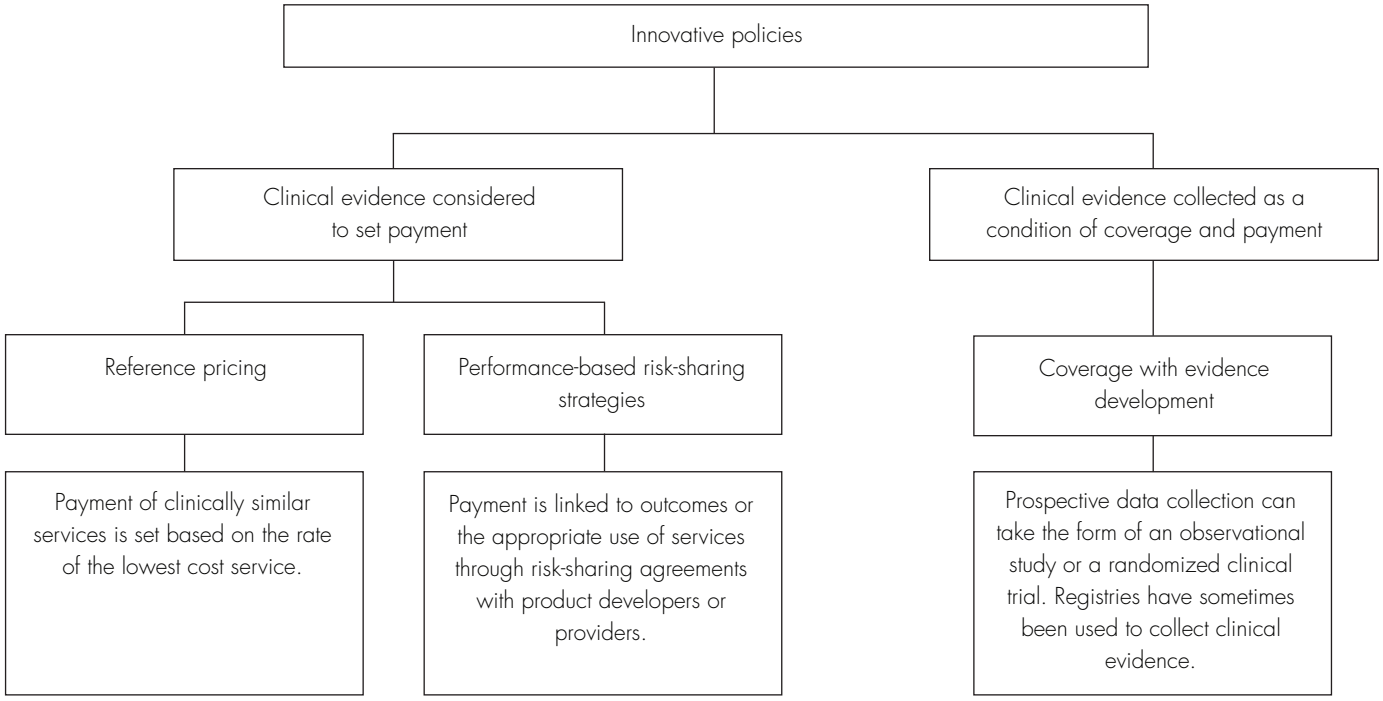
In this chapter

- Performance-based risk-sharing strategies, in which Medicare's payment is linked to beneficiaries' outcomes through risk-sharing agreements with product developers. A change in the law is necessary for Medicare to negotiate with product developers.
- Coverage with evidence development in which CMS requires the collection of clinical data as a condition for Medicare payment. Like reference pricing policies, the program's use of this tool has been hampered because its legal foundation is unclear.

Next, we examine options for giving the Secretary more flexibility to test and implement broader payment policy and health care delivery system improvements through the Medicare demonstration process, including a preliminary analysis of the significant changes made in this area of the program by the Patient Protection and Affordable Care Act of 2010. The Commission has been concerned for several years that funding and process constraints on Medicare's research and demonstration capacity have hindered Medicare's ability to effectively test and rapidly disseminate urgently needed policy innovations. This chapter presents options and reviews changes made by the new law that are designed to increase the Secretary's flexibility and accountability to implement new policies based on empirical evidence to improve the quality of care and reduce the rate of cost growth in the traditional fee-for-service Medicare program. ■

FIGURE 1–1

Clinical evidence is focal point for reference pricing, performance-based risk-sharing strategies, and coverage with evidence development strategies



The Secretary of Health and Human Services and the Administrator of CMS often lack the flexibility to implement innovative payment, coverage, and delivery system reform policies in Medicare. In this chapter, the Commission discusses a continuum of approaches for giving the Secretary and CMS more flexibility to innovate, ranging from applying innovative policies—reference pricing, performance-based risk-sharing strategies, and coverage with evidence development—to testing health care delivery and payment policy improvements, and implementing those approaches that prove to be successful in the demonstration stage. Furthermore, with broader authority to demonstrate (when necessary) and implement policy innovations, Medicare may be able to increase its potential to improve quality and efficiency in the delivery of health care services to beneficiaries. Along with increased flexibility, we consider options for increasing the program's accountability for its performance, including developing a predictable decision-making framework, providing opportunities for public input, and ensuring that the program has sufficient resources to carry out the policy innovations.

Increasing Medicare's flexibility to use selected innovative policies

Reference pricing, performance-based risk-sharing strategies, and coverage with evidence development (CED) are three policies health care purchasers can use to obtain the best value of services purchased (Figure 1-1). The three policies have the potential to improve payment accuracy and decrease knowledge gaps. In addition, they complement the recent federal investment in comparative-effectiveness research (CER). Reference pricing and performance-based risk-sharing strategies use such information in establishing payment for a service or product. CER and CED focus on collecting real-world clinical evidence that patients, providers, and policymakers need to reach better decisions about a service's or product's effectiveness. Medicare's use of each strategy has been hampered because the program's legal foundation is uncertain or lacking (Table 1-1, p. 6). The text box (pp. 8–9) provides four case studies of high-volume or high-growth services for which health policy

TABLE 1–1 **Legal foundation for use of three innovative policies**

	Reference pricing	Performance-based risk-sharing strategies	Coverage with evidence development
Statutory provisions cited to implement policy	A LCA has been applied based on authority that "no payment may be made under Part A or Part B for any expenses incurred for items or services…which…are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."* The functional equivalence standard was based on the authority to make adjustments necessary to ensure equitable payments to the transitional pass-through payments of the hospital outpatient PPS.**	None	CED has been applied based on the Secretary's authority to: (1) cover items and services that are reasonable and necessary;* and (2) "conduct and support research [through the AHRQ administrator] with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically…"***
Medicare's application of policy	Since the mid-1990s, Medicare's claims processing contractors applied LCA policies within their geographic region for durable medical equipment and drugs in the local coverage determination process. CMS applied the functional equivalence standard nationally during the rulemaking process for two drugs paid under the outpatient hospital PPS.	No known application by Medicare.	Since 1995, CMS has nationally applied CED through the national coverage determination process for 12 services using observational and randomized research approaches. More recent CED policies have required prospective studies to address patient-oriented health outcomes rather than just changes in physician guided management.

Note: LCA (least costly alternative), PPS (prospective payment system), CED (coverage with evidence development), AHRQ (Agency for Healthcare Research and Quality).
*Social Security Act section 1862(a)(1)(A).
**Social Security Act section 1833(t)(2)(E).
***Social Security Act section 1862(a)(1)(E).

Source: MedPAC analysis of the statute and information from CMS's website at http://www.cms.hhs.gov/CoverageGenInfo/.

experts recommended their use individually or in some combination to improve Medicare efficiency but have yet to be adopted by the program.

Reference pricing strategies

Medicare's reference pricing strategies are called the least costly alternative (LCA) and functional equivalence policies. Both policies achieve the same function—set a single payment rate for a group of clinically similar services assigned to separate payment codes based on the lowest cost item—but are based on a different statutory foundation. Medicare also uses a form of reference pricing when grouping clinically similar services under a single payment code.

The policy's rationale is that Medicare, beneficiaries, and taxpayers should not pay more for a service when a similar service can be used to treat the same condition and produce the same outcome but at a lower cost. While reference pricing strategies establish payment ceilings, they do not control the price that product developers can set for their items or services. For example, under the LCA policy, Medicare's contractors use the prevailing Medicare payment policy to determine Medicare's payment rate for each clinically comparable item or service and then set the payment rate for all the items and services based on the least costly one. However, a beneficiary can gain access to a more costly service if that is his/her preference. Specifically, if the physician informs the beneficiary in advance and in writing that Medicare is likely to deny

payment for the more costly service and if the beneficiary signs an advance beneficiary notice for each service, then the beneficiary can pay Medicare an additional sum if he/she and the physician choose a more costly service (Centers for Medicare & Medicaid Services 2010c). Under these circumstances, the beneficiary's liability cannot exceed the difference in the Medicare payment between the more costly and least costly services (National Government Services 2009).

Medicare's application of least costly alternative determinations

Since the mid-1990s, Medicare's administrative contractors have applied LCA determinations for durable medical equipment and drugs in their geographic jurisdiction. Although the statutory platform for making LCA determinations is based on Medicare's reasonable and necessary authority, the policy affects the payment rate of a service or product (Centers for Medicare & Medicaid Services 2008). LCA determinations are based on the premise that "if two services are clinically comparable, then Medicare does not cover the additional expense of the more costly service, when this additional expense is not attributable to that part of an item or service that is medically reasonable and necessary" (National Government Services 2009). Examples include manual wheelchair bases, power mobility devices, seat lift mechanisms, supplies for tracheostomy care, and anti-androgen drugs for prostate cancer. However, as this report went to press, several contractors have retired the LCA policy for anti-androgen drugs for prostate cancer. Medicare's contractors consider exceptions to the LCA if documentation of medical necessity is submitted.

A LCA policy is implemented in a local coverage decision (LCD) in which a contractor decides to cover a particular item or service in its geographic jurisdiction (Centers for Medicare & Medicaid Services 2010b, Centers for Medicare & Medicaid Services 2010d). The process of developing LCDs is designed to be transparent with opportunities for public comment. Contractors must follow structured rules, including consulting with physician groups, posting the proposed LCD with a comment period, and publishing the final version, including the evidence used to develop the policy.

There is no statutory provision giving Medicare specific authority to apply LCA determinations nor is there a clear statutory provision prohibiting their use. CMS explains in its interpretive manuals that Medicare's authority to apply LCA determinations is based on the general provision requiring the program to pay the expenses of items and services that are reasonable and necessary (Centers for Medicare & Medicaid Services 2010b, Centers for Medicare & Medicaid Services 2010d) (Table 1-1).

Other federal agencies have recommended that Medicare apply LCA policies. In 2003, the Office of Inspector General (OIG) recommended that CMS encourage all Medicare contractors to apply LCA to a drug used to treat prostate cancer (Office of Inspector General 2003). In another instance, the OIG recommended the use of LCA for the payment of semielectric hospital beds (Office of Inspector General 2002). As described in the text box (pp. 8–9), the Congressional Budget Office suggested the use of LCA to pay for selected Part B drugs.

Two recent court decisions constrain Medicare's future use of LCA determinations. A beneficiary challenged a LCA determination applied to an inhalation drug in U.S. District Court, arguing that Medicare law requires that if the drug is reasonable and necessary, Medicare must pay the statutorily defined payment rate for the drug—106 percent of the average sales price (ASP). The government argued that the reasonable and necessary statutory provision is ambiguous and confers great discretion on the Secretary and that the LCA policy is permissible because the provision explicitly addresses payment and expenses (Table 1-1).

The U.S. District Court agreed with the beneficiary and ruled that Medicare can no longer use LCA policies to pay for Part B inhalation drugs, asserting that the statute's provision that sets the payment rate for Part B drugs based on its ASP precludes Medicare from applying LCA policies (U.S. District Court for the District of Columbia 2008). A December 2009 ruling by the U.S. Court of Appeals upheld the lower court's decision (U.S. Court of Appeals 2009). Both court decisions suggest that Medicare can use LCA only when statutory provisions that establish payment rates specifically allow a LCA approach (Arnold & Porter 2010). The Secretary did not ask the D.C. Circuit Court to reconsider its decision or seek review by the Supreme Court.

Medicare's application of a functional equivalence standard

Like a LCA determination, the functional equivalence standard is a form of reference pricing under which payment for clinically comparable services assigned to separate payment codes is based on the least costly item. Medicare has used the functional equivalence standard once to set the payment rates for anti-anemia products.

Use of innovative policies might improve the value of Medicare spending and create better information

The following four case studies demonstrate products and services for which policy experts have proposed using reference pricing and coverage with evidence development (CED), but they have yet to be adopted by Medicare.

Case 1: Products that treat osteoarthritis

The Congressional Budget Office (CBO) included as a policy option use of the least costly alternative approach to pay for five products that physicians use to treat osteoarthritis of the knee. Although each product differs slightly, they are all approved by the Food and Drug Administration for the same indication—osteoarthritis—and they work through the same clinical mechanism. CBO estimated savings of about $200 million between 2010 and 2014 and almost $500 million between 2010 and 2019 if Medicare set the payment for these five products based on the lowest priced product (Congressional Budget Office 2008).

CMS currently covers and pays for each product based on Medicare's method for paying for Part B drugs (106 percent of its average sales price).

Case 2: Wound therapy care

Policy experts have proposed using CED to pay for negative pressure wound therapy (NPWT) pumps—devices used to treat ulcers and wounds (Tunis 2006). Underlining this proposal is the insufficient comparative clinical evidence demonstrating the circumstances in which the pumps are better than conventional wound care (Samson et al. 2004). Medicare's spending for NPWT pumps is substantial and growing: Between 2001 and 2007, spending increased by 583 percent to $164 million (Office of Inspector General 2009b).

Policy experts have also proposed changing how Medicare pays for the pumps. According to the Office of Inspector General (OIG), Medicare's payment is based on the first pump Medicare covered in 2001 even though newer, less costly pumps have become available. A recent assessment concluded that there is insufficient evidence demonstrating differences between the first and the newer pumps (Agency for Healthcare Research and Quality 2009). Considering the finding that suppliers were paying on average about 20 percent of Medicare's fee schedule for the newer pumps, the OIG recommended applying Medicare's inherent reasonableness authority and including the pumps in a competitive bidding program (Office of Inspector General 2009b). Reference pricing is another alternative that might improve program efficiency.

CMS currently covers this device without any requirement to collect clinical evidence, and its payment rate remains based on the most costly one.

Case 3: Cardiac computed tomography angiography

In 2007, CMS proposed CED for cardiac computed tomography (CT) angiography when used to diagnose coronary artery disease. This proposal was based on the lack of sufficient clinical evidence demonstrating that the imaging service improves beneficiaries' health outcomes and was informed by conclusions from CMS's advisory group, the Medicare Evidence Development & Coverage Advisory Committee, and evidence reviews from the Agency for Healthcare Research and Quality and the Blue Cross Blue Shield Technology Evaluation Center. After posting a draft CED, the agency received public comments that overwhelmingly opposed the use of CED, and CMS withdrew the CED proposal in 2008. A key argument by coverage proponents is that Medicare covers other imaging procedures with even less evidence of benefit (Redberg and Walsh 2008).

CMS currently covers cardiac CT angiography without any requirement to collect clinical evidence. Medicare's claims contractors determine coverage through the local coverage determination process or on a case-by-case basis. This service is paid for under the physician fee schedule and hospital outpatient prospective payment system (PPS).

(continued next page)

Use of innovative policies might improve the value of Medicare spending and create better information

Case 4: Treatments for localized prostate cancer

One medical society recommended linking coverage of proton beam therapy used to treat localized prostate cancer to participation in clinical trials because of the lack of research demonstrating its net clinical benefit compared with other existing treatments, including intensity-modulated radiation therapy (IMRT) and brachytherapy (American Society for Radiation Oncology 2009). There also has been a proposal to apply reference pricing. In 2006, a Medicare contractor proposed paying for proton beam therapy at the same rate as IMRT for some conditions and at the same payment rate as conventional radiation for other conditions (TrailBlazer Health Enterprises 2006). Underlining this proposal was the lack of comparative research assessing whether proton beam therapy results in better outcomes than other treatments and the wide variation in costs, ranging from $820 for outpatient surveillance to $20,000 for IMRT and $49,000 for proton beam therapy in 2007 (Institute for Clinical and Economic Review 2008).

