

Pay for Performance in Health Care: Methods and Approaches

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Converting Successful Medicare Demonstrations into National Programs

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Ever since Medicare was implemented in the mid-1960s, this public program has been a leader in health care payment development and innovation, including pay for performance (P4P) reforms. Many of the P4P projects currently operating are Medicare pilot projects, or demonstrations, that test both the administrative feasibility and success of various performance models.

Though policy makers sometimes use the terms *pilot testing* and *demonstration projects* interchangeably, there are key differences. Demonstrations operate under specific legislative authority that allows the Department of Health and Human Services (DHHS) Secretary to suspend (or waive) specific Medicare payment regulations for the purposes of testing policy alternatives. Pilot tests, likewise, test policy alternatives but do not operate under the Secretary's somewhat limited demonstration authority and, therefore, may sometimes be more expansive. Pilot tests typically operate under specific project-by-project congressional legislative directive and so are less common than demonstration initiatives.

P4P initiatives use both pilot tests and demonstrations to allow sponsors to identify models that best meet their intended goals and that can be operationalized at an acceptable level of cost and burden to health care organizations and clinicians, insurers, and other stakeholders. Pilot tests and demonstrations also enable sponsors to identify opportunities for improvement and modify aspects of new initiatives that do not work—all on a manageable scale. Despite this long history of demonstration programs particularly related to innovative payment approaches such as P4P, findings from major demonstrations rarely become part of permanent Medicare program policy. This chapter examines reasons that Medicare's significant experience in conducting demonstration projects to test program innovations has a less lasting impact on the current national program than might be expected.

Important Early Policy Changes

Medicare's demonstration programs yielded some important policy changes in its early years. In the late 1970s, Medicare granted demonstration waivers to novel hospital "prospective payment rate-setting" systems in several states; Medicare paid the hospitals set fees in advance for groups of services. In 1984 Medicare established its own national Inpatient Prospective Payment System, which bundled all hospital services into a single per-case rate for nearly 500 diagnosis-related groups (DRGs). The background research for such a revolutionary change in payment came from the New Jersey hospital DRG demonstration (Hsiao et al., 1986). Medicare eventually extended prospective payment systems to post-acute care, rehabilitation, and psychiatric hospitals, skilled nursing facilities, home health, and hospice services, in all cases beginning initial implementation with either pilot tests or demonstrations.

After freezing payments for high-cost procedures in the late 1980s, Medicare then designed a prospective payment system for physicians. The Medicare fee schedule put thousands of services on a common scale based on physician work effort. Medicare also pioneered capitated rates for its managed care population, setting separate rates for every county in the United States. All these systems changes divorced payment from the costs of individual clinicians and provider groups, and they supported implementation of Medicare's prospective payment systems.

Caring for more than 35 million elderly and disabled beneficiaries provided the number of patients and data needed to develop these systems. The Medicare program generates significant amounts of administrative data available for the development, implementation, and efficient evaluation of a range of P4P models. Because of its size and financial importance in the marketplace, Medicare is often able to recruit providers and other willing organizations to its projects demonstrating P4P options.

Of course, Medicare's large scale and economic importance also translate to downsides for innovative payment policy development. Because Medicare is the largest health insurance program in the United States, any potential changes to it face close scrutiny. In general, Congress sets out in statute almost all key Medicare program parameters: from the ways clinicians and provider organizations are paid, to the policies governing the covered benefits, the provider groups and clinicians who can participate in Medicare, claims reporting requirements, and other operational policies. Federal regulation then fills in the details required by legislative changes in policy direction, including modifications to payment methodologies and rates.

The agency that administers Medicare (the Centers for Medicare & Medicaid Services, or CMS) is responsible primarily for operationalizing congressional mandates. This is not surprising in that Medicare's scale and scope mean that any payment changes inevitably affect a range of powerful political constituencies, including large numbers of health care professionals and provider groups, health insurance plans that participate in Medicare, medical suppliers, and Medicare beneficiaries. Therefore, national payment changes stemming from Medicare demonstrations—such as P4P—prompt debates in a highly politicized forum and must consider the political environment as well as the research findings. Demonstrations offer an opportunity to test constituency and political responses to programmatic changes.

Turning these lessons learned into national policies requires clearing several formidable hurdles. Given the number of P4P projects under Medicare's experience with demonstrations, it is curious that policy makers have considered only limited and nonspecific moves toward national implementation of any existing P4P model. In this chapter, we are interested in understanding the following:

- Why have so few demonstrations been evaluated as “successful” (i.e., met goals for generated savings and quality improvement)?
- Why has Congress failed to incorporate under national payment reform the lessons learned from Medicare P4P demonstrations?
- What will it take operationally and politically to apply the lessons of successful P4P demonstrations to a national payment system?

The rest of this chapter comprises four broad sections to answer these three important questions. First, we describe the ground rules that Congress and CMS impose on the design of Medicare demonstrations, considering the impact of these rules on national implementation. Next, we discuss common threats to successful evaluation findings that limit the generalizability of Medicare demonstrations. Next we lay out the operational challenges of taking a small, geographically constrained demonstration to the national stage. Each section cites specific Medicare demonstrations described in Chapter 10 (refer to that chapter for details of these demonstrations). The chapter concludes with an analysis of the political challenges that Congress and CMS face in incorporating successful demonstrations into a national payment system.

Demonstration Ground Rules and Practical Limitations

Medicare demonstration projects serve to test and evaluate policy innovation within specific boundaries. Section 402 of Public Law 92-603 grants CMS specific demonstration “waiver” authority for variations in the established payment regulations so long as these variations do not result in increased costs to the Medicare program. Known as demonstration payment waiver authority, this provision allows the DHHS Secretary to try alternative payment methods in small demonstrations prior to implementation in the full program. Although the Medicare demonstration statute permits the DHHS Secretary to waive certain Medicare requirements (such as cost-based or charge-based reimbursement) in conducting demonstrations, the statute’s language focuses on program efficiency and cost reduction rather than on quality enhancement. Some subsections, however, authorize demonstration projects to examine impacts of various provider payment methods on quality of care.

