1 # CMS QUALITY IMPROVEMENT ROADMAP

2 ## EXECUTIVE SUMMARY

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

4 CMS believes that this vision is realistic and substantially achievable and that recent
5 developments create unprecedented opportunities and need for that achievement:

6 1. A growing body of evidence shows that there are major opportunities to improve care
7 with major potential benefits for patients.

8 2. The growing complexity of medical knowledge and the growing number of participants,
9 technologies, and specialties create both enormous rewards for better care and enormous
10 challenges in continuing our current path.

11 3. Stakeholders from many sides are showing a new willingness to come together in
12 partnerships to achieve improvement and are looking to CMS for leadership and
13 broadening recognition that highest quality care is the only care anyone can afford.

14 **GOALS**: The Institute of Medicine studied the "chasm" between what healthcare is and what it
15 could be and identified 6 features of the right care which CMS has adopted as goals. We seek to
16 make care

17 1. Safe – care does not harm patients.

18 2. Effective – care prevents disease and complications and minimizes suffering, disability,
19 and death.

20 3. Efficient – patients receive only effective services without waste.

21 4. Patient-centered – care is coordinated and continuous, patients are informed and
22 educated, patients and families are involved in decisions, and pain and emotional distress
23 are relieved,

24 5. Timely – neither patients nor staff experience unwanted delay

25 6. Equitable – care is of equal quality regardless of race, language, personal resources, diagnosis,
26 or condition.Recently, the CMS Administrator has communicated the vision of CMS as a public
27 health agency, seeking to use its influence, reimbursement systems, regulatory authority and
28 leadership to seek widespread transformation of the United States healthcare system in order to
29 meet these six goals. CMS will follow a two-part plan to move toward these goals and transform
30 the healthcare system:

31 **SYSTEM STRATEGIES:** The first part of the plan is to take a national leadership position that
32 emphasizes five major strategies for improving care:

33 1. Work through partnerships (within CMS, with Federal and State agencies, and with
34 nongovernmental partners).

35 2. Publish quality measurements and information (includes both the beneficiary audience
36 and the professional/provider/purchaser audience).

3. Pay in a way that expresses our commitment to quality and rewards rather than inadvertently punishing providers and practitioners for doing the right thing.

4. Promote health information technology (includes both standards promotion and payment for HIT results).

5. Become an active partner in creating and using information about the effectiveness of healthcare technologies to bring effective innovations to patients more rapidly and to monitor the effectiveness of technologies for which we are paying.

CMS will also conduct a set of focused "breakthrough" projects to demonstrate the feasibility of major improvement. CMS will continue to give technical assistance to providers, to establish and enforce requirements, and to carry out its other traditional responsibilities in quality protection and improvement.

INTERVENTIONS: The second part of the plan uses coordinated CMS activities to support improvement. The cross-cutting nature of the Quality Council workgroups has already been mentioned, but the same principles can produce clinical breakthroughs. For example, promoting influenza immunization 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 vaccine be offered to every patient (Office of Clinical Standards and Quality), 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 rarely require new organizational units because existing units of CMS already have responsibility for most of the needed activities, but strong planning and coordination are necessary to make activities of so many CMS components come together to change care.

To achieve this planning and coordination, CMS has strengthened its Quality Council, which now is chaired by the Administrator and meets every two weeks, and has created workgroups in the areas of 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 groups, with membership drawn from across CMS, report to the Quality Council, which reviews, approves, and tracks their workplans. The Quality Coordination Team supports the Quality Council by managing this tracking and planning process and providing a variety of technical support to the workgroups. 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.

1 CMS QUALITY IMPROVEMENT ROADMAP

2 **INTRODUCTION:** We all know what we want our health care system to deliver: the right
3 care for the every patient every time. As the Institute of Medicine has defined it, high-quality
4 care is care that is safe, effective, efficient, patient-centered, timely, and equitable. And with
5 continuing medical progress, the potential for care that is even better in all of these dimensions is
6 increasingly possible.

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

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

20 The Centers for Medicare and Medicaid Services has many important opportunities to help
21 health professionals, patients, and all of the stakeholders in our health care system turn those
22 promising new ideas into action to close the quality gaps. What our agency does about quality in
23 Medicare and Medicaid is fundamentally important for the future of health care. Because of our
24 size, it's very difficult for all of the other stakeholders in our health care system to make care
25 better if we aren't moving with them and with the current of quality improvement and
26 biomedical science.