Local Medicare contractors that currently cover each treatment strategy (i.e., brachytherapy, IMRT, and proton beam therapy) do so without any requirement to collect clinical evidence. The contractor did not implement the least costly alternative for proton beam therapy. The different treatment strategies are paid for under the physician fee schedule and hospital outpatient PPS. CMS has announced that it is convening the Medicare Evidence Development & Coverage Advisory Committee on April 21, 2010, to review evidence and public testimony and make recommendations to CMS about the sufficiency of evidence on the various radiotherapies for localized prostate cancer. ■

In 2003, CMS nationally set the payment rate for a new biologic (darbepoetin alfa) at the rate of an existing, less costly product (epoetin alfa) after concluding that both anti-anemia products were clinically comparable because they used the same biological mechanism to produce the same clinical result—stimulation of the bone marrow to produce red blood cells.

CMS did not initially set the payment rate of the new product by using the functional equivalence standard. Rather, in the 2003 proposed hospital outpatient prospective payment system (PPS) rule, CMS said that it would continue the new biologic's transitional (higher) pass-through payments.[1] In response, a product developer submitted a comment to CMS arguing that because both the old and the new biologic are substitutes, they should be paid at the same rate (Centers for Medicare & Medicaid Services 2002). In the final rule, CMS reviewed the clinical evidence and concluded that both biologics were functionally equivalent. Noting its authority (under section 1833(t)(2)(E)) to adjust outpatient hospital PPS's transitional pass-through payments that the agency determines are "necessary to ensure equitable payments," CMS determined that the new biologic should be paid for at the same rate as the older one (Centers for Medicare & Medicaid Services 2002).[2] However, CMS also stated that it did "not expect to make nationally-applicable determinations of similarity of drugs or biologicals … on a routine basis. We regard this situation as unusual distinguished by the very strong similarity of the two products and by the size of the potential effects on the Medicare program."

Because the new biologic lost its eligibility for the pass-through payment for new drugs, its payment rate declined from $4.74 per microgram (which included the pass-through payment) in 2002 to $2.37 per microgram (without the pass-through payment) in 2003.[3]

While the marketer of the older biologic supported CMS's action, the developer of the new biologic disagreed with the agency's decision, noting its product's uniqueness and differences from the older product (Amgen 2002, Keenan et al. 2006). The product developer of the new biologic filed suit against CMS's action, but an appeals court dismissed the case, concluding that CMS's statutory rationale for the decision was not subject to judicial review (U.S. Court of Appeals 2004).

Subsequently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) limited use of the functional equivalence standard. The Congress prohibited use of this standard for other drugs

TABLE 1–2 **Reference pricing by including two products in a single payment code**

Coding strategy	2005* 1st quarter	2006* 1st quarter	2007* 2nd quarter	2007** 3rd quarter	2008*** 2nd quarter	2009*** 2nd quarter	2010*** 1st quarter
Combined payment code							
Albuterol				$0.53			
Levalbuterol				$0.53			
Separate payment code							
Albuterol	$0.07	$0.06	$0.08		$0.04	$0.05	$0.05
Levalbuterol	1.28	1.34	1.54		0.28	0.26	0.20

Note: Albuterol is unit dose, 1 milligram. Levalbuterol is unit dose, 0.5 milligram.
*Between the first quarter of 2005 and the second quarter of 2007, Medicare payment was based on 106 percent of the average sales price for each drug.
**Between the third quarter of 2007 and the first quarter of 2008, payment for the single code that included albuterol and levalbuterol was based on the volume-weighted average 106 percent average sales price for both drugs.
***Beginning in the second quarter of 2008, payment for each drug was based on the lower of: (1) the volume-weighted average of 106 percent of the average sales price for both drugs, or (2) the payment rate based on 106 percent of the average sales price for the specific drug.

Source: The Medicare, Medicaid and SCHIP Extension Act of 2007 (section 112(b)(2)), Office of Inspector General 2009a, and information from CMS's website at http://www.cms.gov/McrPartBDrugAvgSalesPrice/.

and biologics in the hospital outpatient setting. However, the Congress did not preclude the agency from continuing to use the policy for the two biologics in the hospital outpatient setting or for setting the payment rate the same for other clinically comparable services in other settings. Medicare continued to use the functional equivalence standard in 2004 and 2005. In response to passage of the MMA, the payment rate for each biologic was set based on 106 percent of its ASP beginning in 2006.

De facto reference pricing by combining similar services in the same payment code

By grouping clinically similar services in one payment code, Medicare is essentially setting payment based on the volume-weighted average of the program's payment for these services, which creates incentives for providers to furnish the lower priced item.

Medicare has some but not all responsibility for developing and maintaining the standardized codes it assigns to pay for medical services and procedures. Medicare maintains the coding systems for the program's prospective payment mechanisms, such as the clinical categorization system for the inpatient hospital PPS called Medicare severity–diagnosis related groups. Both the American Medical Association (AMA) and Medicare are responsible for the Healthcare Common Procedure Coding System, the classification system of services and procedures performed by physicians and other medical professionals.[4] In general, both the AMA and Medicare assign a unique code for a product or service if, in addition to meeting certain other criteria (e.g., Food and Drug Administration (FDA) approval), clinical evidence suggests that the product or service performs a significantly different function than other available products and services.

An example of de facto reference pricing occurred between July 1, 2007, and March 31, 2008, when CMS established a single payment code for two chemically similar drugs used to treat asthma and chronic obstructive pulmonary disease—levalbuterol (a single-source drug) and albuterol (a multisource drug with generic versions).[5] This de facto reference pricing essentially set the Medicare payment amount based on the volume-weighted ASP for both products. (CMS made this change to comply with provisions of the MMA concerning payment for drugs.)

Including products with divergent acquisition costs into a single payment code could result in Medicare's payment rate not reflecting each product's acquisition cost. After both drugs were included in the same code (in the third quarter of 2007), the payment rate for albuterol (the multisource product) increased (by 563 percent) while the rate for levalbuterol (the single-source product) decreased (by 66 percent) (Table 1-2) (Office of Inspector General 2009a). To address the concern that the payment rate did not match each product's acquisition cost, the Medicare, Medicaid and SCHIP Extension Act of 2007 reestablished

separate codes for the products starting in the second quarter of 2008 and calculated each product's payment rate based on the lower of: (1) the volume-weighted average of 106 percent of the ASP for both drugs, or (2) the payment rate based on 106 percent of the ASP for the specific drug.

Reactions vary to reference pricing strategies

Proponents of reference pricing argue that it makes patients and their providers more sensitive to the relative prices of different services and to considering cost when choosing among treatment options (Commonwealth Fund 2003). They also argue that such policies, if applied consistently, could stimulate price competition among products and services that are clinically similar.

The potential fiscal advantage must be weighed against several largely unquantified concerns. Some critics argue that physicians should be given discretion in selecting among clinically comparable services, because the effectiveness of those services may vary among patients. The literature on the effect on patients' outcomes when reference pricing is used to set the payment rate of drugs is mixed. An analysis of 10 studies of reference pricing (primarily implemented in Canada) found no evidence of adverse effects on health and no clear evidence of increased health care utilization (Cochrane 2006).[6] By contrast, an uncontrolled study found an increase in complications when patients switched therapies under a system of reference pricing in New Zealand (Thomas and Mann 1998).

Some critics also argue that reference pricing may decrease manufacturers' investment in research and development. Manufacturers might shift their research toward diseases not currently treated by multiple therapies or reduce investment in products that are incremental improvements of other products (Farkas and Henske 2006).[7] Proponents of reference pricing policies counter that such policies might increase manufacturers' incentive to develop truly innovative products and compare their product with other products in the clinical trials they sponsor. Policy analysts noted the lack of empirical evidence documenting the impact of reference pricing policies on the pace of innovation in the drug industry (Kanavos and Reinhardt 2003).

The literature on whether reference pricing may limit the availability of medical products and services is mixed. For example, one study concluded that reference pricing policies of drugs in New Zealand decreased the availability of new compounds, particularly high-priced new products (Danzon and Ketcham 2003). However, another study reported high availability (exceeding 90 percent) of 249 drugs in countries that use reference pricing policies to a greater (e.g., Germany) and lesser (e.g., United States) extent (Danzon and Furukawa 2003).

Reference pricing generally results in lower prices for drugs internationally than in the United States. Using International Monetary System data, the U.S. Department of Commerce reported that, in 2003, prices for all patented drugs were 18 percent to 60 percent lower in Australia, Canada, France, Germany, Greece, Japan, Poland, Switzerland, and the United Kingdom than in the United States (Department of Commerce 2004). However, several factors can affect the international comparison of drugs, including: (1) changes in currency rates between the year the data were published and 2010; and (2) differences in the use of patented drugs and their generic counterparts in the United States and other countries.

Performance-based risk-sharing strategies

Performance-based pricing strategies link payment of a service or a product to patient outcomes through risk sharing with product developers or providers. Examples of risk-sharing agreements include linking a product's payment to whether it is used appropriately (e.g., according to clinical guidelines) or to clinical outcomes (e.g., reduces the occurrence of adverse events or improves clinical outcomes). The reward tied to the desirable use or outcome could be a higher price, while the penalty for undesirable results could be a lower price. Risk-sharing agreements have the potential to improve value for payers, patients, and product developers. Nonetheless, there is limited experience with such sharing strategies and little empirical information evaluating their use (Towse and Garrison 2010). Although some commercial payers in the United States and other countries have begun to use such strategies, they have not been applied by Medicare. A change in law is necessary for the program to implement such strategies.

In most instances, product developers bear the prelaunch risks of developing products; payers bear the postlaunch risks of making poor adoption decisions (Garrison et al. 2007). A product's price is usually established based on the evidence of its clinical effectiveness known prior to its launch. Performance-based arrangements shift some of the risks to the postlaunch period when more information about the clinical effectiveness of the product or service becomes available.

Performance-based strategies might be particularly applicable to products and services that are costly and have different success rates among subgroups of patients. Using such strategies, payers may face less financial risk from the treatment of demographically different patient groups that were not included in clinical trial testing or did not show substantial improvement (Garber and McClellan 2007).

For drug manufacturers in particular, risk sharing provides a means to offer discounts to payers without lowering the list price. From the perspective of a product developer, risk sharing offers the possibility of receiving credit for attributes of a drug not studied in clinical trials such as cost offsets, ease of administration, and adherence (de Pouvourville 2006). It also makes a drug's price more predictable for the product developer and offers the prospect of future financial rewards while additional data are collected postlaunch. On the other hand, it puts pressure on product developers to demonstrate that their claims are well founded.

Several case studies illustrate the workings of performance-based pricing. In each case, a value-based agreement exists between the payer and the product developer. These case studies were developed by the Center for the Evaluation of Value and Risk in Health at the Tufts Medical Center, under contract to the Commission (Neumann et al. 2010).

A drug to prevent and treat osteoporosis

In 2009, two product developers negotiated an agreement with a provider-sponsored payer that links the payment of their drug, which treats and prevents postmenopausal osteoporosis, to the occurrence of nonspinal osteoporotic fractures. (Health Alliance, the payer, entered into a risk-sharing agreement with Procter & Gamble and Sanofi-Aventis, companies that co-market risedronate sodium.) Under this agreement, the payer receives rebates from product developers to cover the costs incurred to treat fractures if patients adhere to their drug regimen. Product developers gain market share when patients adhere to their drug regimen. Thus, the payer and product developers together share the incentive of encouraging patients' adherence to their drug regimen. Under this agreement, the payer placed the drug on a formulary tier with a lower copayment than a competing drug.

To implement this arrangement, pharmacy and medical data were used to calculate patient adherence and fracture rates. The interim results that were announced after nine months suggest that fracture rates were consistent with the rate experienced in the drug's clinical trials (Drug Benefit News 2009).

Two drugs that treat diabetes

In 2009, a product developer entered into a contract with a payer that links the payment of its two diabetes drugs to patients' overall blood sugar control and adherence to therapy. (Cigna, the payer, entered into a risk-sharing agreement with Merck, the product developer of sitagliptin and sitagliptin plus metformin.) Blood sugar control is measured based on hemoglobin A1c levels. (For this measure, lower values, associated with a lower risk of diabetes complications, are better than higher values.) Under the arrangement, the product developer increases the discount for both drugs if there is an increase in the percentage of patients taking any oral antidiabetic therapy who achieve an outcome of a hemoglobin A1c level that is less than 8 percent. The product developer also increases the payer's discount based on the percentage of patients who adhere to their prescribed regimen. The payer already had an active diabetes management program in place and collected both pharmacy data and hemoglobin A1c laboratory results for internal use, so the agreement's infrastructure was established.

From the payers' perspective, this arrangement is advantageous because they are provided larger rebates if patients adhere to their drug regimen and have hemoglobin A1c levels of less than 8 percent. An added benefit is that lowering hemoglobin A1c levels reduces or delays the risk of developing diabetes-related eye, kidney, and nerve disease in people with diabetes. From the product developers' perspective, this arrangement is advantageous because it improves the placement of their drugs on the payer's formulary, meaning a lower copayment than for some other diabetes drugs (Pollack 2009). The agreement also helps increase the product developer's market share.

A molecular diagnostic test that predicts the likelihood of chemotherapy benefit

A product developer and a large payer developed an agreement that links the price of a molecular diagnostic test to patients' subsequent treatment (chemotherapy regimen). (United Healthcare, the payer, entered into a risk-sharing agreement with Genomic Health, which developed and markets Oncotype DX.) The molecular diagnostic test helps identify which women with early-stage breast cancer are more likely to benefit from adding chemotherapy to their hormonal treatment. This test also helps assess the likelihood that a woman's breast cancer will return.

The agreement links the diagnostic test's payment to its impact on treatment patterns. If patients' chemotherapy usage does not follow the recommendations of the diagnostic test, the payer can renegotiate its payment rate (Pollack 2007). By using the payer's claims database, treatment patterns are monitored by comparing patients' test results to chemotherapy usage. The payer views the arrangement as a success thus far. In the agreement's first year, approximately 15 percent of patients were treated contrary to the results of the diagnostic test; in the second year, the rate decreased to 6 percent, obviating the need for contract renegotiations.

Coverage with evidence development

CED is an approach for health care payers to pay for potentially beneficial medical services that lack clear evidence showing their clinical effectiveness in specific patient populations. Some services diffuse quickly into routine medical care with incomplete information about their clinical effectiveness.[8] Under CED, patients have access to medical services while clinical evidence is being collected and analyzed. CED's goal is to reconcile the tension between evidence-based policies and being responsive to the pressure from product developers, providers, and patients to cover new services and new indications of existing services (Iglehart 2009, Tunis and Pearson 2006).

Because CED provides Medicare the opportunity to generate clinical evidence that otherwise may not have been collected, it enables the program to ultimately develop better, more evidence-based policies. CED also provides an opportunity to collect clinical evidence for groups that are often underrepresented in clinical trials, including older beneficiaries and minorities. In the future, there may be opportunities to more closely align Medicare's CED efforts with the FDA's postmarket safety monitoring efforts (Carino et al. 2006).

Since 1995, Medicare has applied CED—linked Medicare coverage and payment to the collection of clinical evidence in the national coverage determination process—to 12 services (Table 1-3, p. 14). The design of each CED effort has varied, depending on the service and the circumstance leading to the CED policy. Some CED efforts were designed as randomized trials and compared alternative treatment approaches (e.g., lung volume reduction surgery compared with medical management) while others used an observational approach and collected clinical evidence for one medical service (e.g., implantable cardioverter defibrillators (ICDs)).

CMS's statutory justification to apply CED has changed over time. Initially, CMS (then called the Health Care Financing Administration (HCFA)) applied the CED concept to the coverage of lung volume reduction surgery through its general authority established by §1862(a)(1)(A) of the Social Security Act, which states that Medicare can pay only for services that are reasonable and necessary for the diagnosis and treatment of illness and injury. With respect to the lung volume reduction surgery, CMS said that the surgical procedure would not be reasonable and necessary when provided in standard clinical practice but would likely "improve health outcomes" when it was provided under the carefully structured circumstances associated with a clinical trial (Mohr et al. 2010). A similar rationale was later used in the coverage decision on the use of radiotracer [^{18}F]fluorodeoxyglucose and positron emission tomography (FDG–PET) for suspected dementia in 2004, the ICD in January 2005, the off-label use of oncology drugs in January 2005, and the first draft of the CED guidance in April 2005.

In 2006, CMS revised its statutory justification to apply CED. In that year, CMS issued final CED guidance that included two different CED tracks: (1) coverage with appropriateness determination (CAD), and (2) coverage with study participation (CSP). In the guidance document, CMS explained that the basis for implementing CAD is that a service is reasonable and necessary but that additional clinical data that are not routinely available on claims are needed to ensure that the service is appropriately provided. For services studied under CAD, observational registries are usually used to collect clinical evidence.

