

THE CENTERS FOR MEDICARE & MEDICAID SERVICES'
QUALITY IMPROVEMENT ROADMAP

July 2005

EXECUTIVE SUMMARY

VISION: *The right care for every person every time.*

AIMS: *Make care safe, effective, efficient, patient-centered, timely, and equitable.*

The Centers for Medicare & Medicaid Services (CMS) believes that this vision and these aims are realistic and substantially achievable, and that recent developments create unprecedented opportunities and need for that achievement:

- A growing body of evidence shows there are major opportunities to improve care with major potential benefits for patients, providers, and payers.
- The growing complexity of medical knowledge and the growing number of participants, technologies, and specialties create both enormous rewards for better care and enormous challenges in continuing our current path.
- Leading providers are innovating to improve systems of care, and many stakeholders are showing a new willingness to come together in partnerships to achieve improvement. They are recognizing that the highest quality care is the only care anyone can now afford, and they are looking to CMS as essential partners.

CMS is focusing on these opportunities because its size and broad impact make it a public health agency. How the agency acts influences both the health care system and the care it delivers. CMS intends to meet the responsibilities that its influence imposes, and achieve the quality aims, through a set of system strategies linked to specific, clear steps to achieve transformational improvements in health care.

SYSTEM STRATEGIES:

The first part of the roadmap is to implement five major system strategies for improving care:

1. Work through partnerships, including within CMS and HHS, with other Federal and State agencies, and with nongovernmental partners including health professionals.
2. Publish quality measurements and information, including measures directed toward both the beneficiary audience and the professional/provider/purchaser audience.
3. Pay in a way that expresses our commitment to supporting providers and practitioners for doing the right thing – improving quality and avoiding unnecessary costs – rather than directing more resources to less effective care.
4. Assist practitioners and providers in taking advantage of CMS quality initiatives and make care more effective and less costly, in particular greater use of effective electronic health systems.

5. Become an active partner in driving the creation and use of information about the effectiveness of healthcare technologies, to bring effective innovations to patients more rapidly and to help doctors and patients use the treatments we pay for more effectively.

CMS expects that these strategies, implemented with partners throughout the health care system, will help promote changes in the culture of health care organizations that can lead to transformational improvements in health care quality. The second part of the quality roadmap links these system strategies to some particular areas of great opportunity for improving quality and avoiding unnecessary health care costs.

ACTIONS:

As it implements the new roadmap, CMS will work with partners to:

- Expand CMS' public promotion of quality improvement and transformation in the healthcare system;
- Pursue transformational breakthroughs in surgical complication prevention; cardiac care; vascular access for dialysis patients; immunization in nursing homes, dialysis facilities, and home health; reductions in restraints and pressure ulcers in nursing homes; and possibly on other topics, in close partnership with multiple stakeholders;
- Strengthen partnerships within CMS and between CMS and other government agencies;
- Create, in close partnership with other stakeholders, performance measurement systems that support these payment systems and that move the healthcare system toward fulfilling the six aims, especially that of patient-centered care;
- Expand public reporting to reflect expanded quality measures;
- Design, for each major care setting, modifications to payment systems that encourage the right care, and implement them as the law allows;
- Assist providers and practitioners in improving their performance on these measures;
- Implement an Agency-wide health information strategy that supports the Department's transformational health IT strategy for the broad implementation of effective health information technology;
- Develop an Agency-wide strategy to promote use of covered preventive services;
- Implement strategies to make maximum use of existing and new data sources on the actual delivery of health care (such as data for the prescription drug benefit) to develop better evidence on the safety, effectiveness, and cost of healthcare technologies and practices;
- Implement, in close partnership with states, a strategy to improve quality of care for Medicaid beneficiaries; and
- Continue to establish, update, and enforce the agency's other traditional responsibilities in quality protection and improvement, reinforced by our new emphasis, collaboration, and evidence related to quality of care.

Implementing the quality roadmap will feature focused, collaborative “breakthrough” projects to demonstrate the feasibility of major health care improvement. For example, promoting appropriate immunizations in nursing homes might involve a partnership with stakeholders (by the CMS Long-term Care Task Force), addressing the payment for administering vaccine (Center for Medicare Management), requiring that vaccines be offered to every patient (Office of Clinical Standards and Quality) and enforcing that requirement (Center for Medicaid and State Operations), including immunization status in information that nursing homes report to CMS (Office of Clinical Standards and Quality), publishing each home’s immunization rate (Center for Beneficiary Choices), and providing technical assistance and promoting staff immunization (Office of Clinical Standards and Quality). These actions require strong coordination to help ensure that the activities of many CMS components come together to change care, and strong collaboration with other stakeholders in the health care system that have a shared goal of transformational quality improvement.

To implement these initiatives, CMS has redesigned and strengthened its Quality Council, now chaired by the Administrator, and has created workgroups to achieve specific progress in such areas as health information technology, performance measurement and pay-for-performance, technology and innovation, prevention, Medicaid and SCHIP, long-term care, cancer care, and methods for breakthrough improvement. These workgroups, with membership drawn from across CMS, report to the Quality Council, which reviews, approves, tracks and supports their work in each component of the agency.

THE CENTER FOR MEDICARE & MEDICAID SERVICES

QUALITY IMPROVEMENT ROADMAP

INTRODUCTION

We all know what we want our health care system to deliver the right care for every person every time. The Institute of Medicine has defined it as high-quality care is care that is safe, effective, efficient, patient-centered, timely, and equitable. With continuing rapid medical progress, the potential is there for care that continues to get better in all of these dimensions.