27 Part of the problem has been our payment and coverage policies. If we just keep paying the bills
28 the same old way, we won't get higher quality, more efficient care. Medicare has long provided
29 critical support for hospital and doctor care when our beneficiaries have complications from their
30 diseases. But Medicare's benefits haven't kept up with the shift toward preventing diseases and
31 their complications that's been such an integral part of the progress in medical care in the past 35
32 years. Medicare hasn't paid for many preventive tests to detect diseases early or prevent them in
33 the first place, or for programs that help our beneficiaries with chronic illnesses to take proven
34 steps to prevent their complications, or for the prescription drugs that can head off the costly and
35 often deadly consequences of chronic illnesses. Consequently, Medicare has seen rapid spending
36 growth on the complications of diabetes, heart disease and failure, lung disease, advanced
37 cancers, and many other illnesses. With the new Medicare law, this is changing. By closing the
38 gap in prevention-oriented coverage, Medicare has tremendous opportunities to help our health
39 care system deliver higher-quality care.

40 Medicaid benefits have also gotten out of date. For example, the statute entitles beneficiaries
41 with a disability to care in a nursing home, not to the modern long-term care services including
42 institutional care that are actually best for their needs, and are often less expensive than nursing
43 homes. 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've had a very innovative health care system that has tremendous potential, both now and for the future, but it's also a system that's been inefficient because of the way that we pay. In everyday language, we haven't 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.

1. **There is much better evidence on opportunities to improve quality and save money.** From 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. 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. With more treatment options and more complexity in medical care, there are clear opportunities for major improvements in the way we support the health professionals who provide care. Increasingly, with better knowledge about the mechanisms of diseases and how they can be prevented in individual patients, the decisions physicians must make and the test results and other providers they must consult has 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. **We're seeing 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 battles over incremental adjustments to payment rates, more and more people are not just complaining 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 turning point. Medicare is providing new up-to-date preventive benefits, and 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

1 even when the care is covered. Providing up-to-date benefits isn't enough – we need to take
2 steps to encourage, support, and reward the effective use of these benefits to provide high-quality
3 care.

4 **HIGHWAYS ON THE CMS QUALITY ROADMAP.** Building on the foundation of the
5 Medicare law and promising Medicaid and SCHIP reforms, and the strong belief that high-
6 quality care is the only kind we can afford, the CMS quality roadmap features five main
7 strategies to achieve the goal of high-quality care:

8 1. Work through partnerships – within CMS, with Federal and State agencies, and especially
9 with non-governmental partners – to achieve specific quality goals.

10 2. Develop and provide quality measures and information, as a basis for supporting more
11 effective quality improvement efforts.

12 3. Pay in a way that reinforces our commitment to quality, and that helps providers and patients
13 take steps to improve health and avoid unnecessary costs.

14 4. Promote effective electronic health systems to support quality improvement.

15 5. Bring effective new treatments to patients more rapidly and help develop better evidence so
16 that doctors and patients can use medical technologies more effectively.

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

21 To support the quality improvement strategy, CMS has strengthened its Quality Council, which
22 now is chaired by the Administrator and meets every two weeks, and has created workgroups
23 with membership drawn from across CMS to implement quality improvement strategies. The
24 Quality Council reviews, approves, and tracks workgroup plans through the Quality
25 Coordination Team, which also provides a variety of technical support. We support these
26 enhanced quality improvement activities in all parts of our agency, including our expanded
27 Office for Clinical Standards and Quality, the new in the Center for Medicare Management, the
28 expanded beneficiary information activities in the Center for Beneficiary Choices, and the new
29 Division of Quality Evaluation and Health Outcomes in the Center for Medicaid and State
30 Operations. Accountability for individual tasks remains with the CMS unit that carries them out,
31 but accountability for overall integration, and for adjusting the plan in response to events,
32 remains with the workgroup and the Quality Council to which it reports. Some workgroups
33 focus on specific strategies, others cut across strategies and address specific provider groups
34 (such as long-term care), specific diseases (such as cancer care), or specific care strategies (such
35 as prevention and drug treatment).