In addition to this general demonstration authority, over the years Congress has also authorized projects to explore specific policy options, such as payment for case management for chronic illness, cancer prevention for ethnic and racial minorities, and telemedicine.¹ Sections of the law appear to authorize alternative provider payment methods (such as negotiated or discounted fees, bonuses, or withholds) whose objective it is to save program funds,² but Congress did not draft the demonstration authority explicitly to permit these payment methods as incentives for meeting quality goals. Finally, legal interpretations of Medicare’s demonstration waiver authority typically limit projects to those that increase program efficiency (and generate savings) or that are at least budget neutral. Congress can specifically authorize additional spending for pilot projects through specific legislation. The Affordable Care Act contains many specific mandates for Medicare demonstrations and pilot projects.

Despite the DHHS Secretary’s statutory authority to conduct them, Medicare demonstration projects that might disadvantage certain clinicians or provider organizations or beneficiaries relative to the status quo often

¹ These laws are printed in the pocket part following 42 USC section 1395b-1 in US Code Annotated and include specific standards for program design features, types of Medicare standards that can be waived, evaluation, and funding.

² A court upheld the Secretary’s authority to test paying a single negotiated fee for outpatient cataract surgery under this statute in *American Academy of Ophthalmology, Inc. v. Sullivan*, 998 F.2d 377 (6th Cir. 1993).

faced legal challenges. For example, the American Association of Health Plans in 1997 (US General Accounting Office, 1997) challenged the DHHS Secretary's authority to test a bidding approach for Medicare managed care plans in Colorado (the competitive pricing demonstration, proposed before Congress enacted the Medicare+Choice Medicare managed care program). After the federal district court issued a temporary restraining order that raised questions about the Secretary's authority to undertake the project, CMS did not implement it.³ Few courts have decided cases involving the Secretary's authority to waive Medicare requirements as part of a demonstration project.⁴ Courts generally accord great discretion to administrative agencies in interpreting and implementing federal law, especially complex programs like Medicare.⁵ Similarly, legal challenges to CMS's authority to conduct competitive bidding demonstrations for laboratory and durable medical equipment have led both of these potentially promising, competitively based pricing projects to be delayed, with little realistic hope of their being implemented.

The fate of attempts to establish competitive bidding for Medicare managed care is an illustration of the "not in my backyard" (NIMBY) syndrome. Three times CMS attempted to demonstrate competitive bidding bids in markets around the country, and all three attempts failed because of local political opposition (Nichols & Reischauer, 2000). In two of the three attempts to implement this controversial demonstration, congressional representatives quashed the effort once a city was targeted for fear of potential negative impacts on local clinicians and health care organizations and beneficiaries. By the third attempt, the project had been delayed so long that congressional and policy interest waned and was insufficient to counteract continued local opposition; the project was never implemented.

Aside from the political challenges inherent in implementing demonstrations, the legal foundations for Medicare's demonstration

3 *AAHP v. Shalala* (D. Colo. Civ. Action No. 97-M-977, May 20, 1997). The case was dismissed when the Secretary agreed not to pursue the proposed demonstration project.

4 Several cases unsuccessfully challenged the Secretary's authority under 42 USC 1395b-1(F) to choose fiscal intermediaries and carriers based on competitive bidding that are not nominated by providers or carriers already in the program: *Health Care Service Corp v. Califano*, 601 F.2d 934 (7th Cir. 1979); *Blue Cross Assoc. v. Harris*, 622 F.2d 972 (8th Cir. 1980); *Blue Cross Assoc. v. Harris*, 664 F.2d 806 (10th Cir. 1981).

5 See cases cited in note 4.

program also result in three practical limitations that nearly all Medicare demonstrations share:

- *Geographic and participant constraints*: specific legislative mandates often dictate where a demonstration takes place and who is invited to participate. Limiting geographic areas for participation can in turn limit the national generalizability of the demonstrations.
- *Voluntary participation by both clinicians and providers and by beneficiaries*: only willing groups and beneficiaries choose to participate. This condition also limits the generalizability of demonstrations because only selected organizations with a narrow range of characteristics participate.
- *Medicare budget neutrality*: the government must at least break even or save money on every Medicare demonstration. The condition limits Medicare from testing a wider range of projects that may have unclear cost impacts or even short-term additional costs, but the potential for longer-term gains.

Geographic and Participant Constraints

As a public program, fee-for-service (FFS) Medicare operates under an “any willing provider” legal requirement. Health care professionals and provider organizations that meet specified Medicare conditions (including certification and acceptance of Medicare payment amounts and balance billing limitations) are welcome to participate in the program. The same is not true in demonstrations. Almost all demonstrations are geographically limited so as to confine the “experimentation” to a manageable number of clinicians and provider organizations or to target the demonstration to providers who have specific capabilities. CMS issues a solicitation for participating clinicians and providers and then selects from among what appear to be the most qualified. Congress, Office of Management and Budget (OMB) and CMS staff impose project expenditure caps that usually constrain the number of providers and beneficiaries an agency can take. Sometimes CMS fails to select a qualified applicant, resulting in protests and, in extreme instances, pressure from Congress to expand eligibility. Such politically motivated geographic expansions often dilute the demonstration’s focus on the most qualified applicants and the model to be tested, resulting in evaluations with unclear findings.

Voluntary Participation

For research purposes, the law limits demonstrations to *voluntary participation* on the part of both clinicians/providers and beneficiaries. CMS cannot require hospitals, physicians, and other providers to participate in demonstrations. Similarly, the agency must notify Medicare beneficiaries of a demonstration if it will affect them, and it must offer them the opportunity to drop out of the demonstration at any time; clinicians and providers have nearly the same rights (often at the end of a demonstration year). An agency cannot place limitations on the range of legally entitled Medicare services available to beneficiaries.