The statutory authority to apply CSP—which generally links coverage to participation in a clinical trial—is more complex. CMS explained that its authority to cover services using CSP is derived from section 1862(a)(1)(E) of the statute that allows Medicare payment for services determined by the Agency for Healthcare Research and Quality (AHRQ) to reflect the research needs and priorities of the Medicare program. Thus, while CMS judges that the clinical evidence does not meet the reasonable and necessary standard, Medicare coverage may be extended to patients enrolled in a clinical research study conducted under section 1862(a)(1)(E). This legal rationale has increased AHRQ's role in implementing CED.

Because its statutory foundation to apply CED is unclear, Medicare's use of CED has been hampered and is limited (Mohr and Tunis 2010). CED has been used on a case-by-

TABLE 1–3 **Medicare's coverage with evidence development studies**

Service	Year CED released	Type of CED	Status of CED effort
Lung volume reduction surgery*	1995	Clinical trial	Publicly funded study completed and main findings published in 2003. Medicare revised its NCD to cover all patients who matched the characteristics of patients in the trial who experienced a survival or quality-of-life benefit.
Angioplasty of the carotid artery with stenting*	2001	Clinical trial and registry	NINDS (publicly funded) trial ongoing, FDA post-approval studies sponsored by product developers, and privately funded registries.
FDG–PET imaging for dementia	2004	Clinical trial	Trial is ongoing, beginning in 2006 under private sponsorship.
FDG–PET imaging for cancers	2005	Registry	Privately funded registry ongoing. In 2009, CMS removed the clinical study requirement for CED for the initial diagnostic test with PET for most solid tumor cancers. CED will be used for PET scans for subsequent treatment strategies.
Implantable cardioverter defibrillators	2005	Registry	Privately funded registry ongoing. In 2009, an additional effort to collect longitudinal data received private and public funding.
Off-label use of colorectal cancer drugs	2005	Clinical trial	NCI (publicly funded) trials: some ongoing, some completed, some cancelled.
Cochlear implantation	2005	Clinical trial	Study not yet implemented. No source of public or private funding to cover the trial's research costs emerged in response to NCD.
Long-term oxygen treatment	2006	Clinical trial	NHLBI (publicly funded) trial ongoing.
Artificial heart	2008	Clinical trial	Trial ongoing. Manufacturers provide funding for the research costs. A registry of the trial data has received federal funding.
Continuous positive airway pressure therapy for obstructive sleep apnea	2008	Clinical trial	Trial not yet implemented.
Pharmacogenomic testing for warfarin response	2009	Clinical trial	NHLBI (publicly funded) trials ongoing.
PET (sodium-fluoride 18) to identify bone metastasis of cancer	2010	Clinical trial	Study begun or under development.

Note: CED (coverage with evidence development), NCD (national coverage decision), NINDS (National Institute of Neurological Disorders and Stroke), FDA (Food and Drug Administration), FDG–PET ([^{18}F]fluorodeoxyglucose and positron emission tomography), NCI (National Cancer Institute), NHLBI (National Heart, Lung and Blood Institute).
*Although the framework to implement "coverage with evidence development" had yet to be developed, Medicare linked this service's coverage to the collection of clinical evidence.

Source: Mohr et al. 2010, Tunis and Pearson 2006.

case basis in response to specific circumstances at play in each case. In some instances, the lack of clear statutory authority has affected the research questions and study design of the CED effort and the clinical evidence that was collected (Mohr et al. 2010). The absence of a clear statutory foundation has affected Medicare's ability to develop a proactive mechanism to identify potential CED topics (Mohr et al. 2010). Because of the unclear legal foundation, there has been uncertainty, in some instances, about the circumstances under which Medicare can apply CED. This situation is likely to continue to hamper Medicare's ability to implement the policy effectively (Mohr and Tunis 2010).

Some stakeholders argue that CED is beyond Medicare's statutory authority (Dahm 2008). Other concerns cited by stakeholders include: (1) CED may adversely affect manufacturers' incentive to develop new medical services; (2) CED may duplicate or replace FDA's authority in ensuring the safety and efficacy of drugs, biologics, and devices; and (3) CED changes Medicare's threshold for coverage.

Case studies of CED use in Medicare

Taken together, three case studies show the benefits and weaknesses in Medicare's use of CED. On the plus side, they demonstrate that useful clinical evidence can be generated at the same time as providing patients access to a service and that Medicare can use this evidence to refine its coverage policies. On the minus side, the selected cases underscore the lack of a well-defined, consistent approach to (1) designing CED studies, (2) developing methods, and (3) setting a timeline to reevaluate Medicare's payment for the service under study. The Center for Medical Technology Policy under contract to the Commission developed these case studies (Mohr et al. 2010).

In the first case—the use of lung volume reduction surgery for severe emphysema—CMS observed in the mid-1990s that the procedure was increasing among beneficiaries despite extremely limited clinical evidence (Ramsey and Sullivan 2005). The 30-day mortality rates following the procedure ranged between 17 percent and 20 percent. Consequently, CMS, in 1995, issued a national coverage decision (NCD) that paid for the surgery only for beneficiaries treated according to a National Institutes of Health (NIH) clinical trial protocol.

In response to CMS's decision, the Congress mandated that the agency submit a report that: (1) reviewed the treatment of end-stage emphysema and chronic obstructive pulmonary disease and the available studies on lung volume reduction surgery, and (2) made a recommendation about the appropriateness and conditions of Medicare coverage for such a procedure. In addition, the Congress held a hearing about Medicare's coverage decision-making process and beneficiary access to new technologies. Following these congressional activities, in 1997, 17 research centers began enrolling patients (Ramsey and Sullivan 2005). The seven-year trial showed that some patients were more likely to die if they underwent surgery compared with rehabilitation alone, while others achieved a slightly better quality of life or a small survival benefit from the surgery (Tunis and Pearson 2006). Medicare revised its coverage policy to cover all patients who matched the characteristics of patients in the trial who experienced a survival or quality-of-life benefit. Since then, use of this surgery has remained low.

In a second case, in 2002, CMS released a noncoverage decision for FDG–PET in the diagnosis of Alzheimer's disease based on the lack of evidence showing that it would improve beneficiaries' outcomes as well as out of concern that approval of this technology would result in unnecessary exposure to radiation. For this decision, CMS obtained advice from a technology assessment sponsored by AHRQ and an expert panel convened by the National Institute on Aging. After this noncoverage decision, there was considerable pushback from product developers and the clinical and patient communities (Tunis and Pearson 2006). Given the increasing demand from multiple stakeholders, the major burden that dementia represents to the Medicare population, and the lack of conclusive clinical evidence, CMS modified its coverage policy and issued a CED policy in 2004 to cover PET imaging for patients with suspected early dementia if they are enrolled in a large, CMS-approved practical clinical trial. Although researchers developed a CED that met CMS's requirements, they could not obtain public or private funding. As a next step, the lead researchers asked the nine facilities that were originally interested in participating in the CED effort to cover their own research costs; some declined to do so. Most recently, four facilities are participating in the CED effort, although only one of them is currently recruiting patients. A total of 17 patients have been enrolled to date.

In the third case, in 2005, CMS issued a CED for ICDs used to prevent cardiac arrest due to ventricular fibrillation.[9] (ICDs are devices implanted in a patient's chest; when they detect life-threatening heart rhythms, they deliver an electric shock to restore normal rhythm.) An observational registry was used for this CED application to provide access to ICDs across the Medicare population while accumulating large amounts of data for use in subgroup analyses. The registry has been funded by a combination of hospital fees and grants from device companies and payers (Curtis et al. 2009). The American College of Cardiology (ACC) operates the ICD registry; as of June 2009, hospitals have submitted data on 380,000 implants to the registry, representing about 90 percent of all procedures. Information collected by the registry includes the indications for implanting the device, the length of the initial hospital stay, physician training and specialty, the type of device, and the occurrence of in-

hospital complications. For example, using data from the registry, researchers concluded that the risk of in-hospital procedural complication rates was lower for ICD implantations performed by an electrophysiologist than for other physician specialty types (Curtis et al. 2009).

However, the original registry was not designed to answer CMS's questions about beneficiary postdischarge outcomes, including use of the ICD to address life-threatening heart rhythms (i.e., whether the ICD fired) and long-term survival. CMS, the ACC, and other stakeholders later designed a research effort to collect longitudinal firing and survival data over a five-year period; in 2010, AHRQ and the ACC agreed to provide $3.5 million to fund this effort (Agency for Healthcare Research and Quality 2010). The 3.5-year study will follow 3,500 patients with ICDs to determine how often the devices shock (i.e., fire), to establish whether the shocks are appropriate, and to identify the patients who are most likely to require ICD shocks.

Issues in Medicare's use of innovative policies

To improve Medicare's flexibility to use reference pricing, performance-based risk-sharing strategies, and CED, the program would need:

- a clear legal foundation to apply them,
- a transparent process to implement them, and
- sufficient resources to implement them.

The online appendix to this chapter (available at http://www.medpac.gov) discusses additional policy issues associated with implementing each policy.

Reference pricing and performance-based risk-sharing strategies are not the only policies that would promote payment accuracy. There are instances in which the Secretary lacks authority to make technical changes (in a budget-neutral manner) to existing payment methods that would improve payment accuracy. The text box (opposite page) discusses whether Medicare should have more flexibility to maintain existing payment methods or whether the Congress should continue mandating changes on a case-by-case basis.

Creating a clear legal foundation

Over the years, Medicare has had mixed experiences in applying reference pricing strategies and CED. As mentioned previously, despite recommendations from policy experts about the use of these policies for specific services, CMS has not applied them. Medicare lacks a clear legal foundation to implement reference pricing and CED, which has hampered the program's ability to use these tools. A change in law is necessary for the program to implement performance-based risk-sharing strategies.

To improve its ability to promote the efficient delivery of care, Medicare could be given broader authority to implement these innovative policies. Clear statutory authority would enable Medicare to develop a more systematic approach in applying each strategy. Without a change to the statute, the recent two court decisions on LCA may impede CMS's future use of this policy.

Developing a clear and predictable decision-making framework; ensuring transparency and opportunities for public input

To implement these policies, CMS would need to develop a clear and predictable decision-making framework. One example is the process (implemented in 2008) by which CMS considers changes to the list of compendia that identifies medically accepted indications of drugs used in anticancer chemotherapeutic regimens. This process, started in 2008, was developed based on authority from the Deficit Reduction Act of 2005. Each year, beginning on January 15, CMS accepts requests from the public for compendium changes and, no later than March 15, posts the completed requests for public comment. There is a 30-day public comment period, and CMS posts its final decision within 90 days after the close of the comment period. CMS has also posted the criteria that it uses in evaluating compendium requests. Later in this chapter, we discuss the national coverage determination process, another example of a transparent and predictable process that provides opportunities for public input.

One issue is whether the process to implement these policies should be centralized (implemented nationally by CMS officials in Baltimore), decentralized (implemented regionally by Medicare's contractors), or some combination of both. For example, reference pricing policies have been implemented nationally by CMS and regionally by contractors. By contrast, CED has been applied nationally, as it is not clear that the statutory authority to implement local coverage determinations would extend to determinations made under AHRQ's research authority (section 1862(a)(1)(E) of the Social Security Act).

Medicare's flexibility to maintain existing payment methods

In some instances, a change in law is necessary for Medicare to ensure payment accuracy. At issue is whether Medicare should have more flexibility to maintain existing payment methods or whether the Congress should continue mandating changes on a case-by-case basis.

To maintain the payment accuracy of existing payment methods, the Secretary and CMS administrator often need authority from the Congress to make technical changes in a budget-neutral manner. For example, without a change in law, CMS cannot develop an outlier policy for the skilled nursing facility prospective payment system. Such a policy, implemented budget neutral, would improve payment accuracy by defraying the exceptionally high cost of care for some patients.

The Secretary also cannot maintain payment methods when the provisions of the law are very detailed. For example, in 1993, the statute named three drug references (compendia) for the Secretary to consult in determining medically accepted indications of cancer drugs. Over time, only one of these statutorily named compendia was still published. The Secretary could not add new compendia until the Congress, through the Deficit Reduction Act of 2005, gave the Secretary the authority to do so. With the statutory authority, the Secretary, in 2008, implemented a well-defined process, which includes opportunities for public comment, for revising the list of compendia.

Medicare lacks the flexibility to implement policies that pay providers according to their quality or efficiency. As a general rule, providers' payment rates must be applied uniformly across the country. Providers meeting basic conditions of participation cannot be prohibited from billing for covered services. It was necessary for the Congress, through the Patient Protection and Affordable Care Act of 2010, to give authority to the Secretary to implement a pay-for-performance program for acute care inpatient hospitals beginning in fiscal year 2013 and pilot pay-for-performance programs for psychiatric, long-term care, and rehabilitation hospitals; hospice programs; and cancer hospitals exempt from the inpatient hospital prospective payment system. In addition, the law gives the Secretary the flexibility to expand these pilot programs if she determines that they reduce spending and improve quality.

Along with flexibility to maintain payment methods, it is reasonable to consider options for ensuring the program's accountability. As we discuss in this section, added flexibility to make technical changes to existing payment methods would need to be coupled with establishment of a predictable and transparent process by Medicare to implement such changes. ■

Another issue is whether these policies should stem from Medicare's coverage authority or from its payment authority. Although LCAs affect pricing, Medicare's authority to implement them currently stems from its coverage authority (Table 1-1, p. 6). Likewise, Medicare's authority to implement CED partly stems from its coverage authority (as well as AHRQ's research authority). For example, Medicare might implement CED more easily if the program had authority to modify payment while the collection of clinical evidence was under way.

Ensuring transparency and a process for public input would be key if the Secretary and CMS administrator were given flexibility to establish one or all of these strategies. Options for ensuring transparency include consulting with the public issue by issue or establishing an advisory group. CMS's NCD process is an example of an established process that is transparent and provides opportunities for public input. The NCD process determines whether and under what circumstances Medicare will cover and pay for an item or service. Over time, CMS has formalized and strengthened its analytical processes for developing NCDs, which has improved the transparency of the process and increased the opportunity for input and participation by the public. When CMS decides to develop a national coverage policy, the agency provides public notice and seeks input from the general public and clinical evidence from manufacturers and physicians. For example, after CMS posts proposed NCDs, stakeholders may submit written comments to the agency. CMS responds to these comments in its final NCDs.

An example of a way for CMS to gain technical expertise from the public is the Medicare Evidence Development & Coverage Advisory Committee (MedCAC) (originally named the Medicare Coverage Advisory Committee). Established in 1998, it is a 100-member panel that provides independent guidance and expert technical advice to CMS on specific clinical topics considered in the NCD process. This advisory group convenes meetings open to the public in which it evaluates medical literature and technology assessments and examines data and information on the effectiveness and appropriateness of medical items and services that are covered under Medicare or that may be eligible for coverage under Medicare. The MedCAC judges the strength of the available evidence and makes recommendations to CMS on the sufficiency of evidence to answer specific questions.

Establishing a committee consisting of interested stakeholders would be another way to provide opportunities for public input. In its 2011 budget request, AHRQ included funding an effort that would comprehensively engage stakeholders. In the United Kingdom, since 2002, a Citizens Council composed of 30 members of the public convenes twice per year and provides advice to the National Institute for Health and Clinical Excellence, an agency that provides guidance to the United Kingdom's National Health Service on public health, health technologies, and clinical practice.

Ensuring sufficient resources

CMS would require additional resources to develop the infrastructure, establish and maintain the administrative processes, and hire individuals with expertise in developing and managing such policies. For example, even with specific statutory authority, CMS lacks sufficient funding to sustain a well-articulated CED approach. For CED to be successful, CMS needs the necessary funds to establish a well-articulated process to identify services to study under CED and to implement well-designed studies.

As we also discuss later in this chapter, some observers argue that CMS's administrative resources are not commensurate with its current responsibilities, let alone new ones, and that the mismatch between the agency's administrative capacity and its mandate has grown enormously over the past two decades. In the federal budget, spending for Medicare administrative activities—with the exception of antifraud and quality improvement activities—is discretionary, determined by the annual appropriations process, while spending for Medicare (entitlement) benefits is mandatory. Former CMS administrators have pointed out the following funding issues for several years: (1) a persistent mismatch between appropriated dollars for program administration and agency responsibilities (e.g., implementing the Balanced Budget Act of 1997 (BBA) and the MMA); (2) requirements to conduct congressionally mandated projects, which may require diverting limited discretionary resources from other efforts; and (3) competition for funding with other Department of Health and Human Services (HHS) programs, such as funding for NIH, during the annual President's Budget and congressional appropriations processes (Butler et al. 1999, Iglehart 2009, Wilensky and Vladeck 2009).