36 In parallel with our work in Medicare we intend to support States in promoting quality in
37 Medicaid and the State Child Health Insurance Programs (SCHIP). The Medicaid-SCHIP
38 Workgroup is developing a strategic plan that includes partnering with States to share best
39 practices, providing technical assistance to improve performance measurement, evaluating
40 current improvement efforts to inform future activities, and coordinating CMSO activities to
41 assure efficiency. The workgroup is in the process of identifying objectives and formulating the

1 action plan to achieve safe, effective, efficient, patient-centered, timely, and equitable care in
2 Medicaid and SCHIP.

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

9 **1. Working Through Partnerships to Improve Performance.** The first, essential roadway on
10 CMS' quality improvement roadmap is working through partnerships. We have opportunities
11 for system-wide quality improvement today because of the broad interest, commitment, and
12 momentum to create and sustain a better environment for high-quality, personalized care for
13 every patient every time. This is not a CMS-led effort – it comes from all parts of our health
14 care system. Our system has the advantages of flexibility and responsiveness to new ideas and to
15 individual patient needs – we aren't as constrained by one-size-fits all rules that are increasingly
16 bad fits in modern health care, and that's important with all the promising new approaches for
17 delivering health care. But the pluralism of our system also means no one entity can close the
18 quality gap by itself. And because CMS is such an important part of the health care system, we
19 know that we need to participate actively in these collaborative efforts.

20 Many of our partnerships include new or enhanced collaborations with other government
21 agencies including CDC, FDA, AHRQ, the VA, and the Department of Defense. But these
22 partnerships go far beyond government. We are also engaging in unprecedented collaborations
23 with our partners and other stakeholders to move the quality agenda forward, where there are
24 specific opportunities for short-term improvements in quality. Examples of these collaborations
25 include:

26 • Partnering with public- and private-sector groups in the Institute for Healthcare
27 Improvement's Campaign to Save 100,000 Lives. This effort has dozens of partners and
28 about 2000 enrolled hospitals with the aim of reducing the hospital mortality rate by 100,000
29 lives a year by June 14, 2006.

30 • Partnering with the Surgical Care Improvement Partnership, a public-private group led by the
31 American College of Surgeons that is working together to reduce surgical complications.

32 • Partnering with the Fistula First National Renal Coalition in which a dozen partners are
33 promoting the best evidence-based approach to vascular access for hemodialysis patients.
34 Use of fistulas has already increased significantly as a result of the initiative, but fistulas
35 remain underused today.

36 • Partnering with the Alliance for Cardiac Care Excellence alongside more than 30
37 organizations supporting four specific, major improvements in cardiac care.

38 • Partnering to implement performance measurement through the Hospital Quality Alliance
39 (HQA) and the Ambulatory Quality Alliance (AQA), which are described below.

These collaborations include 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 Centers for Disease Control. This will involve a partnership with stakeholders (by the CMS Long-term Care Task Force) that has also improved the payment for administering vaccine (Center for Medicare Management), may require that the vaccine be offered to every patient (Office of Clinical Standards and Quality), may enforce 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 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.

2. Measuring and Improving Quality. The second roadway 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 (HQA). The HQA consists of more that 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 Website, with almost 99 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.

1 • Measures of ambulatory care quality and efficiency are being developed by the Ambulatory
2 Care Quality Alliance (AQA), which includes the American College of Physicians, the
3 American Academy of Family Physicians, and the AMA, AHIP, and AHRQ, among others.
4 The AQA recently endorsed a "starter set" of 28 quality measures, including several
5 measures related to the efficiency of care. These measures focus on preventive care and care
6 for common chronic conditions, and include both measures of processes of care and clinical
7 outcomes. CMS is also collaborating to support the development of quality measures relevant
8 to specialty care, for example through the Surgical Care Improvement Project and new
9 efforts on quality improvement for cancer care.

10 • Measures of nursing home quality as part of the Nursing Home Quality Initiative, which has
11 already achieved important improvements in aspects of nursing home care such as use of
12 restraints and controlling pain. This alliance recently expanded and refined its measures and
13 is taking further steps to improve additional important outcomes and efficiency, such as to
14 reduce pressure ulcers and avoid hospital admissions with preventable complications.

15 • Measures of health plan performance. With a broad range of HMO, PPO, and other
16 coordinated-care and fee-for-service plans available in the Medicare Advantage program,
17 CMS is working to provide information that beneficiaries can use on the quality of these
18 health plans. In conjunction with new opportunities for beneficiaries to save money when
19 they choose a more efficient plan, these measures of health plan performance provide a
20 strong foundation for competition based on quality and cost to help beneficiaries get the most
21 out of their coverage. Quality measures are also being developed for the new prescription
22 drug plans.