More and more, we are finding that high quality care means care that is personalized, prevention-oriented, and patient-centered, based on evidence about the benefits and costs for *each particular* patient. That is the direction of 21st century biomedical science, science that is marked by new approaches in the lab like genomics, or nanotechnology, or next-generation information technology. These new sciences are only just beginning to have an impact on patient care, but they hold tremendous potential.

We also know that there are large gaps, even a chasm, between our goal of high-quality care for every patient every time and what our health care system delivers. We have the potential for the best health care in the world – and in so many ways we achieve it, every day, thanks to the talent and commitment and hard work of health professionals, researchers and product developers, and so many more people who work every day to improve the health of Americans. But too often and in too many ways, these dedicated people – who amount to the world’s greatest asset for improving public health – are frustrated in their efforts to achieve the goal of closing the gap.

The Centers for Medicare & Medicaid Services (CMS) has many important opportunities to help health professionals, patients, and all of the stakeholders in our health care system turn those promising new ideas into action to close the quality gaps. What our Agency does about quality in Medicare and Medicaid is fundamentally important for the future of health care. Because of our size, it is very difficult for all of the other stakeholders in our health care system to make care better if we are not moving with them and with the current of quality improvement and biomedical science.

Part of the problem has been our payment and coverage policies. If we just keep paying the bills the same old way, we will not get higher quality, more efficient care. Medicare has long provided critical support for hospital and doctor care when our beneficiaries have complications from their diseases. But Medicare’s benefits have not kept up with the shift toward preventing diseases and their complications which has been such an integral part of the progress in medical care in the past 35 years. Medicare has not paid for many preventive tests to detect diseases early or prevent them in the first place, or for effective programs that help our beneficiaries with chronic illnesses to take proven steps to prevent their complications, or for the prescription drugs that can head off the costly and often deadly consequences of chronic illnesses. Consequently, Medicare has seen rapid spending growth for treating the complications of diabetes, heart disease and failure, lung disease, advanced cancers, and many other illnesses. With the Medicare Modernization Act of 2003, this is changing. By closing the gap in prevention-oriented

coverage, Medicare has tremendous opportunities to help our health care system deliver higher-quality care.

Medicaid benefits are also out of date. For example, the Medicaid statute entitles beneficiaries with a disability to care in a nursing home, not to modern long-term care services, which include much more than nursing home care, may actually be best for their needs and is often less expensive. More generally, Medicaid pays more when states spend more, not when Medicaid programs get better results for more people who need help. A growing number of states have implemented waivers and demonstration programs, such as “money follows the person” and home- and community-based care for people with a disability, with the goal of improving Medicaid coverage and avoiding unnecessary costs. With greater attention to Medicaid’s unsustainable costs, and with greater evidence from states on Medicaid reforms that deliver better results, there are growing opportunities to improve health care quality through Medicaid as well.

In the language of economics, we have had a very innovative health care system that has tremendous potential, both now and for the future, but it is also a system that has been inefficient because of the way that we pay. In everyday language, we have not been getting as much as we should for our health care spending. But the new up-to-date benefits in Medicare, and the increasing evidence on successful alternatives to traditional Medicaid coverage, provide a stronger foundation for improving health care quality for the future. These improved benefits can combine with three other recent trends to provide critical new opportunities to improve the quality of care. These three emerging trends are:

1. **Much better evidence on opportunities to improve quality and save money.** From a growing range of studies like the IOM’s *Crossing the Quality Chasm* report, we know many specific ways in which patient care lags far behind the evidence on how patients should be treated and we better understand the systems needed to bridge that chasm. More studies have also identified proven steps in medical practice to close the quality gaps. This means great potential to avoid suffering, deaths, and higher health care costs every day, through concrete steps to help more patients get the right care.

2. **Clear opportunities for major improvements in the way we support the health professionals who provide care that involves more treatment options and more complexity.** Increasingly, with better knowledge about the mechanisms of diseases and how they can be prevented in individual patients, the decisions physicians must make, the test results, and the other providers they must consult have become more and more complex. Combined with better health information technology, better coordination of care, and other improved support for high-quality care, health professionals and patients can get much more out of all of our knowledge and medical capabilities.

3. **An unprecedented new willingness of many different stakeholders to come together in partnerships to achieve improvement.** After many years of health care cost growth, facing yet another round of increasingly difficult battles over incremental adjustments to Medicare payment rates, more and more people are not just asking for more but are looking at what they can do right now with the resources they have to change our health care system – to make it more sustainable, not only in terms of lower budgetary costs, but *also* in terms of quality and

efficiency. More and more people and organizations are acting like they mean it when they say high-quality care is the only kind of care we can afford.

We are at a unique turning point. Medicare is providing new up-to-date preventive benefits, new support for beneficiaries with chronic illnesses to prevent disease complications, and of course, new prescription drug coverage. There is growing support for Medicaid reforms, building on successful waivers and demonstrations, to enable Medicaid to provide better support for quality care. To take full advantage of this support and the improved benefits, however, we will have to deal with the health care system's failure to deliver the right care to every patient every time even when the care is covered. Providing up-to-date benefits is not enough – we need to take steps to encourage, support, and reward the effective use of these benefits to provide high-quality care.