Enhancing Medicare's research and demonstration capacity

The Medicare program has used research and demonstrations for decades to test the conceptual and operational feasibility of new payment policies and health care service delivery models. Over the last several years, the Commission and other observers have noted a growing disconnect between Medicare's urgent need to implement payment and service delivery innovations and the program's limited ability to research, test, and evaluate demonstrations that provide the information policymakers need to implement effective policy changes program wide.

The Commission most recently expressed its concerns about the pace of Medicare's demonstrations in a mandated report to the Congress on improving Medicare chronic care demonstration programs (Medicare Payment Advisory Commission 2009). Its analysis of four recent Medicare demonstrations suggested several larger issues with the structure and funding of research and development in Medicare, including: very low levels of funding for research, demonstrations, and evaluations relative to the overall size of the program; constraints on CMS's ability to redeploy research and demonstration funding as the program's needs change; and the existence of time-consuming and resource-intensive administrative requirements in the executive branch demonstration review process.

The Congress has recently acted to address many of these issues in the Patient Protection and Affordable Care Act of 2010 (PPACA), enacted on March 23, 2010 (Public Law No. 111-148). The PPACA authorizes the creation of a Center for Medicare and Medicaid Innovation (CMI)

within CMS no later than January 1, 2011; specifies several changes in the demonstration approval and implementation process; authorizes new funding for CMS to carry out demonstrations; and creates a process by which the Secretary may expand successful policy innovations under certain circumstances without seeking further congressional approval (see text box, pp. 20–21, for more detail). Throughout this section of the chapter, we discuss our initial analysis of the impact the CMI will have on the research and demonstration issues the Commission has been examining, and we note areas for potential further analysis as the new law is implemented.

Commissioners also have raised concerns about the level of Medicare resources allocated for health services research activities, such as funding and staffing for intramural and extramural research projects and to revamp the agency's data infrastructure to provide external researchers with timely access to program and demonstration data. Until relatively recently, Medicare devoted at least a portion of its research and demonstrations budget and staff to data-driven research projects that informed demonstration designs and development of payment policy reform ideas. It remains to be seen whether and to what extent the significant new resources appropriated for the new CMI may be used to support fundamental research activities.

Background on research and demonstrations

Within the Medicare program, research generally refers to data-driven analyses that are designed to suggest policy options for further exploration.[10] A demonstration is applied research; it changes how Medicare operates in a limited geographic area or for a particular group of beneficiaries. Medicare's research and demonstration activities are connected in that demonstrations usually require research to support their development and to evaluate their results. Before implementing a demonstration, CMS uses research to develop and test the demonstration methodology and the performance measures to be used in the evaluation. After a demonstration is completed, a formal evaluation is conducted to determine whether the demonstration's interventions had any observable effects on the use, costs, and quality of care (Cassidy 2008).

Demonstrations by design are time limited. Most demonstrations have an operational phase that typically lasts from three to five years, but the entire demonstration process usually takes considerably longer than that—more than a decade in some cases—when the time for design, review and approval, solicitation of participants, operation, and evaluation is taken into account (the demonstration process is described in more detail below). Demonstrations most often involve testing payment policy innovations—that is, paying for Medicare-covered services in a different way than under traditional fee-for-service Medicare. Some projects also involve paying for items or services not otherwise paid for by Medicare or allowing health care providers not otherwise providing a particular Medicare-covered service to do so.

Ideally, demonstrations allow CMS to gain practical operational experience with policy changes in a controlled manner that provides statistically reliable and valid data with which to evaluate the quality and cost impacts of the policy and delivery system changes being tested. In practice, however, many demonstrations either are too small, in terms of the size of the population in the experimental and control groups, or have effects that are too subtle to produce results with a reasonable degree of statistical confidence and that can be relied on to make decisions about broader policy implementation.[11] On the other hand, even demonstrations that do not yield actionable policy information can give CMS useful operational experience and knowledge that can inform the administration of subsequent demonstrations or program-wide implementation of a policy if it proceeds to that step. Successful demonstrations have led to several of the most significant changes in Medicare policy over the past 30 years, including the inpatient PPS; the skilled nursing facility and home health PPSs; aspects of the Medicare managed care program, including preferred provider organizations and special needs plans; durable medical equipment competitive bidding; programs to improve care for dual-eligible beneficiaries, such as the Program for All-Inclusive Care for the Elderly and social health maintenance organizations; and the hospice benefit (Cassidy 2008).

Overview of the Medicare demonstration process

The process of initiating, designing, implementing, and evaluating a Medicare demonstration is highly complex, involving multiple stakeholders within the legislative and executive branches of the federal government, providers, beneficiaries, and research institutions (both private and academic). In many ways, each Medicare demonstration is a microcosm of the policy and implementation complexities of the larger Medicare program (Kuhn 2008). The following section describes each of the major steps in the current demonstration process.

Center for Medicare and Medicaid Innovation authorized by the Patient Protection and Affordable Care Act of 2010

The Patient Protection and Affordable Care Act of 2010 (Public Law 111–148), enacted on March 23, 2010, creates the Center for Medicare and Medicaid Innovation (CMI) within CMS and directs the Secretary to begin the CMI's operations not later than January 1, 2011 (§3021 as amended by §10306). The new law makes a number of significant changes that will affect the scope, budget, and process by which Medicare tests, evaluates, and expands payment and delivery system reform policies:

- Creates the CMI "to test innovative payment and service delivery models to reduce program expenditures under [Medicare and Medicaid] while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to" Medicare or Medicaid beneficiaries or beneficiaries of both programs (i.e., dual eligibles).
- Directs CMS to "consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management" when operating the CMI.
- Directs the Secretary to select models for testing under the CMI "where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under [Medicare or Medicaid or both] while preserving or enhancing the quality of care received by individuals receiving benefits under" the program(s). The law includes a list of 20 models that may be tested, but the Secretary is not limited to this list. There also are eight general criteria that the Secretary must consider when selecting models to be tested.
- Prohibits the Secretary from requiring, as a condition of initiating a test, that a model be budget neutral during its initial implementation phase. However, the Secretary is required to modify or terminate a test unless she determines (after an unspecified amount of elapsed implementation time) that quality of care will increase without an increase in program spending, will reduce spending without reducing the quality of care, or will reduce spending and increase quality. The CMS chief actuary must certify the spending determination.
- Allows the Secretary to waive any provision of Title 11 and Title 18 of the Social Security Act as necessary for testing models under the CMI. Title 11 includes the federal anti-kickback statute and provider self-

(continued next page)

Initiation of demonstrations

Both the Congress and HHS (typically through CMS) may initiate Medicare demonstration projects. The distribution of congressionally mandated and HHS-initiated projects has varied over time. In the early 1980s, few projects were mandated by the Congress, but this situation changed over the next decade and congressionally mandated demonstrations became the majority (Cassidy 2008). As of April 2010, just over half (17 of 31) of the currently active or upcoming Medicare demonstrations were mandated by the Congress (Table 1-4, p. 22).

Congressional initiation of demonstrations The Congress may mandate particular demonstration projects or research studies when it enacts legislation, typically in a bill that incorporates more extensive changes to the program (e.g., the MMA, which mandated 14 new demonstrations). Because the authorization language for most demonstrations specifies that their implementation must be budget neutral, the provisions typically are scored by the Congressional Budget Office as not increasing the cost of the overall bill and, therefore, few if any budgetary concerns are raised.

Center for Medicare and Medicaid Innovation authorized by the Patient Protection and Affordable Care Act of 2010

referral prohibitions (the Stark law); thus, the ability of the Secretary to waive these provisions would allow testing of payment models that included shared accountability arrangements (also called gainsharing) between participating providers, such as hospitals and physicians. Title 18 includes Medicare's fee-for-service payment and benefit coverage policies, which the Secretary may waive to test alternative provider payment models and coverage of otherwise non-covered benefits or services.

- Exempts from Paperwork Reduction Act review the testing, evaluation, or expansion of models under the CMI.
- Requires the Secretary to evaluate each model tested under the CMI. Each evaluation must include an analysis of the quality of care (including measurement of patient-level outcomes and patient-centeredness criteria) and changes in spending attributable to the model. Evaluations must be made "available to the public in a timely fashion."
- Allows the Secretary to expand, through rulemaking, the duration and the scope of a model that is being tested under the CMI, including implementation on a nationwide basis, if the following criteria are satisfied:
  - the Secretary determines that the expansion is expected to reduce spending without reducing the quality of care, or improve quality without increasing spending;
  - the CMS chief actuary certifies that the expansion would reduce or not increase net program spending; and
  - the Secretary determines that an expansion "would not deny or limit the coverage or provision of benefits" for beneficiaries.
- Directs the Secretary to "focus on models and demonstration projects that improve the quality of patient care and reduce spending" when determining which models or demonstration projects to expand.
- Appropriates $5 million for CMI activities for fiscal year 2010, $10 billion for CMI activities initiated in fiscal years 2011 through 2019, and $10 billion for each subsequent 10-year fiscal period (beginning with the 10-year fiscal period starting in fiscal year 2020). Directs that not less than $25 million of the amounts so appropriated "shall be made available each such fiscal year to design, implement, and evaluate models" under the CMI.
- Directs the Secretary to submit a report to the Congress on the CMI's activities in 2012 and not less than once every other year thereafter. ■

The Congress may also influence the selection and implementation of demonstration projects through the annual appropriations process. The appropriations committees may indicate their support for specific projects in the conference report accompanying the Labor, HHS, and Education Appropriations bill. Appropriators also have been specific in identifying and in some cases allocating exact funding amounts for their preferred projects. Appropriations bills have also included language that prohibits CMS from spending money to implement certain demonstrations, thereby delaying or possibly ending a demonstration (Cassidy 2008).

The Congress also may act to extend projects beyond their original planned timeframe, particularly when a demonstration enjoys strong support from the providers or beneficiaries involved, but expansion of the concept being tested is unlikely (e.g., because savings goals were not reached). An example is the Municipal Health Services Demonstration, which was initiated in 1978 and repeatedly extended by the Congress until it ended in 2006, well beyond its originally planned timeframe of five years (Cassidy 2008). This demonstration was designed to test the effects of increased utilization of municipal

TABLE 1–4 **Active or upcoming Medicare demonstrations, April 2010**

Demonstration project name	Year	Initiated by:
Medicare Physician Group Practice Demonstration	2000	Congress (BIPA 2000)
Informatics for Diabetes Education and Telemedicine Demonstration Project	2000	Congress (multiple acts)
Private, For-Profit Demo Project for the Program of All-Inclusive Care for the Elderly	2001	Congress (BBA 1997)
Medicare Coordinated Care Demonstration	2001	Congress (BBA 1997)
Demonstrations Serving Those Dually-Eligible for Medicare & Medicaid	2002	HHS
ESRD Disease Management Demonstration	2003	HHS
Premier Hospital Quality Incentive Demonstration	2003	HHS
Demonstration Project for Consumer-Directed Chronic Outpatient Services	2003	Congress (MMA 2003)
Rural Community Hospital Demonstration Program	2004	Congress (MMA 2003)
Frequent Hemodialysis Network Clinical Trials	2005	HHS
Care Management for High-Cost Beneficiaries Demonstration	2005	HHS
Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities	2005	Congress (BIPA 2000)
Rural Hospice Demonstration	2005	Congress (MMA 2003)
Demonstration Project for Medical Adult Day Care Services	2005	Congress (MMA 2003)
MMA 646: Medicare Health Care Quality Demonstration Program	2005	Congress (MMA 2003)
Senior Risk Reduction Program	2006	HHS
Medicare Low Vision Rehabilitation Demonstration	2006	HHS
Post Acute Care Payment Reform Demonstration	2006	Congress (DRA 2005)
DRA 5007 Medicare Hospital Gainsharing Demonstration	2006	Congress (DRA 2005)
MMA Section 646 Physician Hospital Collaboration Demonstration	2006	Congress (MMA 2003)
Frontier Extended Stay Clinic Demonstration	2006	Congress (MMA 2003)
Medicare Care Management Performance Demonstration	2006	Congress (MMA 2003)
Home Health Pay for Performance Demonstration	2007	HHS
Medicare Part D Payment Demonstration	2007	HHS
Electronic Health Records Demonstration	2008	HHS
Nursing Home Value-Based Purchasing	2009	HHS
Medicare Acute Care Episode Demonstration	2009	HHS
FQHC Advanced Primary Care Practice Demonstration	2010	HHS
Multi-payer Advanced Primary Care Initiative	2010	HHS
Medicare Imaging Demonstration	2010	Congress (MIPPA 2008)
Medicare Enrollment Demonstration	2011	Congress (BBA 1997)

Note: BIPA (Benefits Improvement and Protection Act of 2000), BBA (Balanced Budget Act of 1997), HHS (Department of Health and Human Services), ESRD (end-stage renal disease), MMA (Medicare Prescription Drug, Improvement, and Modernization Act of 2003), DRA (Deficit Reduction Act of 2005), FQHC (Federally Qualified Health Center), MIPPA (Medicare Improvements for Patients and Providers Act of 2008).

Source: MedPAC analysis of CMS, "Demonstration Projects and Evaluation Reports: Medicare Demonstrations" (www.cms.hhs.gov/DemoProjectsEvalRpts/MD/list.asp#TopOfPage), April 23, 2010.

health centers in four cities by eliminating coinsurance and deductibles for beneficiaries who received care at the participating sites, expanding the range of covered services offered there (e.g., vision and dental care and prescription drugs), and paying the cities the full cost of delivering services at the centers. An evaluation of the cost-effectiveness of the demonstration indicated that a large proportion of the increase in program costs was caused by the rise in the use of services such as prescription drugs, dental care, and vision care and that these costs were not offset by decreases in emergency room and hospital usage (Centers for Medicare & Medicaid Services 2007).

At the other extreme, the Congress has adopted approaches being tested under demonstrations before those demonstrations have even been fully operational, much less evaluated. For example, the Medicare Choices Demonstration tested methods for offering new types of managed care products under Medicare and alternative risk-based payments for managed care. The earliest enrollment in a plan under the demonstration was in February 1997, with most enrollment beginning in spring and summer of that year. However, when the Congress passed the BBA in August 1997, it adopted for the larger Medicare managed care program some of the methods being tested under the Medicare Choices Demonstration (Cassidy 2008), such as preferred provider organizations. Similarly, the Congress authorized the addition of a hospice benefit to Medicare in the Tax Equity and Fiscal Responsibility Act of 1982, only two years after HCFA initiated a hospice demonstration in 1980 (Davis 1988).

HHS initiation of demonstrations The Secretary of HHS has authority to initiate demonstration projects under Section 402 of the Social Security Amendments of 1967 (see text box, pp. 24–25). For more than 40 years, this law has authorized the Secretary to conduct demonstrations that change current Medicare payment policy. This authority generally has been interpreted to limit agency-initiated demonstrations to changes in Medicare payment policy, such as paying providers for services not otherwise covered by Medicare at the time of the demonstration (e.g., care coordination services, remote monitoring, or hospice services before hospice became a covered benefit), or to experiment with changing the basis of provider payments, such as PPSs, bundled payments, or basing a portion of payments on improvements in quality. Such changes must not decrease the quality of care for beneficiaries.

CMS is using Section 402 authority to test the feasibility of bundled hospital and physician payments for certain types of acute care episodes; pay-for-performance policies for inpatient hospitals, skilled nursing facilities, and home health agencies; payments for care management programs serving high-cost beneficiaries with multiple chronic conditions; and Medicare participation with private payers in primary care medical home programs. All of these initiatives could yield insights into program and policy innovations for which the Commission has expressed support in past reports.

However, the Commission and other observers also have raised questions about the Secretary's use of the Section 402 demonstration authority to implement national payment policy changes for certain services or providers, such as ongoing demonstrations affecting Medicare Part D enrollees who also are eligible for the Part D low-income subsidy program, or to make supplemental payments to oncologists who were affected by reduced payments for Part B–covered drugs (Cassidy 2008, Medicare Payment Advisory Commission 2006).

Administration of demonstrations

The current process of designing and implementing demonstrations typically takes several years to complete. The major steps in the process are outlined in Figure 1-2 (p. 26).