The extent of selection bias that this voluntary participation introduces varies by the nature of the intervention and by whether both clinicians and providers and beneficiaries must be recruited. This selection bias is potentially serious when clinicians and providers have to recruit beneficiaries with specific characteristics into the demonstration, which was the case in the Medicare Health Support (MHS) and Care Management for High-Cost Beneficiaries (CMHCB) demonstrations (Centers for Medicare & Medicaid Services [CMS], 2009b), in which only higher-cost beneficiaries with specific diseases were eligible to participate. Voluntary participation was less an issue, however, in the Medicare Physician Group Practice (PGP) and Hospital Gainsharing demonstrations, which required recruiting providers but not beneficiaries with any specific characteristics (Sebelius, 2009).

Still, some important differences might exist between demonstration beneficiaries and regular FFS beneficiaries treated in nondemonstration settings. To preserve its neutral role, the government almost never promotes its own demonstrations through the media or other sources. Provider groups are left to market “weak” imprimaturs to beneficiaries with strict oversight by CMS to ensure fair and accurate information is given to potential beneficiaries.⁶ Randomization is almost never applied under Medicare demonstration projects because, although this approach would result in stronger evaluation results, excluding potentially eligible beneficiaries from participation in their local markets has been considered politically unpalatable.

⁶ One example has been the CMS reticence to refer to some demonstration providers as Centers of Excellence (CoEs), approving instead titles such as Participating Medicare Heart Bypass Center. Providers complain that such titles have little value in gaining market share, even when an expressed goal of the demonstration was to regionalize care in higher-quality institutions.

Budget Neutrality

Unless specifically authorized by Congress, Medicare demonstrations operating under waiver authority must be at least budget neutral, meaning that the total costs under the demonstration cannot exceed those predicted under the existing statutory program. OMB must review and approve the budget neutrality of the demonstrations. OMB usually requires some savings to compensate for additional operational costs incurred during the demonstration (e.g., extra CMS monitoring staff, independent contractors who help set up and evaluate each demonstration). The MHS disease management (DM) pilot originally had a 5 percent savings minimum or organizations had to give back all of their specific DM fees (McCall et al, 2008). CMS staff inserted this requirement in response to the federal legislation that groups must be able to demonstrate that they can bear “financial risk.” After the first 6 months, CMS waived the 5 percent requirement and changed to the budget neutrality standard because DM organizations’ initial savings predictions were unrealistically high. The PGP Demonstration, by contrast, has no upfront management fees but gives Medicare the first 2 percent of savings while sharing with providers any additional savings above 2 percent (Sebelius, 2009). The Medicare Hospital Gainsharing and Acute Care Episode (ACE) P4P demonstrations do not invoke budget neutrality per se because no additional payments were made to providers under this demonstration, but OMB did put limits on the amount of profit-sharing that physicians can receive from their hospital partners (CMS, 2006, 2009a).

Because clinicians and provider organizations must apply (or otherwise actively volunteer) to participate in a demonstration while demonstrating budget neutrality at a minimum, demonstrations have a distinct “carrot” bias toward those clinicians and provider organizations who have the necessary resources and believe the proposed changes will favor their organization. Thus, under most conditions, testing provider organizations’ and clinicians’ behavioral responses to CMS’s simply paying less rather than more is not possible. CMS would get few, if any, physician or hospital groups to apply if the intervention were to test responses simply to lower physician conversion factors or DRG payment rates. Nor would provider groups volunteer for a DM demonstration if the intervention simply reduced payments for poor quality of care. A win-win, silver-bullet philosophy has therefore pervaded Medicare’s demonstration authority simply as a practical effect of these combined requirements for both budget neutrality and voluntary participation.

Given these inherent limitations, CMS has tended toward payment carrots in demonstration projects in four different ways. First, one of the strongest incentives that the government can offer demonstration applicants is *up-front fees* to cover any administrative costs associated with the intervention. In several CMS DM demonstrations (e.g., the Medicare Coordinated Care Demonstration, MHS Demonstration, and the CMHCB Demonstration), CMS pays up-front monthly management fees to cover extra management resources of commercial vendors and provider groups. Costs are substantial for DM interventions that require sophisticated electronic medical records and support staff staying in close touch with high-risk beneficiaries. On the downside, because OMB generally requires demonstrations to be budget neutral, sites failing to generate Medicare savings are at risk of needing to return all or most of their up-front fees. This process has been contentious, even though applicants sign contracts with the explicit acknowledgment that retaining fees is contingent on savings. Prolonged legal negotiations often ensue, with arguments over technical design and implementation issues.

Second, *shared savings* is another way of encouraging participation, but it entails considerably more financial risk for applicants who have to make initial investments on their own. In the PGP Demonstration, physician groups are encouraged to reduce overall billings (from themselves and other health care providers) on Medicare patients for whom they provide most of that patient's primary care (Sebelius, 2009). In return, they share in resulting program savings. By design, Medicare payments must decline more than the savings bonuses paid out.

Third, CMS also uses nonfinancial carrots along with required savings to attract applicants to some demonstrations. In Medicare's Participating Heart Bypass Center Demonstration, 10 hospitals originally applied, and 7 eventually participated by offering Medicare up-front reductions on DRG payments for bypass and valve surgery (Cromwell et al., 1998). In return, they were given the right to market a form of Centers of Excellence (CoE) imprimatur. A major incentive to participate in CMS demonstrations affecting payments has been competitive pressures at the local market level. If Medicare were to designate one hospital a CoE for cardiovascular or orthopedic care, other local hospitals' volumes for these lucrative services may be threatened.

