



Accelerating Health Care Innovation to Improve Quality and Lower Costs: The Role of the Center for Medicare and Medicaid Innovation

Though we spend more per capita on health than any other country and our costs are projected to continue to rise rapidly, Americans often do not get the care they need. Many services may be unnecessary or the result of preventable complications, and use of proveneffective therapies for many chronic diseases remains low. Medical errors and other safety problems remain too common. $^{1\ 2\ 3}$

A key goal of the Affordable Care Act (ACA) is to determine and implement better ways of paying for health care that reward and support higher-value care. The hope is that these payment reforms will make it easier for health care providers to reform the delivery of care in ways that improve quality while slowing cost growth. Broadly speaking, payment reforms would involve greater accountability for cost and quality, moving away from feefor-service payments based on the volume and intensity of services regardless of their quality. Given the limited evidence on the effectiveness of these reforms in many practical contexts, however, the ACA directs the Secretary of the Department of Health and Human Services (HHS) to test a variety of payment and delivery models rather than mandate a specific set of reforms.

In addition to a number of demonstration projects to test specific payment and delivery models like bundled-payments, the ACA directs HHS to establish by January 2011 a Center for Medicare and Medicaid Innovation (CMI). Its purpose will be to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing care quality. With an appropriation of \$5 million in FY 2010 for implementation and \$10 billion for testing models initiated in 2011-2019, the ACA gives the Secretary of HHS broad authority to test promising models and expand successful pilot programs through regulation, without additional legislation.⁴

This event presents a framework for how CMI might be implemented to spur health care delivery and payment innovation, and to identify and diffuse effective models more quickly into the health care system to meet the demands of health care reform. It also describes several policy levers available to HHS through complementary ACA and American Recovery and Reinvestment Act (ARRA) provisions to help facilitate the ongoing, rapid-cycle learning necessary to achieve a high-value learning health care system.

¹ McGlynn EA et al (2003). The Quality of Health Care Delivered to Adults in the United States. New England Journal of Medicine 348: 2635-45.

² Agency for Health care Quality and Research. National health Care Quality Report, 2008. Rockville, MD, 2008.

³ Elixhauser A and Owens P. Adverse Drug Events in U.S. Hospitals, 2004. Health care Cost and Utilization Project Statistical Brief 29. Agency for Health care Quality and Research, 2007.

⁴ Orszag PR and Emanuel EJ (2010). Health Care Reform and Cost Control. New England Journal of Medicine. Article 10.1056/NEJMp1006571 was published on June 16, 2010, at NEJM.org.

Implementing the Center for Medicare and Medicaid Innovation for Efficient Evaluation and System-Wide Impact

Clear Templates for Evaluating Payment Reforms

Providing would-be testing model sites with standardized templates to use in applying for CMI funding, and releasing draft versions of the templates for public comment and feedback, will serve several purposes. First, it will convey consistent expectations to potential models and help assure that those expectations are based on broad public input. Second, it can streamline the approval process for CMS: having clear selection criteria in place—and solicitation announcements that are designed to communicate and screen for them—will enable CMS to more quickly determine which proposals merit consideration. Such an approach has been used successfully for speeding priority Medicaid reforms, such as "Money Follows the Person" waivers, and for reaching conclusions more quickly about particular types of Medicare payment reforms, such as the Medicare Health Support program.

Designing with the End in Mind

Testing models should be selected and implemented with the end in mind. The ACA authorizes HHS to disseminate effective models through regulation without further Congressional approval as long as the CMS Office of the Actuary certifies that such models will result in savings to Medicare and Medicaid. Further, the Office of Management and Budget (OMB) will want to see evidence that overall benefits of the reform outweigh the overall costs associated with its implementation. With that in mind, models should be implemented in such a way that they enable evaluation along the lines of what CMS actuaries and OMB economists will need to know to make these determinations.

To the extent that improving value system-wide is the goal, models should also be implemented in such a way to assess impacts beyond Medicare and Medicaid. Implementing all- or multi-payer models would be the optimal way to accomplish this, but where collaboration is not possible, models should be implemented in such a way to enable the evaluation of spillover effects and unintended effects like cost-shifting. This issue reinforces the importance of developing and collecting consistent measures of cost or resource use as part of an overall measurement strategy. Model designs and pilot sites that are not capable of these types of evaluations should be lower priority.