The administration of Medicare demonstration projects is handled primarily by the CMS Office of Research, Development, and Information (ORDI). After a demonstration concept has been initiated by the Congress or the agency, the demonstration design is developed by ORDI staff and CMS staff from other parts of the agency as needed (e.g., information technology and fee-for-service operations staff), in some cases with input from outside experts on the relevant subject. The external input may be through informal consultation, advisory panels, or a formal federal contract for development design. The demonstration's design must anticipate and incorporate the data needs of the project's eventual evaluation as well as address how Medicare claims processing systems will be able to identify and correctly process claims under the demonstration model.

Next, CMS staff and policy officials must work with HHS and Office of Management and Budget (OMB) staff and policy officials to gain approval for the proposed design. The HHS Office of the Assistant Secretary for Financial Resources, Office of the Assistant Secretary for

Medicare demonstration authority under Section 402 of the Social Security Amendments of 1967 [excerpts]

Sec. 402 [Title 42 U.S. Code §1395b-1]. Incentives for economy while maintaining or improving quality in provision of health services

(a) Grants and contracts to develop and engage in experiments and demonstration projects

(1) The Secretary of Health and Human Services is authorized, either directly or through grants to public or private agencies, institutions, and organizations or contracts with public or private agencies, institutions, and organizations, to develop and engage in experiments and demonstration projects for the following purposes:

(A) to determine whether, and if so which, changes in methods of payment or reimbursement (other than those dealt with in section 222(a) of the Social Security Amendments of 1972) for health care and services under health programs established by this chapter [i.e., Medicare and Medicaid], including a change to methods based on negotiated rates, would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services;

(B) to determine whether payments for services other than those for which payment may be made under such programs (and which are incidental to services for which payment may be made under such programs) would, in

(continued next page)

Planning and Evaluation, and the Office of the Secretary are involved in reviewing and requesting modifications to the demonstration design. The OMB review includes the Office for Intergovernmental and Regulatory Affairs—which is responsible for enforcing the Paperwork Reduction Act (PRA) and therefore, until enactment of the PPACA, reviewed all proposed information collection activities for a demonstration—and the Health Division, which is responsible for reviewing and approving each demonstration's budget-neutrality analysis. According to CMS staff, negotiations with OMB on occasion have increased the length of the demonstration approval process by six to nine months (Magno 2010).

Once a project is cleared internally within the executive branch, CMS issues a public notification and requests participants for the demonstration by publishing a notice in the *Federal Register*, issuing a press release, conducting outreach to relevant provider organizations, or contacting potential applicants. Next, demonstration participants (usually health care providers) are selected, often through an open, competitive contracting process consistent with the requirements of the demonstration. Demonstrations mandated by the Congress may have specific requirements for the types or geographic distribution of the providers selected to participate. For example, the section of the BBA authorizing the Medicare Coordinated Care Demonstration (MCCD) specifically required the Secretary to "implement at least 9 demonstration projects, including—

(A) 5 projects in urban areas;

(B) 3 projects in rural areas; and

(C) 1 project within the District of Columbia which is operated by a nonprofit academic medical center that maintains a National Cancer Institute certified comprehensive cancer center." (Balanced Budget Act of 1997 §4016(b)(2))

Once sites have been selected and contracts with each of them negotiated, the sites are given sufficient lead time to prepare operationally for implementing the demonstration protocol.

Medicare demonstration authority under Section 402 of the Social Security Amendments of 1967 [excerpts]

the judgment of the Secretary, result in more economical provision and more effective utilization of services for which payment may be made under such program; …

(b) Waiver of certain payment or reimbursement requirements; advice and recommendations of specialists preceding experiments and demonstration projects

In the case of any experiment or demonstration project under subsection (a) of this section, the Secretary may waive compliance with the requirements of this subchapter and subchapter XIX of this chapter insofar as such requirements relate to reimbursement or payment on the basis of reasonable cost, or (in the case of physicians) on the basis of reasonable charge, or to reimbursement or payment only for such services or items as may be specified in the experiment; and costs incurred in such experiment or demonstration project in excess of the costs which would otherwise be reimbursed or paid under such subchapters may be reimbursed or paid to the extent that such waiver applies to them (with such excess being borne by the Secretary). No experiment or demonstration project shall be engaged in or developed under subsection (a) of this section until the Secretary obtains the advice and recommendations of specialists who are competent to evaluate the proposed experiment or demonstration project as to the soundness of its objectives, the possibilities of securing productive results, the adequacy of resources to conduct the proposed experiment or demonstration project, and its relationship to other similar experiments and projects already completed or in process. ■

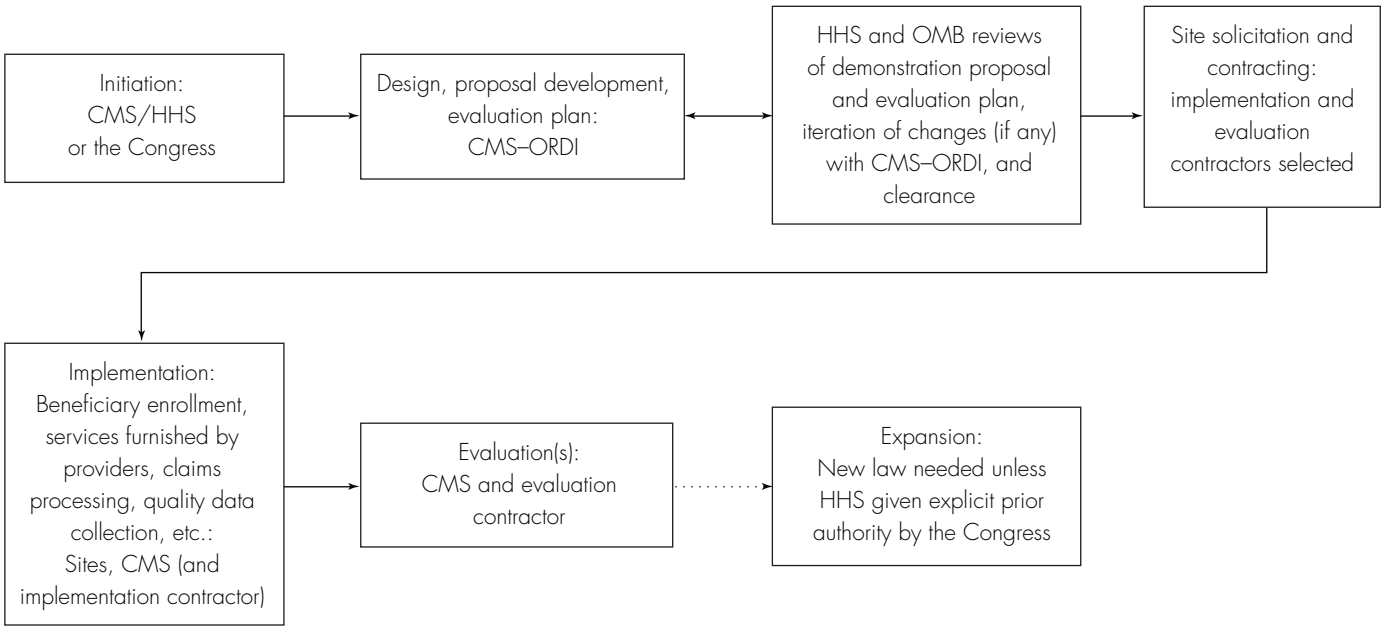
The demonstration is operational for one to five years, depending on the original mandate, if any, and the final study design. Interim evaluations may be conducted during the demonstration, and an overall evaluation is conducted after the demonstration is completed. Evaluations are significant efforts in their own right, typically operating in a separate but parallel design and contracting process from the demonstration. The evaluation must be carefully coordinated with the design and implementation of the demonstration to ensure that CMS and its selected evaluation contractor will have access to claims data, quality measures, and other information needed to complete any required interim reports and the final evaluation. Some demonstrations also involve a refinement stage, in which results are used to refine policies or operational aspects to hone the policy or how it is implemented (Cassidy 2008).

Two recent Medicare demonstrations illustrate how long the demonstration process can take. The MCCD was authorized in the BBA, which was enacted in August 1997 (Figure 1-3, p. 27). The length of the MCCD's design phase was affected by the Congress mandating that the Secretary "evaluate best practices in the private sector of methods of coordinated care for a period of 1 year and design the demonstration project based on such evaluation" (P.L. 105–33, §4016). In mid-2000, CMS solicited competitive proposals for programs to be MCCD sites and made 15 program site awards in early 2002. The sites began enrolling patients in mid-2002 and were initially authorized to operate for four years. The most comprehensive evaluation of the MCCD to date was based on complete Medicare claims data for services rendered through June 2006 (i.e., through the end of the original four-year demonstration period) and this report was delivered to CMS by the evaluation contractor in January 2008 (Peikes et al. 2008).[12]

The Medicare Health Support (MHS) program followed a somewhat more rapid course (Figure 1-4, p. 27). The MHS program was authorized in the MMA, but the design phase was much shorter than in the case of the MCCD because

FIGURE 1–2

Schematic of current Medicare demonstration process



Note: CMS (Centers for Medicare & Medicaid Services), HHS (Department of Health and Human Services), CMS–ORDI (Centers for Medicare & Medicaid Services Office of Research, Development, and Information), OMB (Office of Management and Budget).

CMS had already spent two years developing a large, population-based disease management demonstration that the agency had planned to conduct under its own demonstration authority. CMS staff worked with the Congress to incorporate many of the design parameters from that demonstration design into the statute (Magno 2010). The MMA provision authorizing the program also specified the qualifications of the types of organizations that would be allowed to participate in the program (Section 1807(e) of the Social Security Act, as added by MMA §721). After a competitive solicitation in 2004, CMS awarded three-year contracts to eight program sites that began operations in mid-2005 to early 2006 (McCall et al. 2008).

The MMA required that the evaluation results of the initial three-year phase (Phase I) were to be used by the Secretary to determine whether to proceed to full-scale implementation of the program (Phase II). CMS announced in January 2008 that, on the basis of an interim evaluation of the first 18 months of MHS operations, it would end Phase I as scheduled and not renew the five remaining active MHS contracts beyond their scheduled termination dates in 2008. CMS also announced it would evaluate the results of the final evaluation expected sometime in 2010 or 2011 before making a final decision about whether to proceed to Phase II (Medicare Payment Advisory Commission 2009).

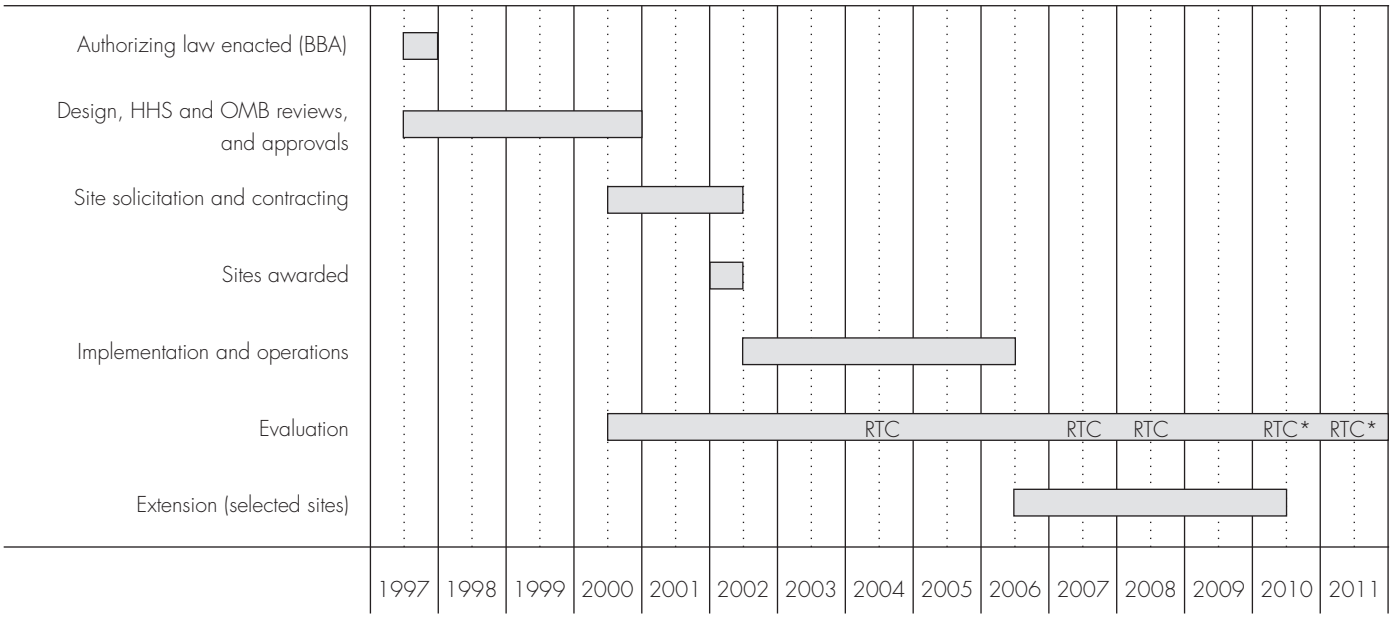
Issues in the current demonstration process

Policymakers began expressing concerns about the timeliness and usefulness of Medicare's research and demonstration activity not long after the Congress granted demonstration waiver authority to the Secretary in 1967. The House Ways and Means Subcommittee on Oversight held a hearing in 1980 "on the relevance and usefulness of the Medicare research and demonstrations projects, the timeliness of reports and feedback to Congress on those projects, the quality of the evaluation of demonstration projects, and the dissemination of demonstration results. Members emphasized that the issues in this hearing were similar to those raised in a 1976 hearing" (Cassidy 2008).

More recently, concerns have been raised from a variety of perspectives about several issues that hinder Medicare's ability to research, experiment, evaluate, and disseminate urgently needed policy innovations in a timely fashion (Crosson et al. 2009, Guterman and Drake 2010, Guterman and Serber 2007, Iglehart 2009, Kuhn 2008,

FIGURE 1–3

Timeline of Medicare Coordinated Care Demonstration, 1997–2011

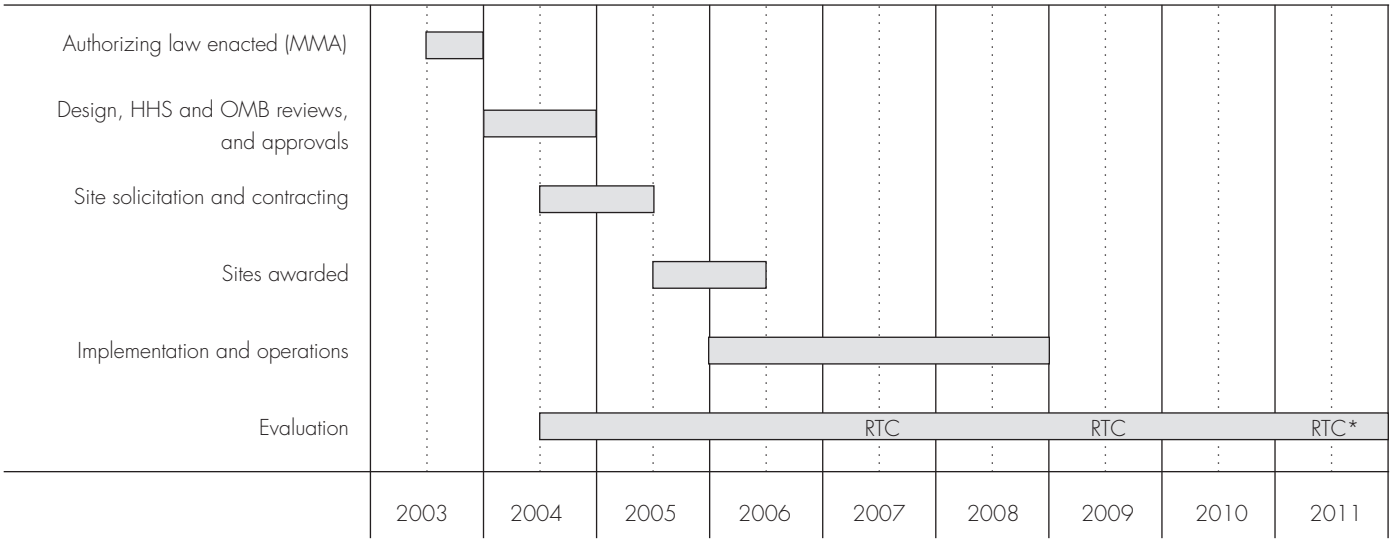


Note: BBA (Balanced Budget Act of 1997), HHS (Department of Health and Human Services), OMB (Office of Management and Budget), RTC (Report to the Congress).
*Planned Reports to the Congress.