The fourth reason for offering payment discounts with no financial carrot is *physician gainsharing* in any hospital cost savings, generally disallowed under Medicare rules and regulations. Both the Participating Heart Bypass

Center and the Hospital Gainsharing demonstrations offer this incentive to the clinician staff in order to align their incentives with the bundled payment incentives the hospital faces in caring for Medicare patients (CMS, 2006; Cromwell et al., 1998).

Threats to Evaluation Findings

The previous sections describe how Medicare's demonstration waiver authority faces both political and legal constraints that can limit the ability of CMS and policy makers to implement promising innovative program concepts. Once a demonstration can overcome these hurdles of authority and design limitations, it must then be implemented and evaluated to assess its effectiveness in accomplishing its goals. In evaluating demonstration success, at a minimum policy makers such as members of Congress, DHHS, and other stakeholder groups need to know whether evaluation findings are a valid indicator of an intervention's impact on health care costs, quality of care, or both. If the answer is no, or even maybe, then it would be premature and potentially both financially and politically risky to promote the intervention to a national program. Unfortunately, Medicare demonstrations face a wide range of threats to robust evaluations. These difficulties in fully evaluating demonstration outcomes in turn undermine support for national implementation. Before a demonstrated intervention can be promoted to a national level, it must first be deemed a success, at least according to the available evaluations. Many Medicare P4P projects have been subject to formal evaluations.

Each demonstration defines success differently, but to be successful, demonstration interventions must do the following:

- reduce Medicare costs, holding quality of care constant;
- improve quality of care, holding costs constant; or
- both improve quality of care and reduce costs.

Policy makers often use both actuarial and research evaluation methods to consider demonstration success. Actuarial tests usually focus on a narrower definition of cost savings by determining whether the intervention cost less for enrollees than for a matched control group. Actuaries do not tend to consider broader questions of statistical reliability, and they apply their results only to the performance of demonstration participants (e.g., participating hospitals, DM organizations). Participants failing the actuarial test usually are required to pay back any fees to the government under the budget neutrality clause in their CMS contract.

By contrast, research evaluation tests do consider the statistical reliability of the results, using standard confidence intervals. Evaluators test whether savings are statistically greater than zero. Because of the substantial variance in beneficiary monthly and annual costs, actuarial savings can be 5 percent or more yet not statistically different from zero.

In recommending expansion of an intervention to a national program, CMS relies on the evaluator's findings because the government must be fairly certain that the intervention will succeed in other environments entailing greater overall financial risk. To demonstrate 20 percent savings on just 100 patients in one county in one state would not justify a large national program because these results may not be replicable on a larger scale for a variety of reasons. Success on the national stage can be considered the product of expected savings per beneficiary and the number of beneficiaries enrolled in the national program. Both necessary components can be jeopardized by numerous internal and external threats to the validity of the evaluation inherent in the demonstration's design and implementation.

Quasi-Experimental Design

Rarely can CMS conduct a trial that randomly assigns beneficiaries to intervention and control groups; the MHS pilot, with 240,000 beneficiaries, is a notable exception. Nearly always the demonstration entails a quasi-experimental design with hierarchical, or nested, assignment of beneficiaries. Under these designs, beneficiaries are assigned to evaluation groups by categories and subcategories according to characteristics that are relevant and hypothesized to affect the outcomes of the demonstration. Random assignment, although preferable from a research evaluation standpoint, is either administratively impractical or problematic because, under this approach, some otherwise eligible beneficiaries are excluded from the additional benefits provided under the demonstration; this is often considered politically unpalatable in a public program like Medicare. Even under demonstration provisions, Medicare does not have the authority to limit a beneficiary's freedom to choose a Medicare participating provider. Because most applicants to demonstrations are groups of providers (e.g., hospitals, physician practices) rather than Medicare beneficiaries, random assignment of beneficiaries to intervention and control groups has not been possible. Patients are naturally loyal to their clinicians and providers; Medicare cannot require them to switch to another.

Nor is it acceptable to randomize beneficiaries to an intervention arm within a provider group because of likely spillover effects onto control beneficiaries in the same group. Spillover effects are essentially unintended consequences that may affect behavior of others not directly involved in an intervention. An example of a spillover effect would be a physician's changing the way he or she treats all patients (i.e., those participating in the demonstration and those not participating) as a result of what the physician learns or is exposed to through the demonstration intervention.

The best that demonstration evaluators can do is to match the comparison group as closely as possible with loyal intervention beneficiaries. (See discussion in Chapter 10 on strategies for matching intervention and control groups.) Rigorous matching can filter out most of the threats to the internal validity of an evaluation that are associated with history, regression to the mean, and experimental mortality, but some level of threat remains. The following discussion summarizes the threats that arise from the "loyal patient" structure of most P4P demonstrations.

Willingness to Take Risks

Clinician or provider demonstration applicants, by virtue of applying to a P4P demonstration, are more willing to take risk than those who do not. That quality may stem from their internal culture of innovation and passion for improving the delivery of health services. It may also be a result of their having already invested heavily in the intervention's infrastructure (e.g., medical homes with extensive information technology [IT] medical record systems), their already being efficient and able to offer deeper payment discounts, or their having a specially trained and experienced staff and a charismatic leader familiar with the intervention. Their patients may be particularly healthy (or unhealthy), less costly, and more compliant with the intervention requirements than are those in the general population. Clinicians and provider groups may be particularly good at targeting beneficiaries most in need, or they may be part of a larger network of providers with more control over where patients go for care. Being larger, they can spread intervention fixed costs across more participating beneficiaries than can other practices. Groups that apply may be in particularly competitive markets and seek an advantage from marketing a Medicare imprimatur that may increase their market share. They may work in markets with greater health needs that the intervention addresses, or where patients have greater access to lower-cost alternatives to expensive hospitals.