23 • CMS is also collaborating in other areas of quality measurement, including home health care,
24 dialysis care, and performance measures specifically related to Medicaid and SCHIP
25 populations.

26 • Finally, much of our work in improving cancer care involves measurement in an effort to
27 understand what care is actually being provided and whether it is meeting our beneficiaries'
28 needs for comfort and support.

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

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

41 **3. Paying More for Patient-Focused, High-Quality Care.** Moving toward payments that
42 create much stronger financial support for patient-focused care is the third route 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 don't have to pay providers to care about quality, 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 can't be found, as is often the case, it's 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 incentives are to order more lab tests or imaging, or to see a patient more often, or to do procedures, in order to make ends meet for the practice. Many Medicaid programs have worked the same way. As a result, 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 need to say so..

CMS isn't 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 bipartisan members of Congress 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'll 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:

- 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 10% will get a 2% bonus of their payments for Medicare fee for service patients, while hospitals with scores in the second 10% will get a 1% bonus. Early results are promising, showing improvement in quality scores for the participating hospitals. We expect to use lessons learned from the Premier demonstration to shape our future hospital pay-for-performance initiatives.

- The Physician Group Practice demonstration, which was implemented in April, is providing rewards to large, multi-specialty group practices for improving the quality of care and

1 reducing the cost increases for their patients. Similarly, our Medicare Care Management
2 Performance demonstration will soon provide rewards to small-to-medium physician offices
3 for improvements in the care they provide to chronically ill patients. These demonstrations
4 recognize that physicians have the expertise, commitment, and knowledge of their patients to
5 make a big difference in getting better quality and lower costs, and that giving them more
6 financial support for improving quality may help them make a difference in doing so.

7 The Medicare Modernization Act gave CMS the authority to implement broad demonstration
8 programs that implement payments that are focused on patient quality of care, not simply on the
9 services received.

10 • CMS is working on pay-for-performance demonstration programs involving long-term care
11 and dialysis. In addition, Medicare is soliciting demonstration programs that provide new
12 financial support for improving care at the area level, for example through regional health IT
13 investments.

14 • We are also working to bring better continuity of care and support for chronically ill
15 beneficiaries in our traditional Medicare plan, by creating financial incentives through our
16 MedicareChronic Care Improvement Program (CCIP). With pilots starting this summer,
17 Medicare CCIP is designed to help beneficiaries who account for a majority of Medicare
18 costs today – those with diseases including congestive heart failure, complex diabetes, and
19 chronic lung diseases. The evidence shows that it is possible to improve outcomes and lower
20 costs by avoiding disease complications, by helping beneficiaries understand their disease,
21 their physician's treatment plan, how they can improve their outcomes through medication
22 compliance and certain lifestyle steps, and what to do with early signs of poor disease
23 control. But until now, Medicare didn't pay for these kinds of support, and so the
24 beneficiaries in our traditional Medicare program didn't have access to them. Now,
25 organizations participating in our new Medicare CCIP initiative will get paid by Medicare
26 when they get improvements in valid clinical quality measures, patient and physician
27 satisfaction measures, and total Medicare costs. Their payments will come from some of the
28 savings they create, and successful programs will have an opportunity to expand.

29 • We are also paying organizations in Medicare to help our chronically ill beneficiaries get
30 better continuity, support, and treatment for their care. This includes Medicare Advantage
31 health plans, including HMOs, PPOs, and fee for service plans that offer additional benefits.
32 Medicare is moving to full "risk adjustment" of payments to these plans, so that to do well in
33 Medicare, a health plan must pay particular attention to providing benefits that are attractive
34 to beneficiaries who are chronically ill, frail, or dually eligible. This year, Medicare
35 Advantage plans are more widely available than ever before in the history of the program,
36 with well over 90 percent of beneficiaries having access. And beneficiaries can save about
37 $100 a month on average compared to the traditional plan with or without a Medigap plan
38 they purchase on their own, with beneficiaries in fair or poor health able to save even more.
39 In fact, this year, there are over 50 plans specializing in coordinated care for dual-eligible and
40 chronically ill beneficiaries around the country, and many more such plans are expected to be
41 available next year.

42 CMS is also working with states on Medicaid waiver and demonstration programs that provide
43 financial support for improvements in quality, beneficiary outcomes, and costs.