Source: MedPAC analysis of demonstration evaluation reports and CMS data.

FIGURE 1–4

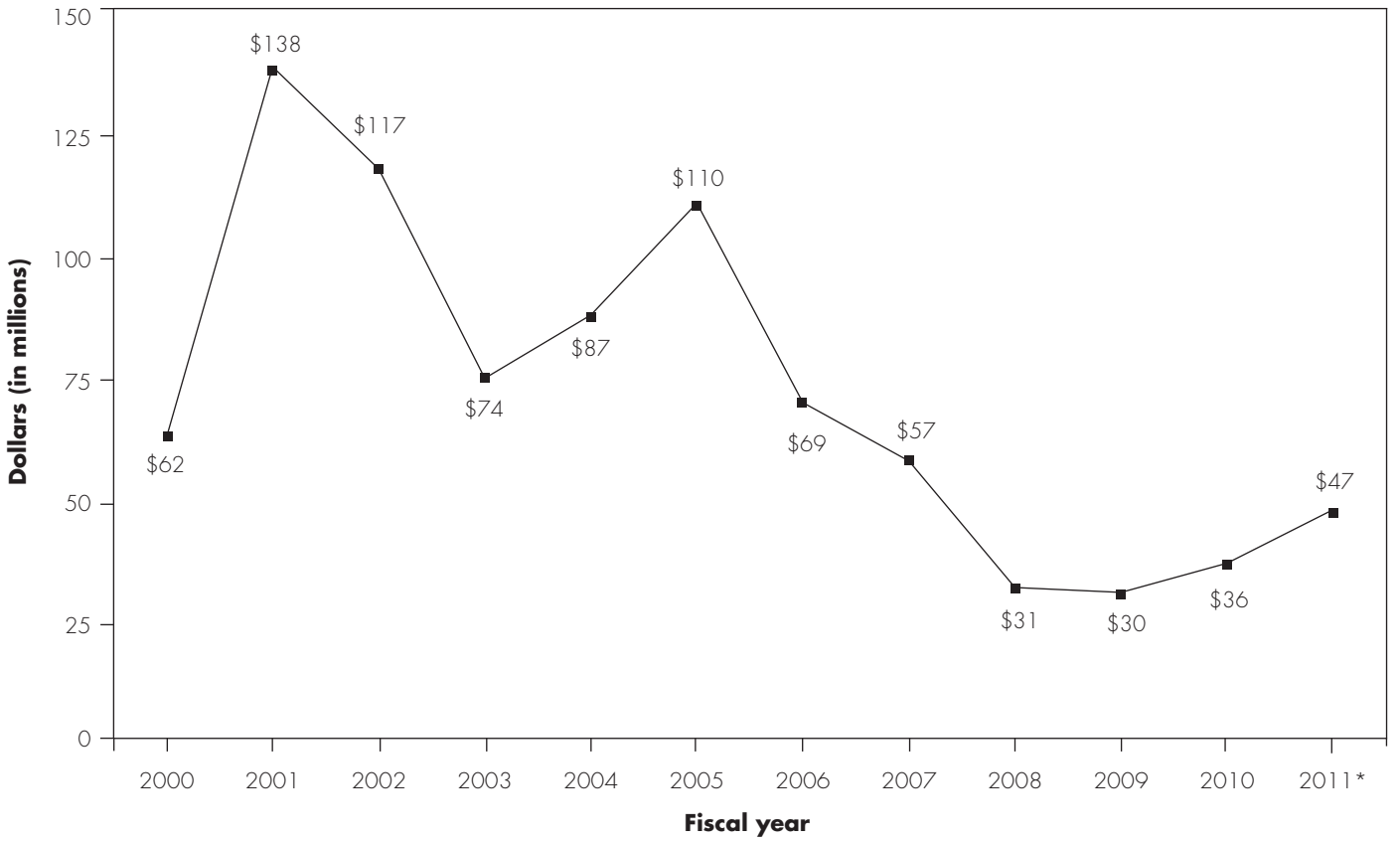
Timeline of Medicare Health Support program, 2003–2011



Note: MMA (Medicare Prescription Drug, Improvement, and Modernization Act of 2003), HHS (Department of Health and Human Services), OMB (Office of Management and Budget), RTC (Report to the Congress).
*Planned Report to the Congress.

Source: MedPAC analysis of Medicare Health Support evaluation reports and CMS data.

FIGURE 1–5 **CMS budget for research, demonstrations, and evaluation, FY 2000–2011**



Note: FY (fiscal year).
*Proposed FY 2011 President's Budget.

Source: MedPAC analysis of the Department of Health and Human Services Budget in Brief for FYs 2000–2011.

Medicare Payment Advisory Commission 2008, Medicare Payment Advisory Commission 2009, Wilensky and Vladeck 2009). These issues can be grouped into three broad categories for purposes of analysis and formulation of policy options: funding, flexibility, and accountability.

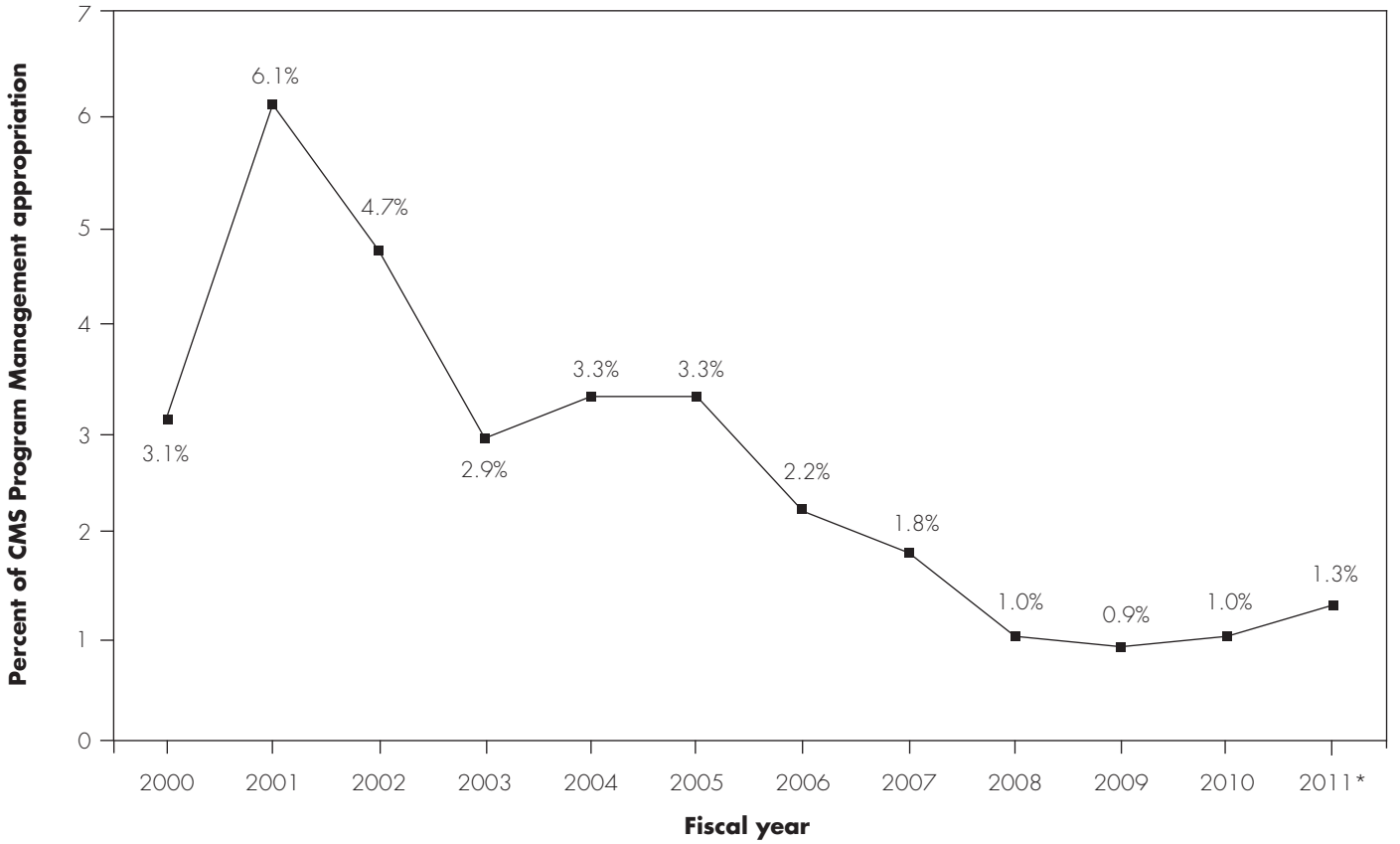
Funding

As shown in Figure 1-5 and Figure 1-6, funding for all CMS research and demonstration activities has declined over the past 10 years, both in nominal dollars and as a percentage of the total amount of discretionary appropriations for CMS program administration. Funding for CMS research, demonstrations, and evaluation activities reached a peak of about $138 million in 2001 (6.1 percent of total discretionary program management funding that year). It declined over the next two years but then increased with enactment of several Medicare demonstrations in the MMA, which included a large short-term increase in funding for CMS administrative activities associated with implementing the MMA. Since 2005, the budget for research and demonstrations has significantly declined to its current level of about $36 million (1.0 percent of total discretionary program management funding in fiscal year (FY) 2010). The FY 2010 funding amount of $36 million is about 0.007 percent of total mandatory spending for Medicare benefits (about $515 billion) projected for the current fiscal year.

Within the current budget, not all the funds are available for implementation and evaluation of demonstration projects. In FY 2010, about 57 percent of the $35.6 million appropriation is allocated to other research activities, most prominently to support ongoing implementation

FIGURE 1–6

CMS budget for research, demonstrations, and evaluation as percent of CMS Program Management discretionary appropriation, FY 2000–2011



Note: FY (fiscal year). Discretionary Program Management appropriation includes Medicare Operations, Federal Administration, Survey and Certification, and Research. *Proposed FY 2011 President's Budget.

Source: MedPAC analysis of the Department of Health and Human Services Budget in Brief for FYs 2000–2011.

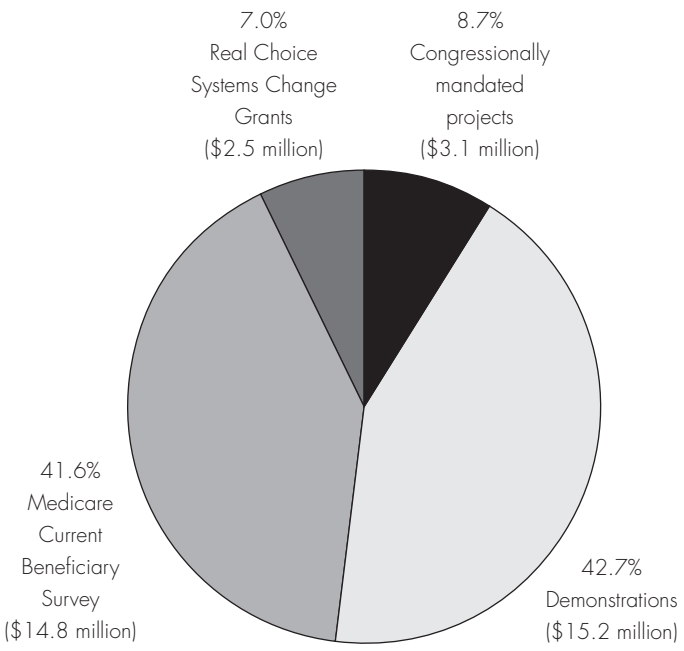
of the Medicare Current Beneficiary Survey (Figure 1-7, p. 30). About 9 percent of the total ($3.1 million) is allocated to congressionally mandated projects (in FY 2008 and FY 2009, about 15 percent of the total research, demonstration, and evaluation budget was directed to congressionally mandated projects). About $15.2 million is available in FY 2010 for all the remaining Medicare and Medicaid research, demonstrations, and evaluation activities.

The impact of limited resources on CMS's ability to implement and evaluate demonstrations has been noted by observers inside and outside the agency (Crosson et al. 2009, Institute of Medicine 2008, Kuhn 2008). In addition to limiting the scope and variety of policy innovations that the program can test, resource constraints also can affect the agency's ability to produce timely evaluations of implemented demonstrations, especially those that are initiated by the Secretary (Love 2010). Funding priority may be given to evaluations of congressionally initiated demonstrations or other required reports to the Congress on demonstration activity.

There also may be a significant return on investment from some of the program's spending on research and demonstrations. For example, CMS estimates that Medicare spent about $13 million on the research and demonstration work underlying the inpatient PPS (IPPS) in the early 1980s, while the program-wide implementation of the IPPS is estimated by the Medicare actuary to have reduced Medicare outlays by about $25 billion over the first 10 years it was in effect—a return of roughly $1,900 over 10 years for every dollar spent on the initial research and demonstration work. Other examples

FIGURE 1–7

Distribution of FY 2010 CMS research, demonstrations, and evaluation budget by activity



Note: FY (fiscal year).

Source: MedPAC analysis of Centers for Medicare & Medicaid Services 2010a.

cited by CMS of large returns on investments in research and demonstrations include the skilled nursing facility PPS, competitive bidding for durable medical equipment, and risk adjustment for payments to Medicare Advantage plans (Love 2010).

To offer CMS a more stable and secure source of funding, funding for CMS research and demonstration activities could be removed from the annual discretionary appropriations process and instead authorized and appropriated directly from the Medicare trust funds, similar to the way the Health Care Fraud and Abuse Control (HCFAC) program[13] and the Medicare Quality Improvement Organization (QIO) program[14] are financed. If Medicare demonstrations were funded through mandatory appropriations, it may be reasonable to apportion the total funding amount between the Hospital Insurance and Supplementary Medical Insurance Trust Funds in proportion to the percentage of Medicare benefit outlays paid from each.

Multiyear funding allocations (e.g., a two-, three-, or five-year mandatory appropriation) also could be used to ensure a stable stream of resources, and this approach may be particularly appropriate for funding multiyear demonstration projects. A particular concern is to ensure that sufficient funds are available at the end of a multiyear demonstration to complete its evaluation. Currently, funding that is initially budgeted for the evaluation of HHS-initiated demonstrations may be unavailable if CMS decides to reallocate resources within its limited total funding to complete evaluations of congressionally mandated demonstrations or other reports to the Congress.

An outstanding issue for further exploration by the Commission is the amount of resources within CMS's research and demonstrations budget that should be devoted by CMS to support basic health services research activities, including enhancing CMS staff capabilities to conduct intramural research projects; funding extramural research; expediting access to Medicare data (which may include data generated from demonstration projects that could be available for external evaluations); and rapidly developing CMS's internal data infrastructure to meet the growing demands of multiple research and demonstration activities. On the latter issue, the agency has included a request for $110 million in two-year funding for a health care data improvement initiative in its proposed FY 2011 budget (Centers for Medicare & Medicaid Services 2010a). The Congress will address this request during the FY 2011 appropriations process later this year.

In the PPACA provision creating the CMI, the Congress authorized the appropriation of $5 million in FY 2010 for the "design, implementation, and evaluation of models" under the new center. It then allocates $10 billion for FY 2011–2019 and for each subsequent decade beginning with FY 2020 for the costs of demonstration programs, presumably to allow for new provider payment and benefits costs under the demonstrations, and further specifies that not less than $25 million in each of those fiscal years (2011–2019) shall be available for designing, implementing, and evaluating the models being demonstrated.

The new funding authorized by the PPACA represents a significant increase in the amount and the stability of resources available to the agency for designing, testing, and evaluating payment policy and health care delivery system innovations. Funding issues include how the Secretary and the Congress will determine the level of annual funding for the center's operations above the

$25 million minimum level authorized in the new law and the distribution of that funding across the center's various activities, including the amount of resources (both funding and staff) devoted to basic research into potential innovations. These issues will become clearer as the law is implemented.

Flexibility

Arguably the most acute problem with the current Medicare demonstration process is the long and resource-intensive process through which demonstrations are designed, implemented, evaluated, and, if warranted, disseminated program wide. Some parts of the process are inherently time-consuming, given the complexity of working through a vast amount of technical detail to design and implement a demonstration, an effort akin to implementing a miniature version of the Medicare program for each demonstration (Kuhn 2008). In addition to the technical design and implementation challenges, the process involves negotiating agreement among all the parties involved, including stakeholders inside the participating executive branch agencies and outside the government (e.g., each demonstration site). During implementation, practical considerations come into play, such as the time it takes for clinical interventions to have measurable effects on service use and quality of care. It may take a longer-than-planned implementation period to determine with sufficient statistical confidence that an intervention in fact had no effect or to detect relatively subtle effects of an intervention in the study population.