For broad acceptance by providers, beneficiaries, and the public, meaningful evidence that quality is better or at least is not reduced by the payment reform will be necessary. By demonstrating that savings have not come at the expense of reduced quality or access to care, such evidence will help overcome the resistance to expanding reforms that reduce costs.

Establishing a Common Core Set of Metrics

To enable broad and rapid implementation of varied models and the identification and expansion of those that prove to be successful, CMS might aim for nationally consistent data collection and exchange across payers and the use of a common core set of both quality and cost metrics to facilitate pilot evaluation and comparison.

Determining consistent and appropriate quality and cost metrics for a given type of payment or delivery model is necessary for timely comparisons across models, and for being able to determine whether promising models have the expected effects when expanded. Sources of such measures include outcome-oriented measures identified by the Office of the National Coordinator and CMS as evidence of "meaningful use" of health IT to improve care, all of which have been endorsed by the National Quality Forum, Many are also included in the physician quality reporting initiative (PQRI) and already frequently used in public and private payment reform pilots. For example, the table below lists the diabetes quality measures that have been used as part of the Physician Group Practice (PGP) Demonstration project and provides a crosswalk to the PQRI program, "meaningful use" incentive program, and their NOF endorsement status. 5 6

Diabetes Measure used in PGP Demo	Included in PQRI?	Included in "meaningful use" regulation?	NQF endorsement status
A1c level measurement and control	PQRI measure #1	Yes	Endorsed: NQF measure #0059
Blood pressure management	PQRI measure #3	Yes	Endorsed: NQF measure #0061
LDL cholesterol measurement and control	PQRI measure #2	Yes	Endorsed: NQF measure #0064
Urine protein testing	PQRI measure #119	Yes	Endorsed: NQF measure #0062
Eye exam	PQRI measure #117	Yes	Endorsed: NQF measure #0055
Foot exam	PQRI measure #163	Yes	Endorsed: NQF measure #0056
Influenza vaccination	PQRI measure #110	Yes	Endorsed: NQF measure #0041
Pneumonia vaccination	PQRI measure #111	Yes	Endorsed: NQF measure #0043

Establishing the metrics in advance—and incorporating them in the templates rather than negotiating them anew for each pilot proposal—will also help to streamline the approval process and ensure that only those models that are capable of demonstrating meaningful impacts will be selected. Further, it will help promote consistent and meaningful measurement beyond the testing models.

Ideally, CMS would take steps to produce at least some of these commonly-used personlevel measures on a routine, ongoing basis for all or many Medicare beneficiaries. Doing so would encourage different reform initiatives inside and outside of CMS to reinforce each other in terms of impact on the health care system, would provide a "dashboard" capacity to track progress, and would make it even easier to implement models quickly. Such routine measures could include readmissions, per-capita spending, and other meaningful personlevel quality and cost metrics.

⁵ Centers for Medicare and Medicaid Services (August 2009). Medicare Physician Group Practice Demonstration. https://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP Fact Sheet.pdf, accessed October 2010.

⁶ Centers for Medicare and Medicaid Services (July 2010). Medicare and Medicaid Programs; Electronic Health Record Incentive Program, Final Rule. http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf, accessed October 2010.

Timely, Relevant Data and Information Exchange for Continuous Real-Time Evaluation

Historically, demonstration projects have often been assessed largely through demonstration-specific evaluation methodologies using data obtained after the fact. In contrast, providing model sites with real-time data on their beneficiaries would enable them to take more effective steps to achieve improvements in results. The regular feeds would consist of beneficiary-level information on use of CMS-covered services, such as hospitalizations and physician visits along with diagnostic information, provided in a standard format rather than raw data. Private health plans and other relevant health care organizations should provide similar data feeds.

In addition to supporting improvements in care delivery, these data would also provide the basis for more timely measures that CMS could use to gain further insights about the course of the model, supporting mid-course corrections or early termination of models that are not performing to expectation.

Of course, as noted above, performance measures for the models will not be limited to measures based on claims that CMS can produce alone. Providers who are participating in the models would be expected to leverage health IT—such as electronic prescription and lab data, and in later or more advanced models, electronic record data—to enable the efficient delivery of care and reporting of the appropriate quality measures to CMS.