FIVE STRATEGIES FOR THE CMS QUALITY ROADMAP: AN OVERVIEW

Building on the foundation of the Medicare law and promising Medicaid and State Child Health Insurance Programs (SCHIP) reforms, and the strong belief that high-quality care is the only kind we can afford, the CMS quality roadmap features five main strategies to achieve the goal of high-quality care:

1. Work through partnerships – within CMS, with Federal and State agencies, and especially with non-governmental partners – to achieve specific quality goals.
2. Develop and provide quality measures and information, as a basis for supporting more effective quality improvement efforts.
3. Pay in a way that reinforces our commitment to quality, and that helps providers and patients take steps to improve health and avoid unnecessary costs.
4. Assist practitioners and providers in making care more effective, particularly including the use of effective electronic health systems.
5. Bring effective new treatments to patients more rapidly and help develop better evidence so that doctors and patients can use medical technologies more effectively.

These are strategies, not goals – highways, not destinations. The destination is safe, efficient, effective, patient-centered, timely and equitable care. But the five strategies are critical to getting us there and will be carried out through systematic efforts that span all parts of CMS, because all parts of our Agency can and must support quality improvement.

To support the quality improvement strategy, CMS has strengthened its Quality Council, which now is chaired by the Administrator and meets every two weeks, and has created workgroups with membership drawn from across CMS to implement quality improvement strategies. The Quality Council reviews, approves, and tracks workgroup plans through the Quality Coordination Team, which also provides a variety of technical support. We support these enhanced quality improvement activities in all parts of our Agency, including our expanded Office for Clinical Standards and Quality, new organizational activities in the Center for Medicare Management, the expanded beneficiary information and quality measurement activities in the Center for Beneficiary Choices, and the new Division of Quality Evaluation and Health Outcomes in the Center for Medicaid and State Operations. Accountability for individual tasks

remains with the CMS unit that carries them out, but accountability for overall integration, and for adjusting the plan in response to events, remains with the workgroup and the Quality Council to which it reports. Some workgroups focus on specific strategies, others cut across strategies and address specific provider groups (such as long-term care), specific diseases (such as cancer care), or specific care strategies (such as prevention and drug treatment).

In parallel with our work in Medicare we will support States in promoting quality in Medicaid and SCHIP. The Medicaid-SCHIP Workgroup has developed a strategic plan that includes partnering with States to:

- Share best practices;
- Provide technical assistance in the areas of performance measurement, payment for quality and performance, and health information technology;
- Evaluate current improvement efforts to inform future activities; and coordinate CMSO activities to assure efficiency.

The workgroup is in the process of identifying objectives and formulating the action plan to achieve safe, effective, efficient, patient-centered, timely, and equitable care in Medicaid and SCHIP.

While it implements this roadmap to higher quality care, CMS will continue to give technical assistance to providers, to establish and enforce quality standards, and to carry out its other traditional responsibilities in quality protection and improvement. In many cases, the new quality initiatives reinforce these traditional activities. For example, the state survey and certification organizations are getting new support not only in identifying facilities with problems, but in helping those facilities identify steps to improve quality.

STRATEGY 1: Working Through Partnerships to Improve Performance

The first, essential highway on CMS' quality improvement roadmap is working through partnerships. We have opportunities for system-wide quality improvement today because of the broad interest, commitment, and momentum to create and sustain a better environment for high-quality, personalized care for every patient every time. This is not a CMS-led effort – it comes from all parts of our health care system. Our system has the advantages of flexibility and responsiveness to new ideas and to individual patient needs. We are not as constrained by one-size-fits-all rules that are inappropriate in modern health care, and that is important with all the promising new approaches for delivering health care. But the pluralism of our system also means no one entity can close the quality gap by itself. Because CMS is such an important part of the health care system, we know that we need to participate actively in these collaborative efforts.

Many of our partnerships include new or enhanced collaborations with other government agencies inside and outside the Department of Health and Human Services, including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality (AHRQ), the Department of Veterans Affairs, and the Department of Defense. But these partnerships go far beyond government. We are also engaging in unprecedented collaborations with our partners and other stakeholders to move the

quality agenda forward, where there are specific opportunities for short-term improvements in quality. Examples of these collaborations include:

- Partnering with public- and private-sector groups in the Institute for Healthcare Improvement's Campaign to Save 100,000 Lives. This effort has dozens of partners and about 2,000 enrolled hospitals with the aim of reducing the hospital mortality rate by 100,000 lives a year by June 14, 2006.
- Partnering with the Surgical Care Improvement Partnership, a public-private group led by the American College of Surgeons that is working together to reduce surgical complications.
- Partnering with the Fistula First National Renal Coalition in which a dozen partners are promoting the best evidence-based approach to vascular access for hemodialysis patients. Use of fistulas has already increased significantly as a result of the initiative, meaning better outcomes and lower costs for patients with renal failure, but fistulas remain underused today.
- Partnering with the Alliance for Cardiac Care Excellence alongside more than 30 organizations supporting four specific, major improvements in cardiac care.
- Partnering to implement performance measurement through stakeholder alliances such as the Hospital Quality Alliance (HQA) and the Ambulatory Care Quality Alliance (AQA), which are described below.

These collaborations include the identification and implementation of a set of focused “breakthrough” projects to achieve large improvements in specific areas where large quality gaps have been demonstrated and stakeholders have identified specific steps to improve performance. For example, one breakthrough goal involves achieving substantial influenza immunization in nursing homes, where immunization rates are much lower than recommended by the CDC for this high-priority population. This will involve a partnership with stakeholders (by the CMS Long-term Care Task Force), addressing the payment for administering vaccine (Center for Medicare Management), requiring that the vaccine be offered to every patient (Office of Clinical Standards and Quality) and enforcing that requirement (Center for Medicaid and State Operations), including immunization status in information that nursing homes report to CMS (Office of Clinical Standards and Quality), publishing each home's immunization rate (Center for Beneficiary Choices), and providing technical assistance and promoting staff immunization (Office of Clinical Standards and Quality). Similar collaborations undergird efforts to improve vascular access for dialysis patients, reduce surgical complications, and achieve other breakthrough goals. These specific transformational projects are an important complement to the five quality strategies, to help ensure that they achieve concrete, meaningful improvements in health care quality.