Nonetheless, there are other parts of the process, before and after the implementation phase, where changes could be made to shorten the time and resources involved. Policymakers must make a trade-off in deciding how to shorten the time and resources involved in the design, approval, and evaluation phases of a demonstration by finding an appropriate balance between eliminating duplicative or otherwise unnecessary steps in the process while maintaining the due diligence necessary during the design phase (ensuring that the demonstration will produce results that are relevant to the policy questions they wish to investigate) and in the evaluation (ensuring it is as accurate as possible to avoid drawing erroneous conclusions from the demonstration results). Once a demonstration is completed and evaluated, there is the issue of accountability for the decision on whether to expand implementation of the tested policy innovation (assuming expansion is supported by the evaluation) and whether that responsibility should remain with the Congress or be delegated to the Secretary.

While many of the demonstration process issues discussed below are addressed in the CMI provisions of the PPACA, the Commission remains concerned that Medicare demonstrations could continue to have difficulty generating statistically significant cost and quality impacts—in the absence of which the Secretary will not be able to expand the use of an innovation—as long as the experiments are limited in duration and scope to the extent that a sufficient critical mass of providers is unwilling or unable to make the painful and costly organizational changes needed to restructure the delivery system to achieve significant results. This matter is a key implementation issue that the Commission will continue to monitor as the new law is implemented.

Reduce administrative requirements in the demonstration review process In the executive branch review and approval phase, there are at least two areas where it may be possible to shorten the process without adversely affecting the overall quality of the research or putting Medicare funds at any more risk than they already may be under in the current demonstration process.

Exempt demonstrations from PRA review—First, CMS staff have indicated that the PRA requirements imposed by OMB during the internal review process often are time-consuming, resource intensive to respond to, and usually do not result in a commensurate improvement in the design or implementation of the demonstration. These requirements may include review and approval of all forms, surveys, site visit protocols, and other types of information collection that will be used in the demonstration and evaluation.

An option for addressing this issue would be to exempt Medicare demonstrations and evaluations from the otherwise applicable sections of the PRA. The newly enacted PPACA includes such a provision, exempting all demonstrations and evaluations from PRA review if they are implemented under the new CMI. The new law is silent, however, on whether there will be oversight of the PRA exemptions. To provide such oversight, a third-party entity such as the HHS OIG or the Government Accountability Office could periodically review and report to the Congress on CMS's activities under the PRA waiver. This oversight activity could be expanded to include any other areas where the Congress grants CMS clear exemptions from statutory or regulatory requirements that otherwise might apply, such as the Federal Advisory Committee Act.

Modify the application of budget neutrality in demonstrations—Before enactment of the PPACA, virtually all Medicare demonstrations were required to meet a budget-neutrality test as a condition of being allowed to move ahead to implementation. Budget neutrality means that actual or (more frequently) projected costs under the demonstration cannot exceed what costs would be if the demonstration were not implemented. In demonstrations authorized by the Congress, a budget-neutrality requirement often would be included to ensure that the provision authorizing the demonstration would not be scored by the Congressional Budget Office as increasing Medicare outlays. For demonstrations initiated by the Secretary, OMB required HHS to submit estimates showing that each proposed demonstration would be budget neutral. For both types of demonstrations, OMB was responsible for deciding what assumptions would be used to calculate budget neutrality and whether a demonstration proposal satisfied the test.

The use of budget neutrality in the demonstration approval process was criticized for its narrowness and inflexibility (Cassidy 2008, Guterman and Serber 2007). OMB usually required that all demonstrations be estimated to show budget neutrality over their relatively short operational duration, estimates that typically could not take into account any potential longer term savings (or costs) from the proposed intervention. The policy also considered only the estimated costs and savings from a demonstration and usually did not consider cases in which significant quality improvements could be achieved with relatively small net increases in spending.

While the PPACA expressly prohibits the application of budget neutrality as a condition of approving and implementing a demonstration, the new law requires the Secretary to terminate or modify a model at any point after implementation unless she determines that the model is expected to be budget neutral or reduce spending (and the Medicare actuary must independently certify the estimated costs or savings) and that the quality of care for beneficiaries participating in the model also is expected to increase or at least not decrease. An option for implementing this provision would be for the Secretary to establish a spending level or growth rate target for each demonstration and then assess actual costs against the target for the first year or two of operations. The Secretary could immediately terminate or modify a demonstration (or an individual site participating in the demonstration) if the assessment found that the model had costs in excess of the predetermined level or growth rate target.

Accelerating evaluations—Almost all demonstrations, whether initiated by the Congress or by the Secretary, include an evaluation and public report on the findings and recommendations regarding the tested policy changes. CMS enters into a contract for a demonstration's evaluation with research firms through a process separate than that used for design and implementation of the demonstration. The evaluation design often is developed at the same time the demonstration is being developed (Cassidy 2008), and CMS often begins working with the evaluation contractor as soon as the demonstration sites are operational (Magno 2010). The fundamental challenge in designing and executing an evaluation is maintaining the appropriate balance between scientific rigor and policy usefulness.

Most evaluations currently use a full or partial randomized controlled trial (RCT) design to assess the success or failure of interventions. Several concerns have been raised about whether the RCT methodology is an appropriate approach for evaluating Medicare demonstrations. One concern is that RCT-based evaluations may not yield critical information to explain why the intervention succeeded or failed to produce the expected outcomes (Gold et al. 2005). For instance, the demonstration may have imperfect controls and deliver incomplete data, hindering the evaluator's attempts to control for mitigating factors and isolate the effects of the demonstration's intervention. Some experts question whether the RCT approach is poorly suited to demonstrations in which one characteristic that may be critical to the development of successful innovations in the real world—continuous local adaptation in response to learning—violates the fundamental RCT premise of "holding all else constant" (Berwick 2008, Gold et al. 2005, Guterman and Drake 2010, Guterman and Serber 2007).

A separate but related issue is the timeliness of evaluations. The RCT-based evaluation approach requires accurate and complete data, but the process of collecting, cleaning, and analyzing those data is inherently time-consuming and, in the case of the care management demonstrations the Commission examined in 2009, significantly increased the administrative complexity and cost to CMS and participating providers of implementing the interventions (Medicare Payment Advisory Commission 2009). CMS has taken several steps to accelerate evaluations, including concurrent award and implementation of contracts for demonstrations and evaluations, continuous monitoring of demonstration projects and preparation of interim evaluation reports

(when resources are available, which has not always been the case in the past), and the use of alternative evaluation methods (Magno 2010). All these approaches can allow more rapid-cycle feedback to expedite the incorporation of demonstration findings into consideration of policy changes (Gold et al. 2005, Guterman and Serber 2007). A challenge for CMS as it implements the CMI will be to ensure that sufficient resources are deployed to sustain and build on the steps the agency has taken to accelerate evaluations, while maintaining a balance between scientific rigor in evaluations and the information needs of the policymaking process.

In addition to efforts to speed evaluations, efforts could be made to encourage additional evaluations by researchers outside of CMS. One way to do so would be to increase the availability of the Medicare data—such as claims data and quality measures—that are generated during a demonstration. By making these data available as quickly as possible with appropriate privacy protections, policymakers could benefit from alternative analytic perspectives on the outcomes of demonstrations. For example, health services researchers have used data from the Medicare Premier Hospital Quality Incentive Demonstration to evaluate the effect of a hospital pay-for-performance program on quality of care (Glickman et al. 2007, Grossbart 2006, Lindenauer et al. 2007). The largest and most rigorous of these studies found that, when controlling for baseline performance and condition-specific patient volumes, the observed percentage point improvement over a two-year period in composite quality scores for participating hospitals compared with nonparticipating hospitals decreased from 4.3 percentage points to 2.9 percentage points, a statistically significant difference (Lindenauer et al. 2007). This analysis suggests that the incentive program did increase participating hospitals' quality somewhat (as measured by the process metrics used in the demonstration) but not by as much as it initially appeared.

The PPACA's changes to the Medicare demonstration process do not directly address alternative evaluation criteria or publicly releasing Medicare demonstrations data to external researchers. The new law requires the Secretary to evaluate each model tested under the CMI and states that the evaluation must analyze the impacts on cost and quality (specifically including patient outcomes) of the tested interventions. It further directs the Secretary to make each evaluation publicly available "in a timely fashion" but does not define "timely" (§1115A(b)(4)).

Allow successful models to move from demonstration to program policy without further congressional action—The Commission and others have observed that Medicare could speed up its pace of innovation if the Congress gave the Secretary the authority to expand demonstrations, up to and including nationally or program wide, without further congressional action if the Secretary determined that doing so would decrease (or at least not increase) costs, while increasing or maintaining quality of care (Medicare Payment Advisory Commission 2008). The Congress adopted this approach in the MMA provision enacting the Medicare Health Support program and in the BBA provision authorizing the MCCD. The Secretary's determination to expand a demonstration could be based in part on a joint determination with the Medicare actuary that the expansion is expected to be budget neutral and either increase or at least not decrease the quality of care for Medicare beneficiaries.

The PPACA adopts this approach for models tested under the new CMI, with a requirement that expansions of policy innovations must be expected to reduce or at least not increase net program spending (i.e., total spending net of any costs for new benefits or provider payments that are made under the tested model), while also improving or at least not decreasing the quality of care for participating beneficiaries. Because the new law requires the Secretary to use the rulemaking process to implement any policy expansion, there will be an opportunity for external stakeholders to comment on proposed expansions through the usual public "notice-and-comment" process.

Provision of the PPACA increasing the Secretary's flexibility to waive current law and prohibiting administrative or judicial review of demonstrations

In addition to the specific areas of PRA review, budget neutrality, and expansion authority, the PPACA makes two other significant changes to the Secretary's demonstration authority that should increase the program's ability to implement policy innovations more rapidly. First, the Secretary is explicitly allowed to waive the requirements of Title 11 of the Social Security Act (as well as the main Medicare statutes in Title 18) for purposes of carrying out projects under the CMI. Title 11 includes the anti-kickback statute (Section 1128B) and the civil monetary penalty statute (Section 1128A), and therefore the Secretary's ability to waive those provisions appears to allow the use of shared accountability arrangements (also called gainsharing) between physicians and hospitals and potentially other providers in a local delivery system for models tested under the CMI. This provision is consistent

with a 2005 Commission recommendation that the Congress should grant the Secretary the authority to allow shared accountability arrangements between providers to better align financial incentives, with appropriate regulation of those arrangements to protect the quality of care and minimize financial incentives that could inappropriately affect physician referrals (Medicare Payment Advisory Commission 2005). The Secretary's ability to waive the requirements of Title 11 could permit more expansive demonstrations of shared accountability arrangements than it has been possible to implement to date.

Second, the PPACA stipulates that there shall be no administrative or judicial review of the Secretary's decisions on the following aspects of demonstrations under the CMI:

- the selection of models for testing or expansion;
- the selection of organizations, sites, or participants to test the selected models;
- the elements, parameters, scope, and duration of a demonstration;
- the determination regarding budget neutrality in the design and approval process;
- the determination of the cost and quality impacts of an implemented demonstration and the resulting decision (if applicable) to terminate or modify it; and
- the determination about expansion of the scope and duration of a demonstration, including the determination that a model is not expected to reduce program costs and increase or at least not reduce the quality of care.

This provision is significant because the implementation or expansion of some Medicare demonstrations, such as competitive bidding for clinical laboratory services and durable medical equipment, have been delayed by judicial review. This provision also could give the Secretary flexibility to contract with entities such as practice-based research networks (PBRNs) to test policy innovations on a smaller scale before expanding them (if successful) to full-blown demonstrations. The Commission discussed the potential value of PBRNs, or a similar standing network of competitively contracted provider sites, in its 2009 report on a Medicare chronic care practice research network (Medicare Payment Advisory Commission 2009).

Accountability

Along with increased funding and flexibility to design, implement, evaluate, and disseminate Medicare policy innovations, it is reasonable to consider options for increasing the program's accountability for its performance in this area.

First, the Secretary could be required to consult with private sector entities, such as health plans or integrated delivery systems, about the agency's Medicare research agenda and directed to examine and report on the feasibility of adapting private-sector policy innovations for application in Medicare (Lee et al. 2010). The consultation process also could involve creating a formal advisory committee of external experts from other federal agencies, including AHRQ and the Institute of Medicine, academic research institutions, private payers and purchasers, and provider and beneficiary representatives. The Congress also could direct CMS to consult periodically with the Commission to discuss Medicare's research and demonstrations agenda and ongoing projects, including the preliminary operational or evaluation results of demonstrations. The PPACA requires the Secretary, in carrying out the functions of the CMI, to consult with relevant federal agencies and experts in medicine and health care management through the use of open door forums or other mechanisms to be decided by the Secretary.

Medicare may also consider directly engaging in joint demonstration projects with private payers (Crosson et al. 2009, Guterman and Drake 2010, Lee et al. 2010). The Secretary has some ability to do so under the Section 402 demonstration authority, as evidenced by HHS's announcement in September 2009 that CMS would establish a demonstration program that will enable Medicare to join Medicaid and private insurers in state-based advanced primary care initiatives (Department of Health and Human Services 2009). Some analysts argue that a sustained and transparent process of coordination with private-sector payment policy and care delivery innovations would magnify the impact of payment incentive innovations at the provider level, while reducing the administrative barriers for providers to participate in demonstrations, thereby increasing their population size and the statistical power of their results (Guterman and Drake 2010). This process in turn could result in obtaining more actionable information from demonstration evaluations, which would speed the process of disseminating policy innovations from demonstrations into program-wide implementation. On the other hand,

multipayer collaborations involving Medicare would need to be carefully designed, implemented, and evaluated to ensure that the cost and quality of care for participating beneficiaries is appropriately accounted for and closely monitored and that Medicare's research needs are met—for example, by capturing differences in clinical profiles between privately insured participants and Medicare beneficiaries, who are more likely to have multiple chronic conditions.

Another option to increase transparency and accountability would be to require the Secretary to periodically report to the Congress about what is being learned from ongoing demonstrations and what the potential effects could be if they were expanded (Guterman and Serber 2007). The PPACA requires the Secretary to submit a report to the Congress on the activities of the CMI beginning in 2012 and at least every other year thereafter. As specified in the new law, this report must at a minimum include the numbers of Medicare (and Medicaid) beneficiaries participating in ongoing demonstrations, the amounts of program payments made on behalf of participating beneficiaries, and the results of any formal evaluations. It also could be informative to policymakers and reduce the reporting burden on CMS if this biannual report encompassed any Medicare demonstrations operating outside of the CMI and included any preliminary or interim evaluation findings. As noted above, obtaining the information for this kind of report would require a different approach to demonstration evaluations than CMS currently uses. The Commission could submit a comment letter to the Congress after examining this report from the Secretary and communicate its views on the substance and process of Medicare's research and demonstration activity. ■

Endnotes

1 In 2003, epoetin alfa was no longer eligible for a transitional pass-through under the hospital outpatient PPS. (Pass-through payments were paid for two to three years until standard payments could be modified to incorporate the cost of the new technology.) In 2003, payment for epoetin alfa was based on its acquisition cost, which was usually at 68 percent of the average wholesale price (Medicare Payment Advisory Commission 2002). By contrast, a drug in the transitional pass-through payment status was paid based on 95 percent of the average wholesale price for the drug.

2 Section 1833(t)(2)(E) states that under the outpatient hospital PPS, "the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals."

3 Because the biologics are dosed in different units, CMS developed a conversion ratio with assistance from the product developers and an independent contractor.

4 The AMA is responsible for level I of the Healthcare Common Procedure Coding System (HCPCS), more commonly referred to as Current Procedural Terminology, that codes professional services provided by physicians. Medicare is responsible for level II of the HCPCS, which includes codes for services and procedures not included in level I such as durable medical equipment.

5 Albuterol is a racemic mixture containing equal parts of two isomers (the R-albuterol and S-albuterol). Levalbuterol contains only the R-albuterol isomer.

6 Most of the reference pricing studies were for senior citizens in British Columbia, Canada. The use (dispensing) of reference drugs increased in five studies, between 60 percent and 196 percent immediately after introduction of reference drug pricing, whereas the use of cost-sharing (i.e., more costly) drugs decreased by between 19 percent and 42 percent in four studies. In three studies, the reference drug group expenditures decreased (range 19 percent to 50 percent), whereas in the fourth study the expenditures increased by 5 percent in the short term.