The demonstration's design can influence an evaluation's conclusion of success. Clinicians and health care organizations may not be responsible for certain services (e.g., post-acute care) that encourage early discharges and lower hospital costs. They may receive considerable government support in terms of claims and administrative data that demonstration sponsors and participants use to help monitor progress and refine the intervention. The very fact that the government is closely monitoring the intervention is likely to redouble practitioners' and providers' efforts and keep members of the group in the intervention. Medicare may have chosen a particularly unusual, high-cost population for the demonstration that will likely regress to the mean during the demonstration period. Even if the comparison group similarly regresses to the mean, the churning of patients will add to the statistical "noise" and reduce the likelihood of significant results. Beneficiary exposure to the intervention may be short, either because the demonstration period is too short to capture longer-term success or because something delays patient recruitment into the intervention. These threats undermine the replicability of demonstration results in a much larger program. The biases that voluntary participation and geography introduce suggest less success per beneficiary for other provider groups elsewhere in the country. They also suggest less interest in other groups that are not in the same position to take advantage of the incentives and support associated with the demonstration.

Given the number and range of demonstrations that Medicare has undertaken, it is puzzling that so few have succeeded and become eligible for expansion to a national program. Although Medicare has tested and implemented a range of demonstrations over its almost 50-year history, very few demonstration projects become incorporated into the national program. Occasionally, failure of demonstrations to become national programs results from a lack of applicants or from early dropouts—not from factors affecting the few that remain.⁷ Demonstrations may fail to attract a large enough group of voluntary participants initially, sometimes because of long and complex application and approval processes. Others may begin implementation with a robust group of participants but lose some as the demonstration proceeds as a result of operational difficulties, costs, or other reasons. More often, however,

⁷ Medicare's Residency Reduction Demonstration in New York had 49 participating hospitals early on but only 6 completed the full 3 years. Five of six completers successfully reduced their resident counts, although they may have intended to do so anyway (Cromwell et al., 2005).

participants are unable to show cost savings, although most show modest gains in quality indicators.

One P4P initiative that did show significant success in cost savings was the Medicare Participating Hospital Heart Bypass Demonstration. The demonstration realized substantial savings from discounts on hospital payments, with some regionalization of surgery performed at greater frequency by providers with lower mortality rates (Sebelius, 2009). Yet, as successful as this initiative was, CMS never pursued a national program. The next two sections consider why successfully demonstrated and evaluated Medicare program innovations do not seem to be extrapolated to national programs, particularly for P4P models.

Operational Challenges to National Implementation

Many significant obstacles impede P4P models' implementation as national programs. Some barriers stem from practical operational problems inherent in the way these promising projects begin as demonstrations or other pilot projects. These challenges arise from many of the models' dependence on achieved savings for financing, their operational complexity, and their high operational and data requirement costs.

Paying for Innovation

Current Medicare policy often focuses on finding ways to improve the program's efficiency and to lower its costs while maintaining or improving quality of care. Therefore, most new initiatives—including P4P—aim at either achieving savings for Medicare or, at a minimum, funding the new quality improvement programs from efficiencies gained (termed *budget neutrality*). The fiscal realities of the Medicare program and the political climate in Congress seem to suggest little interest in a major programmatic change that would significantly increase program costs. The promise of savings and increased efficiency accounts for the appeal of various P4P models under a variety of provisions in Affordable Care Act health care reform legislation passed in early 2010.

The need to operate a successful clinical model that is funded on achieved savings creates a challenging obstacle to both implementation and evaluation of success. Some P4P projects have achieved sufficient efficiencies to cover operational costs and still net additional savings to the Medicare program; most notably, these are the original Participating Heart Bypass Center Demonstration and the top-performing Premier Hospital Quality Incentive

Demonstration. Others, once they factor in operational costs, find net savings difficult to achieve. For example, under the MHS pilot, none of the sites achieved the target 5 percent net savings and hence could not keep the up-front management fees they had already received from Medicare. CMS is still evaluating performance for many of the other current Medicare demonstration projects. (See Chapter 2 for detailed discussions of relevant Medicare demonstration projects and available evaluation findings.)

The practical necessity that demonstrations rely on achieved savings to fund P4P initiatives entails what can amount to significant financial risk to both participating sites and the Medicare program. If these projects do not achieve savings, the Medicare program faces the often difficult task of negotiating close-out of operating sites. Because they can measure savings only retrospectively, lack of achieved savings can also represent potential additional costs to Medicare. For participating sites, focus on achieved savings often means that providers must bear the financial risk of the operating costs of the P4P intervention. For example, clinicians and provider organizations that invest in care models, additional staff, and/or upgraded data collection and health IT systems may or may not receive the expected performance-related payments. All these factors may make P4P models that are funded by achieved savings too risky for some groups and, on a large scale, for the Medicare program.

Start-Up and Implementation Operational Complexity

Many P4P models that include carefully defined performance metrics can entail significant operational complexity, both in the process of designing demonstrations and throughout implementation. Negotiating the specific terms and conditions of the measures, payments, and other operational specifics may be enormously time-consuming and thus expensive both for the Medicare program and for participating clinicians and provider groups. Experience from the Medicare demonstrations suggests that the parties make these decisions based on detailed negotiations that attempt to address very specific facility/practice small-scale concerns. For example, despite initial interest from a range of hospital-based organizations, only a subset of the original applicants to the Medicare Hospital Gainsharing, Medicare Physician-Hospital Collaboration, and ACE demonstrations actually participated in the project because sites found it difficult to reconcile their internal goals for participation with the CMS requirements for savings generated, evaluation reporting, and/or other mandated guidelines. In several recent cases (e.g.,

Medicare Hospital Gainsharing and ACE demonstrations), years have passed between the selection of potential demonstration participants and the official start of the demonstration projects. It is not unusual for sites to withdraw during this period.