These are just a few examples of the central role of strong partnerships in the CMS Quality Roadmap. The bottom line is that we recognize that to achieve real improvements in quality, we need to work together with other stakeholders from throughout our health care system. Partnerships are an essential feature of every single element in our quality strategy.

STRATEGY 2: Measuring Quality

The second highway on the quality roadmap is developing and applying useful measures of quality of care, including outcomes and consumer experience and cost of care, and to use them collaboratively to improve quality.

Without clinically valid and reliable measures of what we are trying to improve, it is difficult to turn a shared commitment to improving quality into clear, meaningful achievements.

Consequently, CMS is working to support and collaborate on the development of useful quality measures in virtually all areas of care. Much of this activity is taking place through broad partnerships focused on measuring quality and then achieving measurable improvements in quality. CMS is one of many stakeholder participants in these collaborations. The measures being developed, applied, and improved through these collaborations include:

- Measures of hospital quality have been developed through the Hospital Quality Alliance. The HQA consists of more than a dozen organizations including AARP, AFL-CIO, AHRQ, AHA, AHIP, AMA, ANA, and JCAHO to facilitate nationwide public reporting of useful quality measures by hospitals. All of this activity was done in a transparent, collaborative fashion with the goal of providing more information to consumers and practitioners to lead to better performance. That collaboration is now backed by higher payments (0.4 percent) for hospitals that report a “starter set” of ten measures of clinical quality, which in turn has resulted in quicker adoption and more steps to improve performance measures. On April 1, the HQA expanded the set to 17 measures and successfully launched the Hospital Compare Web site, with almost 98 percent of U.S. hospitals (over 4200 hospitals) providing data for comparative quality measures. Within the next year, the measures will be expanded to include outcomes such as patient satisfaction and surgical complications. Measures of hospital efficiency are also under consideration.
- Measures of ambulatory care quality and efficiency are being developed by the Ambulatory Care Quality Alliance, which includes the American College of Physicians, the American Academy of Family Physicians, and the AMA, AHIP, and AHRQ, among others. The AQA recently endorsed a “starter set” of 28 quality measures, including several measures related to the efficiency of care. These measures focus on preventive care and care for common chronic conditions, and include both measures of processes of care and clinical outcomes. CMS is also collaborating to support the development of quality measures relevant to specialty care, for example through the Surgical Care Improvement Project and new efforts on quality improvement for cancer care.
- Measures of nursing home quality are part of the Nursing Home Quality Initiative, which has already achieved important improvements in aspects of nursing home care such as use of restraints and controlling pain. This alliance recently expanded and refined its measures and is taking further steps to improve additional important outcomes and efficiency, such as to reduce pressure ulcers and avoid hospital admissions with preventable complications.
- Measures of health plan performance include HEDIS and the Consumer Assessment of Health Plans Survey. With a broad range of health maintenance organization (HMO), preferred provider organization (PPO), and other coordinated-care and fee-for-service plans available in the Medicare Advantage program, CMS is working to provide information that beneficiaries can use on the quality of these health plans. In conjunction with new opportunities for beneficiaries to save money when they choose a more efficient plan, these

measures of health plan performance provide a strong foundation for competition based on quality and cost to help beneficiaries get the most out of their coverage. Quality measures are also being developed for the new prescription drug plans.

- CMS is also collaborating in other areas of quality measurement, including home health care, dialysis care, and performance measures specifically related to Medicaid and SCHIP populations.
- Finally, much of our work related to improving cancer care involves measurement in an effort to understand what care is actually being provided and whether it is meeting our beneficiaries' needs for comfort and support.

All of these quality measurement and improvement initiatives have several common elements. First, they have broad inclusiveness of stakeholder groups ranging from consumers to payers to health care experts. Second, they feature real leadership from health care providers themselves; for example, the hospital quality improvement efforts are led by hospitals and the ambulatory quality improvement efforts are led by physicians. They are the experts who know the most about how quality can be improved, and their leadership is essential to get valid, reliable performance measures.

In efforts like these to develop broad consensus around valid measures of performance, CMS continues to support and rely on the National Quality Forum (NQF). The NQF's consensus development process provides the best and only broad, consensus-based method by which potential quality measures are publicly vetted and broadly endorsed, on their way to widespread use.

STRATEGY 3: Paying More for Patient-Focused, High-Quality Care

Moving toward payments that create much stronger financial support for patient-focused, high-value care is the third highway on our quality roadmap. We know that the leadership of physicians and other health professionals is the only road to solving the big quality problems in our current system. We know we do not generally have to pay health care professionals to care about quality: that is their professional goal. But today, when physicians and hospitals take proven steps to improve quality and lower costs, their reward is often getting paid less. For a long time, Medicare's fee-for-service program has simply paid for specific covered services, regardless of their quality or impact on patient health. The result is that Medicare often pays more in cases of poor continuity of care – when the result of a scan or lab result cannot be found, as is often the case, it is simply redone. Medicare also tends to pay more if there are complications that might have been prevented, from unnecessary procedures, medication errors, poorly executed care, or patient ignorance of necessary self-care. Conversely, when physicians and other health professionals take steps like using an electronic health record or answering emails or providing a telephone reminder system to avoid complications and keep patients out of the hospital and maybe even out of their office, we pay them less. Instead, the financial payments are greater for ordering more lab tests or imaging, or having more specialists see a patient, or to do more procedures, in order to make ends meet for a medical office. Thus, well-intentioned health care providers have difficulty getting the financial support they need to improve quality and reduce costs, because resources tend to be directed to providing more care.