7 Some analysts have specifically raised concern about the potential negative incentives for pharmaceutical innovation when brand-name products are covered by reference pricing (Lopez-Casasnovas and Puig-Junoy 2000).

8 For services that go through the FDA regulatory process—drugs, biologics, diagnostic tests, and devices—safety and efficacy evidence obtained through clinical trials is usually not collected for all patient populations. For example, clinical trials often exclude older patients and those with multiple illnesses. For diagnostic tests, such as imaging tests, product developers sponsor clinical studies that often focus on the tests' accuracy rather than the tests' impact on patient outcomes. Moreover, it is difficult to encourage product developers to conduct additional clinical research after obtaining FDA approval (Tunis and Pearson 2006). Surgical procedures do not go through any formal regulatory review process by the FDA.

9 The CED includes patients with class II and class III heart failure and measured left ventricular ejection fraction at or below 35 percent.

10 For example, CMS currently has a contract with the University of Minnesota for a five-year research project entitled "Monitoring Chronic Disease Care and Outcomes Among Elderly Medicare Beneficiaries with Multiple Chronic Diseases," which is using data from the Medicare Chronic Conditions Warehouse and Part D claims to conduct analytic studies designed to better understand the nature of chronic disease among Medicare beneficiaries and to improve the care of these populations (Centers for Medicare & Medicaid Services 2009).

11 A notable exception was the Medicare Health Support program, which was significantly larger than other recent Medicare care coordination and care management demonstrations. Approximately 290,000 chronically ill Medicare beneficiaries were randomly assigned to the program's intervention and control groups in eight geographic areas, with approximately 30,000 intervention and control group members in each area's original target population.

12 CMS expects to submit another report to the Congress in 2010 on the operation of the two remaining MCCD sites, using claims data for services provided through 2008 (Magno 2010).

13 The Health Insurance Portability and Accountability Act of 1996, which created the HCFAC program, appropriates funds from the Hospital Insurance trust fund to an expenditure account, called the Health Care Fraud and Abuse Control Account, in amounts that the Secretary and attorney general jointly certify as necessary to finance antifraud activities. The Tax Relief and Health Care Act of 2006 allowed for yearly increases in the program's annual funding levels, based on the year-to-year change in the consumer price index for all

urban consumers for FY 2007 through FY 2010. For FY after 2010, the program's funding level may not be any less than—and may be more than—the amount appropriated for it in FY 2010. The FY 2010 HCFAC appropriation is about $1.5 billion, of which $1.2 billion is mandatory funding and $0.3 billion is discretionary funding (Centers for Medicare & Medicaid Services 2010b).

14 The Medicare QIO program is funded through an executive apportionment from the Medicare trust funds rather than through the annual congressional appropriation. Every three years, the Secretary and OMB determine the program's statement of work (SOW) and funding level for the following three-year period. The QIO program's ninth SOW began on August 1, 2008, and ends on July 31, 2011; the funding level for the ninth SOW is $1.1 billion (Centers for Medicare & Medicaid Services 2010b).

References

Agency for Healthcare Research and Quality. 2009. *Negative pressure wound therapy*. Technology assessment. Rockville, MD: AHRQ. June. http://www.ahrq.gov/clinic/ta/negpresswtd/.

Agency for Healthcare Research and Quality. 2010. http://www.ahrq.gov/news/press/pr2010/accicdpr.htm.

American Society for Radiation Oncology. 2009. http://www.astro.org/HealthPolicy/MedicareAndPrivateInsurerPayment/ManagedCareCoveragePolicies/documents/HighmarkProton.pdf.

Amgen. 2002. http://www.amgen.com/media/media_pr_detail.jsp?year=&releaseID=515417.

Arnold & Porter. 2010. http://www.arnoldporter.com/resources/documents/Advisory_DCCircuitInvalidatesMedicareLeastCostlyAlternativePolicy_010410.pdf.

Berwick, D. M. 2008. The science of improvement. *Journal of the American Medical Association* 299, no. 10 (March 12): 1182–1184.

Butler, S. M., P. M. Danzon, B. Gradison, et al. 1999. Crisis facing HCFA & millions of Americans. *Health Affairs* 18, no. 1: 8–10.

Carino, T., R. D. Williams II, A. M. Colbert, et al. 2006. Medicare's coverage of colorectal cancer drugs: A case study in evidence development and policy. *Health Affairs* 25, no. 5: 1231–1239.

Cassidy, A. 2008. *The fundamentals of Medicare demonstrations*. National Health Policy Forum background paper no. 63. July 22.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2002. Medicare program; changes to the hospital outpatient prospective payment system and calendar year 2003 payment rates; and changes to payment suspension for unfiled cost reports. *Federal Register* 67, no. 212 (November 1).

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2007. *Active projects report: Research and demonstrations in health care financing—2007 edition*. Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008. Nebulizers LCD—response to comments June 2008 revision. Baltimore, MD: CMS. http://www.cms.hhs.gov/mcd/lcd_attachments/11488_50/NebuResponsetoCommentsJune2008Revision2.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009. *Active projects report: Research and demonstrations in health care financing—2009 edition*. Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010a. Fiscal year 2011 justification of estimates for appropriations committees. Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010b. Medicare benefit policy manual. Chapter 15. Baltimore, MD: CMS. http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010c. Medicare claims processing manual. Chapter 30. Baltimore, MD: CMS. http://www.cms.gov/manuals/downloads/clm104c30.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010d. Medicare program integrity manual. Chapter 13. Baltimore, MD: CMS. http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf.

Cochrane. 2006. http://www.cochrane.org/reviews/en/ab005979.html.

Commonwealth Fund. 2003. *Reference pricing for drugs: Is it compatible with U.S. health care?* New York: Commonwealth Fund.

Congressional Budget Office. 2008. *Budget options, volume one: Health care.* Washington, DC: CBO. http://www.cbo.gov/ftpdocs/99xx/doc9925/12-18-HealthOptions.pdf.

Crosson, F. J., S. Guterman, N. Taylor, et al. 2009. *How can Medicare lead delivery system reform?* Issue brief no. 1335. New York: The Commonwealth Fund. November.

Curtis, J. P., J. J. Luebbert, Y. Wang, et al. 2009. Association of physician certification and outcomes among patients receiving an implantable cardioverter-defibrillator. *Journal of the American Medical Association* 301, no. 16: 1661–1670.

Dahm, L. L. 2008. The elusive "reasonable and necessary": Making a determination of coverage with evidence development. http://www.law.uh.edu/healthlaw/perspectives/(LD)CMSCoveragewithEvidence.pdf.

Danzon, P. M., and M. F. Furukawa. 2003. Prices and availability of pharmaceuticals: Evidence from nine countries. *Health Affairs Web Exclusive*. October 29.

Danzon, P. M., and J. D. Ketcham. 2003. *Reference pricing of pharmaceuticals for Medicare: Evidence from Germany, the Netherlands, and New Zealand.* Cambridge, MA: National Bureau of Economic Research.

Davis, F. A. 1988. Medicare hospice benefit: Early program experiences. *Health Care Financing Review* 9, no. 4 (Summer): 99–111.

Department of Commerce. 2004. *Pharmaceutical price controls in OECD countries: Implications for U.S. consumers, pricing, research and development, and innovation.* Washington, DC: DOC. http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf.

Department of Health and Human Services. 1999–2010. *Budget in brief FY 2000 through Budget in brief FY 2011*. Washington, DC: HHS. http://www.hhs.gov/asrt/ob/docbudget/.

Department of Health and Human Services. 2009. Secretary Sebelius announces Medicare to join state-based healthcare delivery system reform initiatives. Press release. Washington, DC: HHS. September 16. http://www.hhs.gov/news/press/2009pres/09/20090916a.html.

de Pouvourville, G. 2006. Risk-sharing agreements for innovative drugs: a new solution to old problems? *European Journal of Health Economics* 7, no. 3: 155–157.

Drug Benefit News. 2009. Payers may ink performance-based deals, as insurer unveils results of pilot study. *Drug Benefit News* 10, no. 22 (November 13). http://www.aishealth.com/SampleIssues/sampledbn.pdf.

Farkas, C., and P. Henske. 2006. Reference pricing for drugs. *Forbes Magazine*. April 14. http://www.forbes.com.

Garber, A., and M. B. McClellan. 2007. Satisfaction guaranteed—"payment by results" for biologic agents. *New England Journal of Medicine* 357, no. 16 (October 18): 1575–1577.

Garrison, L. P., Jr., P. J. Neumann, P. Erickson, et al. 2007. Using real-world data for coverage and payment decisions: The ISPOR Real-World Data Task Force report. *Value Health* 10, no. 5: 326–335.

Glickman, S. W., F. S. Ou, E. R. DeLong, et al. 2007. Pay for performance, quality of care, and outcomes in myocardial infarction. *Journal of the American Medical Association* 297, no. 21: 2373–2380.

Gold, M., T. Lake, W. E. Black, et al. 2005. Challenges in improving care for high-risk seniors in Medicare. *Health Affairs Web Exclusive* (April 26): w5-199–w5-211.

Grossbart, S. R. 2006. What's the return? Assessing the effect of 'pay-for-performance' initiatives on the quality of care delivery. *Medical Care Research and Review* 63, no. 1 (Supplement): 29S–48S.

Guterman, S., and H. Drake. 2010. *Developing innovative payment approaches: Finding the path to high performance*. New York: The Commonwealth Fund. Forthcoming.

Guterman, S., and M. P. Serber. 2007. *Enhancing value in Medicare: Demonstrations and other initiatives to improve the program.* New York: The Commonwealth Fund. January.

Iglehart, J. K. 2009. Doing more with less: A conversation with Kerry Weems. *Health Affairs Web Exclusive* (June 18): w688–w696.

Institute for Clinical and Economic Review. 2008. *Brachytherapy and proton beam therapy for treatment of clinically-localized, low-risk prostate cancer.* Boston, MA: ICER. http://www.icer-review.org/index.php/bt-pbt.html.

Institute of Medicine. 2008. *Retooling for an aging America: Building the health care workforce*. Washington, DC: The National Academies Press.

Kanavos, P., and U. Reinhardt. 2003. Reference pricing for drugs: Is it compatible with U.S. health care? *Health Affairs* 22, no. 3: 16–30.

Keenan, P. S., P. J. Neumann, and K. A. Phillips. 2006. Biotechnology and Medicare's new technology policy: Lessons from three case studies. *Health Affairs* 25, no. 5: 1260–1269.

Kuhn, H. B. 2008. CMS demonstrations: Background briefing. Presentation at National Health Policy Forum: Medicare and Medicaid demonstrations: Experimenting for the future. December 11.

Lee, P. V., R. A. Berenson, and J. Tooker. 2010. Payment reform—The need to harmonize approaches in Medicare and the private sector. *New England Journal of Medicine* 362, no. 1 (January 7): 3–5.

Lindenauer, P. K., D. Remus, S. Roman, et al. 2007. Public reporting and pay for performance in hospital quality improvement. *New England Journal of Medicine* 356, no. 5 (February 1): 486–496.

Lopez-Casasnovas, G., and J. Puig-Junoy. 2000. Review of the literature on reference pricing. *Health Policy* 54: 87–123.

Love, T. 2010. Personal communication with the author, March 5.

Magno, L. 2010. Personal communications with the author, March 3 and April 13.

McCall, N., J. Cromwell, C. Urato, et al. 2008. *Evaluation of phase I of the Medicare Health Support pilot program under traditional fee-for-service Medicare: 18-month interim analysis—report to Congress.* Washington, DC: RTI International.

Medicare Payment Advisory Commission. 2002. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2005. *Report to the Congress: Physician-owned specialty hospitals.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2006. *Report to the Congress: Effects of Medicare payment changes on oncology services.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2008. *Report to the Congress: Reforming the delivery system.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2009. *Report to the Congress: Improving incentives in the Medicare program.* Washington, DC: MedPAC.

Mohr, P., and S. Tunis. 2010. Access with evidence development: The U.S. experience. *Pharmacoeconomics* 28, no. 2: 153–162.

Mohr, P., S. Tunis, R. Sabharwal, et al. 2010. *Final report. The comparative effectiveness research landscape in the United States and its relevance to the Medicare program.* Baltimore, MD: Center for Medical Technology Policy.

National Government Services. 2009. *LCD for luteinizing hormone-releasing hormone (LHRH) analogs (L26369).* Baltimore, MD: CMS. http://www.cms.hhs.gov/mcd/viewlcd_pdf.asp?lcd_id=26369&lcd_version=20&contractor_id=183.

Neumann, P., J. D. Chambers, and L. Meckley. 2010. *Final report: Case studies of value-based coverage and payment policies in the U.S. and internationally.* Boston, MA: The Center for the Evaluation of Value and Risk in Health at the Tufts Medical Center.

Office of Inspector General. 2002. *Review of Medicare Part B fee schedule amounts for semi-electric hospital beds.* Washington, DC: OIG. http://oig.hhs.gov/oas/reports/region9/90100109.pdf.

Office of Inspector General. 2003. *Medicare reimbursement for lupron.* Washington, DC: OIG. http://oig.hhs.gov/oei/reports/oei-03-03-00250.pdf.

Office of Inspector General. 2009a. *Beneficiary utilization of albuterol and levalbuterol under Medicare Part B.* Washington, DC: OIG. http://oig.hhs.gov/oei/reports/oei-03-07-00440.pdf.

Office of Inspector General. 2009b. *Comparison of prices for negative pressure wound therapy pumps.* Washington, DC: OIG. http://oig.hhs.gov/oei/reports/oei-02-07-00660.pdf.

Peikes, D., R. Brown, A. Chen, et al. 2008. *Third report to Congress on the evaluation of the Medicare Coordinated Care Demonstration.* Princeton, NJ: Mathematica Policy Research, Inc.

Pollack, A. 2007. Pricing pills by the results. *New York Times.* http://www.nytimes.com/2007/07/14/business/14drugprice.html.

Pollack, A. 2009. Drug deals tie prices to how well patients do. *New York Times.* http://www.nytimes.com/2009/04/23/business/23cigna.html?_r=1&pagewanted=print.

Ramsey, S. D., and S. D. Sullivan. 2005. Evidence, economics, and emphysema: Medicare's long journey with lung volume reduction surgery. *Health Affairs* 24, no. 1: 55–66.

Redberg, R., and J. Walsh. 2008. Pay now, benefits may follow—the case of cardiac computed tomographic angiography. *New England Journal of Medicine* 359, no. 22 (November 27): 2309–2311.

Samson, D., F. Lefevre, and N. Aronson. 2004. *Wound-healing technologies: Low-level laser and vacuum-assisted closure.* Summary, evidence report/technology assessment: no. 111. AHRQ Publication 05–E005–1. Rockville, MD: AHRQ. December. http://www.ahrq.gov/clinic/epcsums/woundsum.htm.

Thomas, M., and J. Mann. 1998. Increased thrombotic vascular events after change of statin. *Lancet* 352, no. 9143: 1830–1831.

Towse, A., and L. P. Garrison Jr. 2010. Can't get no satisfaction? Will pay for performance help? Toward an economic framework for understanding performance-based risk-sharing agreements for innovative medical products. *Pharmacoeconomics* 28, no. 2: 93–102.

TrailBlazer Health Enterprises, LLC. 2006. *Draft LCS for proton beam radiotherapy-R18B (DL22108).* Baltimore, MD: CMS. http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=22107&lcd_version=3&show=all.

Tunis, S. 2006. Comparative effectiveness: What, why, how, who, were, when? Technology Assessment Roundtable. http://healthforum.brandeis.edu/meetings/materials/2006-30-Nov./Tunis.pdf.

Tunis, S., and S. Pearson. 2006. Coverage options for promising technologies: Medicare's 'coverage with evidence development.' *Health Affairs* 25, no. 5: 1218–1230.

U.S. Court of Appeals. 2004. http://pacer.cadc.uscourts.gov/docs/common/opinions/200402/03-5046a.pdf#xml=http://www.cadc.uscourts.gov/isys/Alldbs/isysquery/1b383b14-3139-45a8-abbe-432a432de2de/1/hilite/.

U.S. Court of Appeals. 2009. http://pacer.cadc.uscourts.gov/common/opinions/200912/08-5508-1221815.pdf.

U.S. District Court for the District of Columbia. 2008. Ilene Hays and Dey, L.P., plaintiffs, v. Michael O. Leavitt, Secretary of the United States Department of Health and Human Services, et al., defendants. Memorandum opinion. https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2008cv1032-22.

Wilensky, G. R., and B. C. Vladeck. 2009. Discussion at National Health Policy Forum. Great expectation: Managing the Centers for Medicare and Medicaid Services. May 1.