1 • ***Indiana*** recently submitted an amendment to its State Plan to enhance the delivery of child health
2 through the *Indiana Health Information Exchange*, a collaboration of Indiana health care
3 institutions. The collaborative was formed for the purpose of using information technology and
4 shared clinical information to improve the quality, safety, and efficiency of health care to
5 children in Medicaid and SCHIP.

6 • ***California, Michigan and New York*** have implemented *Performance Based Auto-Assignment*
7 *Programs* that rewards health plans with superior performance. The programs create an
8 incentive to improve Medicaid quality and preserve the safety net by increasing enrollee volume
9 and payment to those plans that provide a consistent level of quality improvement.

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

15 The Premier demonstration, and the response of more than 98% of eligible hospitals to the
16 requirement of data reporting in order to receive the 0.4% more annual Medicare payment
17 update, show that effective performance-based payment systems need only involve a few percent
18 of provider payments – not all of them. They have also shown that extra technical support can
19 help these programs achieve important quality improvements for small providers and those with
20 rural, underserved, and otherwise challenging patient populations. Through these and related
21 programs, CMS will continue to work with health care providers and the private sector to
22 identify and support effective ways to provide more financial support for improving quality and
23 reducing avoidable costs.

24 **4. Supporting the Effective Use of Health Information Technology.** The fourth roadway is
25 promoting the adoption of health information technology that is effective in improving health
26 and reducing costs. As the Administration's health IT initiatives emphasize, wider use of
27 effective health information technology represents one of the best opportunities to improve
28 health and costs. With our quality measurement and payment reforms focused on supporting
29 better care, CMS is creating a much better business case for investments in health IT and other
30 steps to provide better quality – rather than simply more investments in providing more services.

31 CMS is working with the rest of the Department and the Administration to take other steps to
32 make it easier and more beneficial to adopt effective health IT. The Administration has already
33 made great progress in electronic standards in many areas, and critical further steps are
34 underway. In addition, CMS is taking other steps to promote health IT, including better support
35 for electronic prescribing with the implementation of the drug benefit and new support for
36 decision tools to help patients. All of these steps increase the value and the attractiveness of
37 electronic health records and other ehealth systems. Some of the specific steps include:

38 • Support for electronic prescribing, through the adoption of new standards and updates to the
39 regulations affecting how different components of the health care system interact. The
40 Medicare Modernization Act requires us to implement e-prescribing no later than 2009. We
41 are accelerating that schedule by already issuing a proposed regulation for all of the new
42 Medicare prescription drug plans to support widely-used "foundation standards" for e-
43 prescribing. 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 lowers costs through interoperable systems, without creating improper financial arrangements. The rules will be finalized in time 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, and is supporting those steps through HIPAA regulations and the Health Informatics Initiatives.

- CMS is also making sure that providers have the support they need to take advantage of health IT to lower costs and improve quality. First, CMS is working with the Veterans Administration to adapt their VISTA system for electronic records to the public domain. Second, CMS is providing technical support through our state-based Quality Improvement Organizations (QIOs). 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 implement health IT systems, using advice and support that has worked well for similar providers and that is well-coordinated with other Administration efforts to support effective, interoperable IT systems. These IT systems will help physician offices and other providers measure quality of care and improve it. The emphasis for technical assistance is on small offices, rural areas, and underserved areas.

- 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 2006, right down to the prices and pharmacies available. We're also using IT tools to make localized performance information available to the public. Out Quality Compare tools already provide consumer-friendly information on the quality of Hospitals, Nursing Homes, Home Health agencies and Dialysis facilities – and we're going to keep building on these systems. Beneficiaries and their caregivers who don't 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.

- 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 that Medicare covers and which experts recommend but which they have not used. Beneficiaries will also be able to access this information through 1-800-MEDICARE. We're working to build on these systems so that beneficiaries can use their information securely to populate their own Personal Health Records.

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

4 **5. Improving Access to Better Treatments and Evidence to Use Them Effectively,** Our fifth
5 roadway is supporting the availability of better treatments for our beneficiaries, along with better
6 evidence on the benefits, risks, and costs of using medical treatments. Health IT systems,
7 improved quality measures, and quality-based payments to support better decisions can only be
8 as effective as the treatments available and the evidence on what actually works to improve
9 patient care. To help get the most out of our health care system, we need to speed up the
10 availability and effective use of better treatments. Empowering doctors and patients through
11 better treatments and evidence is the best path toward a sustainable, innovative, personalized
12 health care system, one that is based on the best possible decisions about patient care.