Many Medicaid programs have worked the same way. In Medicare and Medicaid, providers and practitioners often cannot get the resources they need to do to improve quality, coordination, and continuity of care such as implementing effective patient reminder systems or electronic records. Physicians who are taking steps like answering emails or adopting electronic records or sending out health aides to visit their high-risk patients should not have to swim against the financial tide to do so. If better quality is to be our focus, our payments should not imply something else.

CMS is not alone in this thinking. There is a growing consensus that the best way to help health care providers deliver high-quality, efficient care is to pay for it. MedPAC and members of Congress from both parties have urged Medicare to pay more for higher-quality, efficient care. And leading provider groups representing physicians, hospitals, nursing homes, dialysis centers, and others have also endorsed the movement toward quality-based payments that improve patient care. As in our other initiatives, we will be looking to health care providers to help lead this effort.

We are implementing and evaluating these payment reforms now. Initiatives already in place include:

- In the Premier Hospital Quality Incentive Demonstration, CMS is collaborating with Premier, Inc., a group of non-profit hospitals, to operate a demonstration to improve their quality of care. This demonstration tracks and reports quality data for 34 measures at each of about 270 participating hospitals. Under the demonstration, top-performing hospitals will receive incentive payments for the care of inpatients with any of five conditions: acute myocardial infarction; heart failure; community acquired pneumonia; coronary artery bypass graft; and hip and knee replacement. Participating hospitals will get composite scores for each of the five clinical conditions, and the hospitals will be ranked in order of their scores. Hospitals with scores in the top ten percent will get a two percent bonus of their payments for Medicare fee-for-service patients with similar conditions, while hospitals with scores in the second ten percent will get a one percent bonus. Early results are promising, suggesting improvement in quality scores across the board for the participating hospitals. We expect to use lessons learned from the Premier demonstration to shape further progress in hospital pay-for-performance implementation.
- The Physician Group Practice demonstration, which was implemented in April, 2005, is providing rewards to large, multi-specialty group practices for improving the quality of care and reducing the cost increases for their patients. Similarly, our Medicare Care Management Performance demonstration will soon provide rewards to small-to-medium physician offices for improvements in the care they provide to chronically ill patients. These demonstrations recognize that physicians have the expertise, commitment, and knowledge of their patients to make a big difference in getting better quality and lower costs, and that giving them more financial support for improving quality may help them get the resources they need to do so.
- The Medicare Modernization Act of 2003 gave CMS the authority to implement additional demonstration programs that implement payments focused on patient quality of care, not simply on the services received. CMS is also working on pay-for-performance demonstration programs involving long-term care and dialysis. In addition, Medicare is soliciting demonstration programs that provide new financial support for improving care at

the area level, for example through regional health information technology (IT) investments that achieve improvements in quality and reductions in unnecessary costs.

- We are also working to bring better continuity of care and support for chronically ill beneficiaries in our traditional Medicare plan, by creating financial incentives through our Medicare Health Support Program (formerly the Medicare Chronic Care Improvement Program). With pilots starting this summer, this program is designed to help beneficiaries who account for a majority of Medicare costs today – those with diseases including congestive heart failure, complex diabetes, and chronic lung diseases. The evidence shows that it is possible to improve outcomes and lower costs by avoiding disease complications, by helping beneficiaries understand their disease, their physician’s treatment plan, how they can improve their outcomes through medication compliance and certain lifestyle steps, and what to do with early signs of poor disease control. But until now, Medicare did not pay for these kinds of support, and so the beneficiaries in our traditional Medicare program did not have access to them. Now, organizations participating in our new Medicare Health Support Program initiative will get paid by Medicare when they get improvements in valid clinical quality measures, patient and physician satisfaction measures, and total Medicare costs. Their payments will come from some of the savings they create, and successful programs will have an opportunity to expand.
- Along with providing good information on quality, we are also concentrating health plan payments in Medicare to help our chronically ill beneficiaries get better continuity, support, and treatment for their care. This includes Medicare Advantage health plans, including HMOs, PPOs, and fee-for-service plans that offer additional benefits. Medicare is moving to full “risk adjustment” of payments to these plans, so that to do well in Medicare, a health plan must pay particular attention to providing benefits that are attractive to beneficiaries who are chronically ill, frail, or dually eligible. This year, Medicare Advantage plans are more widely available than ever before in the history of the program, with well over 90 percent of beneficiaries having access. And beneficiaries can save about \$100 a month on average compared to paying for care in the traditional Medicare plan with or without a Medigap plan they purchase on their own, with beneficiaries in fair or poor health able to save even more. In fact, this year, there are over 50 plans specializing in coordinated care for dual-eligible and chronically ill beneficiaries around the country, and many more such plans are expected to be available next year.