Negotiated issues, such as specifics of payment mechanisms, risk responsibilities, and other terms and conditions, are extremely important to both Medicare and potential sites. Still, the negotiation period is costly for both—a factor that adds to these projects' overall operational complexity. This approach of individually negotiating performance metrics and payment terms may not ever be feasible at a national level from either a timeliness or a cost perspective. Reaching agreement on these important specifics on a national scale would only increase this complexity. The difficulty of gaining agreement on details such as which is the appropriate entity to be monitored and “paid” for performance (e.g., the group practice versus the individual physician) will be magnified at the national level. Geographic differences in practice patterns may also complicate a nationally agreed-upon standard.

Once policy makers and purchasers set the performance standards, payment amounts and conditions, and other operational details, implementation is very data intensive and therefore costly. Who would bear this cost? The Medicare program, which is under persistent pressure to reduce costs? Where would these additional resources come from? Experience from several of the current Medicare demonstrations suggests that reconciliations necessary to finalize payments for each initiative can sometimes be arduous and contentious. Because CMS commonly assesses performance of these initiatives relative to comparison groups, determining whether demonstration participants have achieved performance targets—and, consequently, whether they can be paid—requires a significant amount of data processing and analysis.

Historically, the reconciliations—even for a limited number of demonstration sites—have sometimes taken more than a year following queries and questions on methodology from affected sites. The processing of site-specific reconciliations at the national level would likely be time-consuming and expensive at best—and, at worst, potentially unworkable if actual performance payments lag so far behind interventions as to have little behavior-changing incentive value. Policy makers considering nationalization of similar demonstrations would need to identify a method for streamlining final payment reconciliations that is at the same time clearly tied to individual performance. Thus far, this kind of streamlining has been elusive.

Data Demands

One factor related to the high operational costs of P4P initiatives is their data intensity. The data necessary to set and evaluate standards are usually significant. For example, some demonstrations require additional clinical diagnostic and outcome information beyond what is available on Medicare claims. Other demonstrations require reporting of internal provider micro-cost data, necessary to understand how and where the demonstration achieved savings and whether savings are likely to be generated by other similar health care provider organizations should the demonstration be expanded or nationalized. To the extent that some standards require data that are unavailable from administrative sources (such as Medicare claims), a high degree of variability is likely in terms of either provider ability or willingness to collect and report accurate data. Many P4P models require an analysis of costs and/or other performance metrics for each individual patient followed by an analysis of comparison group patients—a resource-intensive activity.

Although advances in health IT have made the necessary data collection and analysis more feasible than we could have imagined even 10 years ago, these costs for participating providers can be substantial and often difficult to justify in an era of shrinking Medicare and private reimbursement. Initiatives to improve electronic health records and overall health IT systems may make these data requirements more feasible in the future, though currently these costs can create a barrier to participation.

In addition to the necessary collection and analysis of requisite data to measure performance, clinicians and providers must contend with regulatory requirements to protect the privacy of these data. Meeting data privacy and protection requirements, set forth in the Health Insurance Portability and Accountability Act (HIPAA) and subsequent regulatory requirements, increases the complexity and price of collecting much of the data necessary for P4P. Detailed clinical and health status information not available through administrative claims sources is an example of HIPAA sensitive data often necessary for P4P initiatives. Therefore, national implementation of P4P models, which rely on data that exceed typical administrative data collection, will raise the costs of participation for both Medicare and provider organizations and clinicians. As a result, these additional data needs may, as a practical matter, limit participation either to those initiatives with the greatest potential savings or to participating clinicians and provider organizations that can afford the additional expense.

Implications for the Future: Political Challenges to National Implementation

The previous sections focused on the programmatic, evaluation, and other analytic challenges to national implementation of Medicare P4P demonstrations. An additional obstacle further accounts for the dearth of demonstration projects that actually transition to a national program: politics. As noted earlier, Medicare is the largest insurer in the United States and as such has enormous market influence. Changes to the Medicare program have a substantial impact on a large proportion of the US economy, affecting a wide range of direct medical care clinicians and provider organizations, insurers, medical device/supply manufacturers and distributors, the pharmaceutical industry, beneficiaries, and other stakeholder pocketbooks. This makes change a highly visible and potentially politically dangerous activity for those who hold this responsibility. Demonstrations, particularly the majority that are designed with voluntary participation, and ones that are crafted to offer primarily positive rewards and incentives, are much more palatable politically than national implementation that would in many cases remove such impact-limiting features.

In addition, because legislative action determines virtually all central provisions of Medicare program eligibility, program payments, and benefits offered, the authority for significant change rests mostly with elected officials (i.e., Congress) rather than with political or career executive branch staff at DHHS or CMS. This is not to imply that DHHS and CMS staff have no impact or influence on the program; CMS staff are in fact responsible for the myriad of details that govern the program and operationalize day-to-day policy. Still, elected officials with accountability to a wide range of interests and organizations focused on self-interest rather than improved performance of the Medicare program are the ones making major programmatic changes such as national implementation of P4P models. The Affordable Care Act health care reform legislation includes specific language to create a Medicare Center for Innovation within CMS, likely to create a forum for reform more removed from the congressional political arena.

The fact that most major policy changes to Medicare occur through federal legislation significantly hampers significant and innovative change to the program. Recognizing this principle, some early health care reform proposals considered shifting cost-cutting policy implementation to the Medicare Payment Advisory Commission (MedPAC) or other nonelected entities. Other proposals would extend to the DHHS Secretary the authority to expand

successful demonstrations on a national level (Weaver & Steadman, 2009). The Affordable Care Act ultimately tasked MedPAC with several studies related to Medicare payment reform. The legislation also tasks the DHHS Secretary and, by extension, the DHHS agencies with literally hundreds of health care reform-related projects aimed at improving quality of care and expanding access, in addition to dozens of P4P-related demonstrations and pilot initiatives. These wide-ranging reform initiatives may introduce more examples of demonstration projects that may improve quality and lower costs at some level. Still, the fragmented nature of this “thousand points of light” approach to policy making may not address the core question: *Why* is it so politically difficult to enact large-scale Medicare policy innovations?