Health IT policies and future Federal investments could be dedicated to further developing these bidirectional, consistent data streams between payers and model sites and the data infrastructure required to enable this continuous performance monitoring and feedback capacity.

Spurring Innovation through Performance Standards and Results, Rather than Design Standards

In soliciting proposals for promising payment and delivery models, CMI should communicate priorities and desired outcomes but leave flexibility for how these models are designed, allowing innovative solutions to emerge from the ground up. In keeping with this results-oriented focus, payment and delivery reform models should be allowed to evolve over time and be combined with other complementary financial and regulatory changes, as individual reform models in isolation are unlikely to achieve the desired level of quality and efficiency gains.

This approach presents new challenges from an evaluation standpoint, as it may be difficult to isolate the effects of specific payment reforms. However, since multiple payment reforms are being implemented and are likely to continue to be implemented in simultaneous and overlapping ways, and since multiple reforms are likely to be essential to have substantial effects on costs and quality, dealing with this problem is an evaluation necessity. Modeling methods using projected benchmarks rather than or in conjunction with imperfect "control" groups, and other evaluation tools, can help address this issue.

Leverage Models with Demonstrated Proof of Concept and Build the Evidence Base

To maximize the probability of picking proposals that will prove to be effective, CMI might consider prioritizing payment and delivery models that are able to demonstrate proof of concept rather than seeding untested ideas. A significant amount of experimentation has

already been conducted and is underway now through state Medicaid programs, local initiatives, and private health plans.

Promising payment and delivery models might be identified by creating an inventory of strategies they have tried—such as accountable care organizations (ACOs), medical homes, and bundled payments—and tracking their results. Participating payers and providers in many of these initiatives are interested in CMS participation, and conversely, CMS support for initiatives that are being tried outside of Medicare would encourage more system-wide innovation that reflects the CMS templates and goals. Piloting of some ACO models by building on the experimentation that is already taking place in the private sector could also provide useful evidence to guide the ACO Shared Savings Program to be implemented in January 2012.

In building this inventory, CMI could also facilitate the development of a national platform for knowledge sharing on failures and successes of innovations, including reforms implemented in the private sector. A fast-paced innovation process would require CMI-funded models to share results in a timely and transparent manner to continually build the evidence base.

Asserting Federal Leadership for System-Wide Impact and Continuous Quality Improvement

Transforming the fragmented, uneven health care delivery system we have today into one that consistently delivers high-quality, efficient care will require a concerted effort by all stakeholders. HHS can play a key role in facilitating that transformation using policies in the ACA and ARRA in areas besides payment reform models, including:

- Enhanced performance measurement,
- Enhanced claims and clinical data availability, and better performance measures;
- The development of a robust data infrastructure for performance measurement, comparative effectiveness research, and public health surveillance

The National Quality Strategy: An Opportunity for Federal Leadership to Enhance Performance Measurement Around Clearly Articulated Priorities and Goals

Innovation is fostered when investments are tied to achieving clearly articulated goals and outcomes, leaving flexibility for how innovations are designed. System-wide impact will require clear and consistent signals about what those goals and outcomes are. The National Quality Strategy, which the ACA requires HHS to develop by January 2011, represents an important opportunity for HHS to articulate (a) national priorities, (b) ambitious but achievable outcome goals that are aligned with those priorities, and (c) a parsimonious but clear set of core performance metrics that can promote coordinated efforts and assess objective progress in meeting those goals. In developing and implementing the National Quality Strategy, multi-stakeholder collaboration will help build support for this common set of metrics.

Alignment of the CMI with Other Complementary Reforms will Maximize Impact

The National Quality Strategy is an opportunity to promote alignment across reform provisions in the ACA and ARRA, as well as other reform-related initiatives. Consistent objectives should be reflected in the selection of performance measures, and alignment

should include supportive data sharing and a vision for how all of these policy reforms reinforce each other.

For example, the "meaningful use" health IT payments can help enhance the availability and secure exchange of important clinical data, while the more timely provision of actionable claims data to providers and pilot sites by CMS and private health plans can facilitate better care coordination, and the use of consistent quality and cost measures for both programs can enhance each of their impacts. The measures selected as part of implementing other ARRA health IT provisions like the Beacon program and Health Information Exchanges, and the use of consistent performance measures in other reform efforts like ACOs, could further enhance the collective impact of reform on quality and cost.