CMS is also working with states on Medicaid waiver and demonstration programs that provide better information and financial support for improvements in quality, beneficiary outcomes, and costs. For example:

- **Indiana** recently submitted an amendment to its State Plan to enhance the delivery of child health through the *Indiana Health Information Exchange*, a collaboration of Indiana health care institutions. The collaborative was formed for the purpose of using information technology and shared clinical information to improve the quality, safety, and efficiency of health care to children in Medicaid and SCHIP.
- **California, Michigan and New York** have implemented *Performance Based Auto-Assignment Programs* that reward Medicaid health plans with superior performance. The programs create an

incentive to improve Medicaid quality and preserve the safety net by increasing enrollee volume and payment to those plans that provide a consistent level of quality improvement.

- **Louisiana** is currently planning to expand a *Disease Management Outcomes Measurement System* that utilizes nationally recognized performance measures to improve outcomes in diabetes, asthma and cancer screening. The expansion will promote improvement in the delivery system design, clinical information systems, patient self-management, and electronic decision support tools for practitioners.

The response of more than 98 percent of eligible hospitals to the requirement of data reporting in order to receive a 0.4 percent higher Medicare payment update, along with the high enrollment in the Premier demonstration, show that effective performance-based payment systems can be achieved even if only a modest portion of provider payments are involved. They have also shown that extra technical support can help these programs achieve important quality improvements for small providers and those with rural, underserved, and otherwise challenging patient populations. Through these and related programs, CMS will continue to work with health care providers and the private sector to identify and support effective ways to provide more financial support for improving quality and reducing avoidable costs.

STRATEGY 4: Assisting practitioners and providers in making care more effective, particularly including the use of effective electronic health systems.

The fourth highway is promoting the adoption of health care practices, particularly including health information technology, that are effective in improving health and reducing costs. Publishing performance information and developing supportive payment methods gives practitioners and providers impetus, opportunities, and incentives to improve care and strive for the quality vision. However, many providers may need help to identify and implement the changes needed to improve care. This is particularly important for making sure that small providers, rural providers, providers in underserved areas, and “safety net” providers can take full advantage of these opportunities. The Medicare Quality Improvement Organizations (QIOs) are CMS’ major vehicle to deliver this help (most Medicare QIOs also have contracts with State Medicaid Agencies to evaluate and improve care for Medicaid beneficiaries).

In every state and territory, a QIO is working under a standard contract with CMS. The QIOs are about to begin new contracts (the “8th Scope of Work”), under which they will offer assistance to nursing homes, home health agencies, hospitals, and physician offices in measuring and actually improving the quality of care, with a new emphasis on performance-based evaluation and incentives within the QIO program itself. To help providers give the right care for every person every time, the QIOs will help providers begin to make changes in four key areas: measuring and reporting on quality, redesigning care processes, transforming organizational culture, and adopting and effectively using health IT to support these objectives. One key set of measures of success will be improvement in provider performance on measures that are included in public reporting and may be part of pay-for-performance. In turn, QIOs will be evaluated on how much care improves in the providers with whom they work (in comparison to similar providers that do not receive QIO assistance), and they will receive incentive payments and contract renewals if they are successful.

In addition to giving assistance to practitioners and providers, the QIO program develops tools and information which practitioners and providers can access directly and which other entities

(medical specialty societies, trade associations, integrated delivery systems, vertical multi-provider corporations, etc.) can use in providing assistance.

As the Administration's health IT initiatives emphasize, wider use of effective health information technology represents one of the best opportunities to achieve improved quality and lower costs. With our quality measurement and payment reforms focused on supporting better care, CMS is creating a much better business case for investments in health IT and other steps to provide better quality – rather than simply more investments in providing more services. However, making practice investments and changes that actually pay off in higher quality and lower costs may require new approaches for many providers. Assisting these providers may enable Medicare and Medicaid beneficiaries to achieve greater benefits more quickly, because they are less likely to be left out of effective quality improvement activities. A prominent example is health IT, where small physician offices, nursing facilities, and other providers may have difficulty identifying, installing, and using health IT systems effectively.

Consequently, CMS is working with the rest of the Department of Health and Human Services and the Administration to take assist health care providers in using health IT systems that will be effective in improving quality and reducing costs. The Administration has already made progress in electronic standards in many areas, and CMS is supporting critical further steps that are underway. In addition, CMS is taking other steps to promote health IT, including better support for electronic prescribing with the implementation as the new drug benefit is implemented and new support for electronically based decision tools to help beneficiaries. All of these steps increase the value and the attractiveness of electronic health records, and help make it easier for providers to use e-health systems effectively. Some of the specific steps include:

- CMS is supporting electronic prescribing, through the adoption of new standards. The Medicare Modernization Act requires us to implement e-prescribing no later than 2009. We have accelerated that schedule by already reviewing public comments on proposed requirements for all of the new Medicare prescription drug plans to support widely-used e-prescribing “foundation standards.” We will also seek public comment on appropriate exceptions to the Stark law, to allow support for physician e-prescribing within electronic record systems by other health care organizations, when it is likely to improve care and lower costs through interoperable systems, without creating improper financial arrangements. We expect the rules to be finalized for the drug benefit implementation in 2006.
- CMS is taking new steps toward secure, Internet-based transactions that can lower costs and improve service for health professionals working with Medicare and Medicaid, and is supporting those steps through HIPAA regulations and other ehealth initiatives.
- CMS is also helping providers take advantage of health IT to lower costs and improve quality support through the QIOs. As noted above, in their new three-year quality improvement strategy, the QIOs will assist providers in using evidence-based approaches to achieve measurable quality improvements and get the most benefit from quality-based payment systems. One important method for doing so is to help them choose and install health IT systems that are effective in quality measurement, reporting, and improvement, and that are committed to the Administration's core goal of interoperable electronic record systems. The QIOs are currently working with medical professional organizations and more than 60 private vendors who are committed to the shared goals of measurable quality improvement,

avoidance of unnecessary medical costs and complications, and interoperability. The emphasis for technical assistance is on small offices, rural areas, underserved areas, and safety-net providers.