Theoretical Explanations

Various theories of political decision making may hold some answers. One classic theory describes policy making along the lines of a cost/benefit analysis (Wilson, 1973). Proposed policies have certain constituencies or supporters, and these groups can be either distributed (such as the tax-paying public) or concentrated (such as a special interest group). As a balance to the support gained from different types of constituencies, costs associated with certain policies can be borne either by a broad or distributed group (such as a general tax increase) or by a concentrated group (e.g., the cost associated with a regulation on a specific industry). Policies that have both distributed constituencies and costs can succeed through political strategies that advocate majoritarian politics, essentially on the logic that a lot of good can be achieved for a lot of people with only limited costs per person (Wilson, 1986). In contrast, the process of entrepreneurial politics refers to distributed constituencies but concentrated costs. In this case, policies with these characteristics can be advocated by arguing for large benefits to large numbers and with costs borne only by a limited group. A third strategy focuses on policies with concentrated benefits but distributed costs: client politics. Policies with client political strategies can face an uphill battle because they argue for limited benefits for the few and a cost burden on many. Finally, policies with both concentrated costs and benefits are commonly interest-group politics (Wilson, 1986).

The purpose of this theoretical model is to describe the most common and successful ways for politicians to approach prospective policies, weighing both their potential benefits and their real costs. The perceived distributions of costs versus benefits can predict the kind of political coalitions that are likely

to form successfully around policies that fall into each category. Policies that can be driven by majoritarian politics will likely have the largest supportive constituencies; those supported by interest group politics have the smallest (Wilson, 1986). Unfortunately, Medicare program policy, particularly any aspect that affects payments, does not fit neatly into Wilson's political constituency model. This may explain partly why policy change and innovation within Medicare are relatively rare: essentially, significant Medicare policy change requires a unique political strategy.

Described within the Wilson framework, additional programmatic costs for Medicare are often widely distributed in that tax revenues frequently finance them. However, specific providers affected by payment changes—particularly those that cut payments and generate any kinds of savings—bear these concentrated costs. When payment changes increase reimbursement, we commonly see disagreement and competition for resources among different provider groups and medical specialties—hence, a lack of consensus on policy direction is the norm.

On the benefit side, policy makers see Medicare beneficiaries as a large and powerful political constituency around which a majoritarian political consensus might form. Current Medicare policy options such as P4P, however, rarely grant additional benefits to large groups without additional costs. Moreover, like provider organizations and clinicians, Medicare beneficiaries rarely speak as a group, leading to lack of agreement concerning the most desired benefits or the appropriate costs to support them. This conflict with theory on building political constituencies to support policy making suggests that significant policy changes to Medicare have difficulty creating viable groups of political supporters. Finding the ideal win-win situation in making major Medicare changes is difficult. Strong and united coalitions fail to form, which results in an absence of innovations in policy making.

Punctuated Equilibrium

Although Wilson's classic theory may explain in part why successful coalitions for major policy change can be difficult to achieve, other political theories may suggest hope for major policy changes within Medicare of the sort that might be suggested from the Medicare P4P demonstration and pilot projects. True and colleagues (2007) describes a policy model of "punctuated equilibrium": long periods of equilibrium, during which small incremental change is the norm. According to this theory, policy stability rather than drastic change typifies American policy making. Instances of major change sometimes

disrupt, or punctuate, these periods of equilibrium, however. Punctuated equilibrium theory suggests that, under most circumstances, political discourse that generally reinforces existing policies with only small marginal changes drives stable policies. Wildavsky (1964) has also cited the tendency for policy driven by small incremental change to describe federal budgeting.

True and colleagues (2007) note that although maintenance of the policy status quo and general lack of policy change are the norm, simple observation suggests that in some instances—albeit infrequent—major change does occur. This occurrence is more likely when a particular issue gains increased prominence on the overall political agenda because of political newcomers, a crisis, or both. As media attention or other external pressure raises an issue's visibility, the likelihood of a major change increases significantly.

The actions of these newcomers and the extra attention also tend to remove certain issues from their typical forums for debate, such as within congressional committees. Status quo forums, in which many issues are considered simultaneously, have been described as “parallel processing.” When certain issues rise to higher-level political institutions, however, such as the interest of a new president, they move to a policy forum of serial processing by macropolitical institutions (Jones, 1994). It is under these circumstances that major change is most likely (True et al., 2007).

Passage in 2010 of the Affordable Care Act health reform legislation, championed as a key priority of then-popular President Obama, is consistent with this theory (i.e., attention from a political newcomer and the news media or other organizations outside the normal political institutions make change possible—but they cannot guarantee it). Original versions of health care reform supported by the Obama Administration called for more substantial policy changes, including development and implementation of a public health care option. As a compromise to accomplish enactment of some measure of health care reform, more modest initiatives including dozens of P4P-related demonstration initiatives were mandated. Inclusion of these models based on the Medicare demonstrations, referred to generally as models of accountable care organizations, does suggest hope for applications of the lessons learned. Unfortunately, the current debates also underscore the serious difficulties surrounding policy change driven by Congress (the primary political organization responsible for Medicare change).

Political scientists often refer to Congress as “the broken branch” because of persistent shortcomings “in the ethical process, the failure to improve the quality of deliberation in committees, and the many moves to restrict the role

of the minority” (Mann et al., 2008, p. x). Essentially, the common view is that Congress, driven by partisan politics and the pressures of a “permanent election,” has great difficulty enacting policy of any type, including the annual mandated federal government appropriation bills. It is hardly surprising that any policy making that requires difficult choices for the Medicare program will face great barriers in a largely dysfunctional legislative body. No matter the policy change advocated, it will harm some likely powerful constituency in some way, and major costs at a minimum will be concentrated and sometimes distributed through large increases in taxes. Given that significant Medicare policy changes are often lose-lose rather than win-win, that such changes are infrequent should not be much of a surprise.