Leveraging health IT and the electronic infrastructure that is developing should enable the use of electronic health information and administrative claims data to conduct evaluations of a myriad of promising payment and delivery models using pre/post experimental designs. With this very same clinical data used for performance measurement, a number of other important quality improvement efforts can also be furthered such as improving patient safety through enhanced post-market drug and device surveillance and the comparative effectiveness research that will be conducted through the Patient Centered Outcomes Research Institute (PCORI).

Because the analysis for these activities is typically at the population level rather than at the level of the individual patient, only summary data in the form of ratios are relevant. While the "numerators" and "denominators" for each type of quality improvement activity might differ, the data needed for these ratios are typically the very same clinical information generated in the routine delivery of patient care. Within diabetes, for example, provider performance, comparative effectiveness of different medications, and post-market drug safety surveillance could all occur using the same data typically found in condition lists, medication lists, and lab results, albeit with different numerators and denominators.

Though this clinical information is widely distributed in the US health care system across physician offices, hospitals, payers (both public and private, Federal and State), pharmacies, clinical labs, imaging centers, registries, public health agencies, and other entities, these data can be analyzed within and across sources as long as patient health information is recorded consistently and reported using standardized formats. And because identifiable data are generally not required to answer these important public health and policy questions, potentially sensitive, identifiable patient-level health information can remain securely behind each data source's own security firewalls.

Health care reform is a complex undertaking but the ultimate goal is clear: to provide better, safer, more cost-effective care. Achieving this goal hinges on the more efficient collection and exchange of the type of information providers and patients need to support better clinical decision-making. Learning from patient care data is essential for improving health and lowering costs and will therefore be fundamental to successfully implementing health reform. As such, the investments made by the CMI—and the performance measures selected to evaluate the promising payment and delivery models it funds—can be an integral part of advancing a coherent and effective National Quality Strategy.

Reducing Cycle Time & Assessing System-Wide Impact

Pre-Implementation Strategic Planning

Implementation

Evaluation

Diffusion/ Translation or Termination

Strategic Planning for Systemwide Impact

- •Align investment and performance metrics with and advance the National Quality Strategy
- •Define and focus on clear priorities, results, and performance metrics with multistakeholder collaboration
- Design with the end in mind: ensure pilots are designed to enable the desired evaluation at each stage of CMI
- Optimize pre-implementation process through standardization and clear selection criteria (e.g. standardized templates to use in applying for CMI funding; clear selection criteria will enable quick selection process)
- Leverage projects that have already demonstrated "proof of concept" from private sector or other public programs

Implementation Strategies to Enable Rapid Evaluation

- Leverage health IT for realtime data collection and evaluation; provide additional HIT funding where needed.
- Promote nationally consistent data collection and exchange across payers
- Utilize alternative research designs that do not rely on identifying and selecting "control counties" and "interventions" (e.g. the "enhanced use" of existing electronic claims and clinical data across distributed EHR networks to conduct studies employing pre/post experimental research designs).
- Make data available to pilot sites in a timely fashion to enable continuous performance tracking

Strategies to Reduce Evaluation Time

- Focus on system-wide impact evaluation; effects outside of Medicare need to be considered & evaluation of those impacts built-in to pilot design
 - Private sector impacts (e.g. costshifting)
 - Impacts on safety net providers
 - Potential disparities of care (e.g creamskimming)
 - Other unintended consequences
- Evaluation plans for testing a model's efficacy in multiple settings, across the country and patients with different characteristics
- Performance measures identified a priori to provide meaningful evidence of cost and quality impacts & to ensure sites are capable of providing needed information for performance measures.
- •At least a standardized subset of measures (e.g. overall PMPM costs) utilized to the greatest degree possible to facilitate relative comparisons of pilot impacts

Strategies to Quickly Ascertain whether a Pilot Should Be Scaled Up or Terminated

- Facilitate the development of a national platform for knowledge sharing on failure and success of innovations
- •Different tracks available for sites showing quick results meriting expansion or termination versus sites meriting continuation and further analysis
- -Upfront understanding of policy and actuarial thresholds that need to be met & what key policy concerns would hold back the diffusion of promising delivery and payment models to ensure pilots are designed to explicitly measure and evaluate the extent to which those thresholds have been met and concerns are warranted