- To help get more personalized health care, consumers need better IT support as well. CMS is working to use up-to-date IT systems to help beneficiaries and the organizations that support them to get the personalized assistance they need to take advantage of Medicare's new coverages and new information on quality and costs. For example, beneficiaries will be able to get personalized information about benefits, prices, and other aspects of the Medicare drug plans and Medicare Advantage plans that will be available in their area in 2006, right down to the specific drug prices and pharmacies available. We are also using IT tools to make localized performance information available to the public. Our Quality Compare tools already provide consumer-friendly information on the quality of Hospitals, Nursing Homes, Home Health agencies and Dialysis facilities – and we are going to keep building on these systems. Beneficiaries and their caregivers who do not use the Internet themselves can get the same kind of support by calling 1-800-MEDICARE, or use the quality and cost information through many senior and consumer advocacy groups. Readily available, relevant, personalized information can increasingly help our beneficiaries get the medical care they want at the lowest possible cost.
- We are also working to give our beneficiaries more control and use of their own electronic health information, with their permission and control, and with full security protections. For example, this year we are making available our Medicare Beneficiary Portal, an online tool that will enable beneficiaries to get access to all their Medicare information, such as claims, deductibles, eligibility, enrollment and other personal data. They can use it to improve their care, for example, by learning about the specific preventive services which they may not have used, but which Medicare covers and experts recommend. Beneficiaries will also be able to access this information through 1-800-MEDICARE. We are working to build on these systems so that beneficiaries can use their information securely to populate their own Personal Health Records.

Combined with our increasing financial support for higher quality and lower overall costs, these steps to make it easier to adopt and use effective health IT systems provide a big push toward effective health IT systems.

STRATEGY 5: Improving Access to Better Treatments and Evidence to Use Them Effectively

Our fifth highway is supporting the availability of better treatments for our beneficiaries, along with better evidence on the benefits, risks, and costs of using medical treatments. Health IT systems, improved quality measures, and value-based payments to support better decisions can only be as effective as the treatments available and the evidence on what actually works to improve patient care. To help get the most out of our health care system, we need to speed up the availability and effective use of better treatments. Empowering doctors and patients through better treatments and evidence is the best path toward a sustainable, innovative, personalized health care system, one that is based on the best possible decisions about patient care.

Last year, CMS created the Council on Technology and Innovation (CTI) to address these critical issues involving medical technology. The CTI aims to achieve two main goals: making coverage and payment decisions more easily understood and transparent, which includes accelerating the pace at which effective technologies are made available to beneficiaries; and taking advantage of much greater opportunities to develop evidence on the effectiveness of devices, procedures, drugs, and other medical treatments that doctors and patients can use to make better decisions.

The first major charge of the CTI is to improve our processes in Medicare Part A and Part B for getting valuable new treatments to patients. (In the new drug benefit, Medicare does not make specific coverage decisions; rather, we provide oversight to make sure that formularies and other features of the drug plans reflect modern medical practice.) To make new treatments available to patients in Medicare, three steps need to happen: coding, coverage, and payment. Making treatments available more effectively means making improvements in these three processes.

In October 2004, we announced improvements to the Healthcare Common Procedure Coding System (HCPCS) process that are being phased in over an 18-month period. These improvements will help make it easier to pay for certain health care items and services and will help to get new technologies to patients more quickly.

The HCPCS was established in 1978 to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. Such coding is necessary for Medicare, Medicaid, and other health insurance programs to ensure that claims are processed in an orderly and consistent manner. The major new changes include:

- Expanding the Public Meetings to include all public coding requests for HCPCS products, supplies and services, not just durable medical equipment (DME).
- Publishing all preliminary decisions on the CMS Web site.
- Implementing a reconsideration process in the 2007 coding cycle, whereby denied applicants will be allowed to appeal the decision and have an opportunity to have their application reconsidered during the same coding cycle.
- Revising the HCPCS Application Form to make it more streamlined and user-friendly.
- Eliminating the 6 month marketing data requirement for drugs.

The vast majority of coverage decisions for Medicare Part A and Part B treatments continue to occur locally, as they always have. In the limited set of cases where National coverage decisions are necessary, we are meeting the accelerated time frames and the requirements for more predictable and extensive public input that were envisioned in the Medicare Modernization Act. In fact, CMS has met these faster time frames with enhanced public comment 100 percent of the time.

We also want to be sure our coverage decisions in Medicare are as predictable and science based as possible. The best way to do that is through a public process. To this end, we recently issued a set of draft guidances for public comment and input on specific aspects of the coverage process. We asked for input on the process we use to decide which issues to address at the National level, the process of asking for external help in reviewing evidence, and the issues we

will refer to our Medicare Coverage Advisory Committee (MCAC). We have received numerous constructive comments on these and will be posting final guidance documents soon.

In addition to guidance documents on our overall coverage process, we are also working to provide more transparency and opportunity for public input on the standards we apply in our coverage decisions in particular areas of strong public interest. For example, we are currently working on a draft guidance document for the evidence we would like to see for the management of chronic, non-healing wounds in response to recommendations from a recent MCAC meeting. We also plan to issue a guidance document on the evidence surrounding surgical treatment of back disease.