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

19 The first major charge of the CTI is to improve our processes in Medicare Part A and Part B for
20 getting valuable new treatments to patients. (In the new drug benefit, Medicare doesn't make
21 specific coverage decisions; rather, we provide oversight to make sure that formularies and other
22 features of the drug plans reflect modern medical practice.) To make new treatments available to
23 patients in Medicare, three steps need to happen: coding, coverage, and payment.

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

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

32 • Expanding the Public Meetings to include all public coding requests for HCPCS products,
33 supplies and services, not just durable medical equipment (DME).

34 • Publishing all preliminary decisions on the CMS website.

35 • Implementing a reconsideration process in the 2007 coding cycle, whereby denied applicants
36 will be allowed to appeal the decision and an opportunity to have their application
37 reconsidered during the same coding cycle.

38 • Revising the HCPCS Application Form to make it more streamlined and user-friendly.

39 • 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 new Medicare law. In fact, CMS has met these time frames with public comment 100 percent of the time.

We also want to be sure the coverage decisions themselves are as predictable and science-based as possible, and 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 national, 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 comments on these and will be posting final guidance documents later this summer.

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. We are currently working on a draft guidance document for the evidence we would like to see for the management of chronic, nonhealing wounds in response to recommendations from a recent MCAC meeting. We also plan 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.

To complement its work to make valuable new treatments available more quickly, the CTI is also taking steps to help doctors and patients use these treatments effectively. Too often, treatments takes 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. 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 doesn’t in actual medical practice involving our beneficiaries. We can use information in Medicare and other health care programs to conduct lower-cost practical studies of outcomes for particular types of patients in real-world medical settings, and we can help answer important post-market questions much 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. Further evidence related to the risks, benefits, and costs in the actual delivery of health care can help improve treatment 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 issued draft guidance describing how “coverage with evidence development” can help reach a determination that broader, faster coverage is “reasonable and necessary.”

1 Today, some innovative diagnostic and therapeutic technologies appear promising, but often
2 important unanswered questions remain about risks, benefits, and costs, as well as important
3 opportunities for helping individual patients get better care in these circumstances. CMS is
4 responding by covering these technologies faster and more broadly – *if* they're provided in the
5 context of registries or other clinical studies that we reasonably expect will generate valuable
6 medical evidence. In other words, we are supporting the development of the better medical
7 evidence we need, and this means we can be confident in more circumstances that the treatments
8 are reasonable and necessary for the care of our beneficiaries.

9 Doctors and patients can also benefit from better evidence for informed, personalized decisions
10 involving prescription drugs as well. But it has been challenging to develop comprehensive
11 evidence on prescription drugs for seniors and people with a disability. Elderly patients are far
12 less likely to participate in clinical studies. It is also harder to determine the outcomes associated
13 with a drug in patients who have multiple chronic conditions and who use multiple medicines.
14 As a result, we often lack high-quality evidence on the benefits and risks of drugs in the senior
15 population. However, the new drug benefit and the new technology we are using to implement it
16 gives us unprecedented opportunity to work together to develop better evidence on how these
17 drugs actually work in seniors, through new data related to drug utilization patterns, safety,
18 effectiveness, quality of care, and consequences for other Medicare costs.

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

35 CMS is ready to contribute to using electronic drug data to develop significantly better evidence
36 on safety issues, on how drug use can help avoid other costly complications, and on what works
37 best for our beneficiaries. But CMS does not intend to work alone. Other health plans as well as
38 pharmacy benefit managers have electronic data on drug use, health outcomes, and overall costs
39 of care similar to those that we will develop with the Medicare drug benefit and our other
40 information on medical complications and costs. A public-private collaboration to find ways to
41 use data available now or soon to be available on drugs and other aspects of medical care
42 together would allow for even better evidence development. We expect that the same kind of
43 stakeholder partnership that has been used in the Hospital Quality Alliance and the Ambulatory
44 Care Quality Alliance can help us learn even more about drugs than can be done by Medicare
45 alone. In addition, the Quality Council's Part D Workgroup will be looking for ways to use

these data to improve the quality of care based on knowledge that is already available about what works and does not.

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, and especially patients and health professionals – 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 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: increasingly, high-quality care is the only kind of care we can afford.

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