To illustrate these political dilemmas, consider a theoretical, modest P4P model that would pay a bonus, on a national level, to provider organizations and clinicians who meet specific improved quality performance metrics. Funding for this bonus would come from an overall lowering of base payment rates for all similar providers. The primary political landmine for elected officials would be the outcome that some clinicians and providers would be paid more and others *less* than the status quo, creating winners but also losers. Because most providers participate in Medicare, it is the largest US insurer, and because these clinicians and provider organizations depend on this steady stream of revenue, this modification would potentially create a large number of losers, who may in turn pressure Congress to hold them harmless to policy change.

Such political pressure may then put a strong emphasis on the use of only carrots, or win-win, P4P scenarios. More politically appealing proposals include the use of lower fee updates or fee freezes (as opposed to actual reductions) and payment for higher quality or process improvements (such as data reporting) but no penalties for relatively inefficient providers. Carrot-only approaches may be feasible on a small demonstration scale. Their potential cost implications for Medicare program spending if they do not achieve (at least) budget neutrality, however, make such methods untenable and impossible to implement.

Using Carrots Rather Than Sticks

One way in which Congress had attempted to shift the burden of politically difficult payment and improved-efficiency models was to rely on incentives for clinicians and providers to make simultaneous price reduction and quality improvement changes themselves, using internal mechanisms. These

approaches, including competitive bidding, bundled payment, and the CoE models, give participants some type of reward (e.g., access to bonus payments, competitive advantage in Medicare markets, and/or use of an imprimatur for marketing purposes). Still, even these indirect models can encounter significant problems in building successful political constituencies. Congress overturned competitive bidding for Medicare laboratory services based on lower pricing and minimum quality standards, for example, because of political pressure from the laboratory industry—despite specific authorization initially by legislative mandate. In this case, large national laboratory firms launched a campaign that convinced Congress that any limits on laboratory access would be potentially detrimental to beneficiary choice, and CMS (under significant pressure from Congress) halted the demonstration just as implementation was set to begin in 2009. Similarly, in the mid-1990s, Congress specifically mandated, then canceled, competitive bidding for Medicare managed care after local lawmakers raised objections in multiple designated demonstration sites.

For competitive bidding, selection of starting demonstration sites has invoked strong NIMBY responses from lawmakers, despite their professed support for the general concept of market-driven competition as a mechanism for improved quality and lower cost. Medicare Advantage payments feature competitive bidding. However, given that bidding under Medicare Advantage payment rules is pegged against a known, administratively set benchmark and that final payment rates include *minimum* payment rates, it poses little price-reducing risk to bidding insurers. In this case, Congress is able to take credit for implementing “competitive bidding” though under such constrained regulations that the impact—political or otherwise—is limited.

Although pressure to reduce—or at least not increase—Medicare program expenditures is a constant factor in congressional political deliberation, this pressure clearly is not sufficiently strong to force specific action. Congress, unlike most states and localities, is under no legal obligation to pass fiscally balanced budgets. This situation has allowed Congress annually to overturn requirements to cut Medicare physician payments in adherence with sustainable growth limits. Therefore, although Medicare demonstrations have suggested numerous policy innovations that might cut programmatic costs, Congress has likely little political motivation and certainly no legal requirement to enact them.

Awarding marketing imprimaturs as rewards for quality standards and Medicare savings has also faced political opposition. Follow-ons to the original successful CoE demonstrations for cardiac care encountered political

issues from the perceived impact of selective designation of the valuable CoE title. Competing local provider groups and clinicians argued that using this imprimatur in marketing gave awardees an unfair advantage. Designers of the demonstration considered this imprimatur simply an objective assessment of participating groups' outcomes and performance, as well as a reward for giving Medicare discounts. Partly in response to this issue in the earlier project, the current implementation of this model (the ACE Demonstration, implemented in five sites in 2009) is permitted to market itself as a "Value-Based Care Center" instead, a potentially less valuable term than the original CoE label.

Another politically unpalatable feature of P4P models implemented on a national scale may be the additional required administrative and operational costs. Experience from the Medicare demonstrations suggests that terms and conditions of demonstration participation and payment are based on detailed negotiations that attempt to address very specific facility/practice small-scale concerns. Gaining agreement on thorny details such as the appropriate entity to be monitored and "paid" for performance (e.g., small rather large group practices) will be magnified at the national level. Geographic differences in practice patterns may also complicate a nationally agreed-upon standard. Once CMS sets the performance standards, payment amounts and conditions, and other operational details, implementation is very data-intensive and therefore costly. Experience from several of the current Medicare demonstrations suggests that reconciliations necessary at payment points for each initiative can be arduous and contentious. All these challenging aspects provide Congress and other policy makers ready fodder for discussion and study—rather than forward momentum and national implementation.

Summary

Change is complicated for a program like Medicare, which has enormous market power, is a critical source of revenues for most US providers of care, and provides essential benefits to a large and vulnerable beneficiary population. It should not be surprising that members of Congress support concepts such as P4P, but only insofar as the effects do not negatively affect segments of their local constituencies. The political status quo of making incremental rather than major policy change certainly applies to Medicare. As a result, despite the long history of policy experimentation through Medicare demonstrations and pilot tests, few if any of these projects result in national program changes. Such is the case with P4P models.

Whether the current focus on implementation of health care reform, and the legislation's numerous calls for new and expanded P4P demonstrations, can change these political realities remains to be seen. Several of the current Medicare P4P demonstrations are highlighted in health care reform efforts even though many have yet to be evaluated—and not one of the demonstrations has been converted to national implementation. That said, the lessons learned from demonstrations can be a road map to continued health policy reform. The good news from Medicare's extensive demonstration experience in P4P is that the problems and challenges in many of these models are generally well known and, as such, can be addressed and accounted for—if the nation sees either a political constituency for real change or a rare confluence of events that opens a policy window enabling real progress to occur.

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