CMS is also providing new opportunities for early discussion of our coverage requirements with product developers. CMS has been working with FDA to develop a parallel review process where manufacturers could request that both Agencies review their application for FDA approval and CMS coverage simultaneously.

Making valuable new treatments available more quickly is important, but too often, medical treatments are not used effectively by doctors and patients. Too often, effective treatments take many years to diffuse to the patients who can use them. And many “off-label” uses of treatments are based on limited evidence even after a product has been in use for many years, with only limited analysis of the experience of patients who actually receive these treatments. Using electronic data that are available now, or that will be available soon, we have new opportunities to learn much more, more quickly, about what works and what does not in helping our beneficiaries in actual medical practice. Especially with the growing availability of electronic data, information from Medicare and other health care programs can potentially be used in the practical analysis of how treatments and other practices influence outcomes for particular types of patients in real-world medical settings, while maintaining effective protections for patient confidentiality. Such data can help answer many important “post-market” questions more quickly and reliably than has been the case before. To this end, CMS is providing better data to develop better evidence on the actual use and experience involving the treatments we cover, so that doctors and patients can make more informed decisions.

In certain cases, Medicare’s coverage processes can support evidence development, while making new treatments available more widely and quickly. In Part A and Part B of the Medicare program, Medicare can only cover interventions that are considered “reasonable and necessary” for diagnosis and treatment. The purpose of this statutory requirement is to ensure that Medicare funds are spent on services that are likely to improve the health outcomes of beneficiaries in actual practice. Medicare has recently received public comments on its first draft guidance describing how “coverage with evidence development” can help reach a determination that broader, faster coverage is “reasonable and necessary.”

Today, some innovative diagnostic and therapeutic technologies appear promising, but often important unanswered questions remain about risks, benefits, and costs, as well as important opportunities for helping individual patients get better care in these circumstances. CMS is responding by covering these technologies faster and more broadly – *if* they are provided in the context of registries or other clinical databases that we reasonably expect can improve care for beneficiaries. In other words, we are supporting the development of the better medical evidence

we need, and this means we can be confident in more circumstances that the treatments are reasonable and necessary for patient care.

However, most of Medicare's efforts to help develop better evidence will occur outside of these specific coverage applications. For example, doctors and patients can also benefit from better evidence for informed, personalized decisions involving prescription drugs. But it has been challenging to develop comprehensive, population-based evidence on prescription drugs for seniors and people with a disability. Elderly patients are less likely to participate in clinical studies, and they are more likely to take drugs for very long time periods for chronic illnesses. It is also harder to determine the outcomes associated with a drug in patients who have multiple chronic conditions and who use multiple medicines. As a result, we often lack high-quality evidence on the benefits and risks of drugs in particular types of Medicare beneficiaries. However, the new drug benefit and the new technology we are using to implement it gives us unprecedented opportunity to work together to develop better evidence on how these drugs actually work in seniors, through new data related to drug utilization patterns, safety, effectiveness, quality of care, and consequences for other Medicare costs.

The electronic data developed in the Medicare drug benefit will create a foundation for this evidence. To implement the drug benefit, we will be collecting 36 electronic data elements for each prescription drug purchase under Part D, such as information on quantity dispensed, days' supply, and the particular form of a medication. This will be the largest scale implementation ever of such electronic data on prescription drugs, by far. Following strict guidelines that meet all HIPAA privacy protections, we will use these Part D data in conjunction with the data we already have on hospital and physician services used by our beneficiaries (existing Medicare Part A and B data). This will give us some unprecedented opportunities to learn more about how our patients using certain medications actually do. Our QIO program already gathers evidence in a similar, confidential manner for studies involving medical devices and procedures. Of course, patient privacy and data security are our primary concern, and drug data used in these evidence-gathering efforts would be "de-identified" before any analysis begins. Studies using these data would not be for the purpose of Medicare coverage decisions, because Medicare is not making coverage decisions for particular drugs. Rather, the goal is to help doctors and beneficiaries get the most out of our drug coverage, and the best way to do that is to give them the best possible evidence about how to use the drugs effectively.

CMS intends to pursue this quality improvement work through partnerships as well. Other health plans and payers, as well as pharmacy benefit managers, have electronic data on drug use, health outcomes, and overall costs of care similar to those that we will develop in the Medicare program. A public-private collaboration to find ways to use data available now or soon to be available on drugs and other aspects of medical care together would allow for even better evidence development. We expect that the same kind of stakeholder partnership that has been used in the HQA and the AQA can help us learn even more about drugs than can be done by Medicare alone. In addition, the Quality Council's Part D Workgroup will be looking for ways to work with health professionals, plans, and other partners to use these data to identify opportunities to improve the quality of care based on our existing knowledge of prescription drugs.

Conclusion

The CMS Quality Improvement Roadmap represents a major, Agency-wide effort to use the new Medicare law and other new opportunities to work in partnership with the rest of the health care system to achieve major improvements in the quality of health care. This is a shared mission. It is up to all of us – government officials and health care stakeholders, especially health professionals with their patients – to work together to achieve the major quality improvements that should be possible today.

Through this five-part roadmap, we can work together to establish a health care system that is safe, effective, efficient, patient-centered, timely and equitable. As we strive to make these improvements to the health care system, our collective ideas, thoughtful consideration, and broad participation are needed. CMS will work to do its part, by strengthening our partnerships and using them to strengthen our ability to identify, support, and improve high-quality, personalized care. This is absolutely essential for the sustainability of Medicare, Medicaid, and our health care system: more than ever, high-quality care is the only kind of care we can afford.