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# Health Care Quality Improvement Program: A New Approach

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*The Health Care Financing Administration (HCFA) has embarked on a new program to ensure the quality of care provided to Medicare and Medicaid beneficiaries. The approach, entitled the Health Care Quality Improvement Program (HCQIP), focuses on improving the outcomes of care, measuring improvement, and surveying for patient satisfaction. HCQIP, still in its infancy, is undertaken in collaboration with the providers of care. This article describes HCQIP.*

## INTRODUCTION

HCQIP's mission is to enhance the quality, effectiveness, and efficiency of services provided to HCFA beneficiaries. The basic premise of the HCQIP is that beneficiaries will benefit most from a quality-management program that emphasizes improving the processes by which care is delivered.

HCQIP is evolving, yet five goals remain in constant focus:

- Improving outcomes.
- Promoting quality measurement.
- Informing and educating providers and promoting practice guidelines.
- Informing and educating beneficiaries.
- Establishing and enforcing health and safety standards.

HCQIP is a HCFA-wide<sup>1</sup> effort that integrates the development of health and safety standards with improved surveillance methods, quality-of-care improvement initiatives and projects, and recognition of HCFA's consumer information responsibilities. In this article, the background of

HCQIP, the conditions leading to its development, and the regulatory environment in which it functions, are outlined in addition to a general overview of HCQIP.

## BACKGROUND

The major quality-management instruments for the Medicare program are:

- Peer review organizations (PROs) (Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97-248). HCFA has a contract with an organization in each State to promote the quality, efficiency, and effectiveness of care to Medicare beneficiaries.
- End stage renal disease (ESRD) networks (ESRD Amendments of 1978, Public Law 95-292, Section 1881(c)). HCFA has contracts with regional networks to ensure and improve care for Medicare beneficiaries with ESRD.
- Survey and certification programs (Social Security Act Amendments of 1965, Public Law 89-97, Section 102(a)). HCFA, working through State agencies, surveys hospitals, home health agencies (HHAs), nursing homes, hospices, dialysis centers, and a variety of other providers for compliance with Medicare (and sometimes Medicaid) health and safety requirements.

These organizations and their functions are established in law and have far-reaching effects. One in four Americans receives health care coverage through Medicare or Medicaid from more than

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<sup>1</sup> Key HCFA offices involved are: Bureau of Policy Development; Bureau of Data Management and Strategy; Health Standards and Quality Bureau; Office of Managed Care; and the Office of the Associate Administrator for External Affairs.

56,000 institutional providers and 700,000 physicians and other health care practitioners. Participation in Medicare and Medicaid is dependent on the provider meeting Medicare health and safety standards and on the physician providing care consistent with generally recognized professional standards of care.<sup>2</sup>

Historically, HCFA quality-assurance (QA) programs, each of which is an external quality-management program for providers, were directed toward identifying instances of poor care that would either be corrected or lead to exclusion of the health care provider or physician from Medicare and Medicaid payments. With few exceptions, such efforts have been only marginally successful (Lohr, 1990; Institute of Medicine, 1986), and have not addressed the care provided to the majority of Medicare and Medicaid beneficiaries.

At the same time that HCFA was recognizing the limited achievements of its approach to QA, it developed its 1993 strategic plan and established as a major goal the promotion of improved health status of its beneficiaries. That goal envisions a balanced approach of enforcement of essential health and safety standards combined with improvement of all care provided to beneficiaries. Neither enforcement nor improvement by itself can serve beneficiaries well.

## **HCFA as a Purchaser**

HCFA is also focusing increasingly on its role as a purchaser of health care services rather than a regulator. The PROs, ESRD networks, and the survey and certification

programs were enacted because the Federal Government was a purchaser of health care for aged, disabled, and poor people and needed to assure itself that it was buying quality care for its beneficiaries. Hence, the law required that hospitals and other institutions meet standards prescribed by the Secretary of the Department of Health and Human Services in order to receive payment for care rendered to Medicare and Medicaid eligible patients. Similarly, professional standards review organizations (PSROs), the predecessors of the current PROs, reviewed hospital care and conducted studies on utilization and quality.

Today, HCFA purchases care for over 70 million Medicare and Medicaid beneficiaries. Thus, HCFA is like General Motors, Xerox, and other major purchasers of health care services—we want to buy the best we can for our beneficiaries. Like other purchasers, HCFA has found that trying to ensure quality without trying to improve quality for all patients leads to perpetual problems with marginal providers and sacrifices the potential improvement in the mainstream of care.

Partnership between HCFA and the beneficiary and provider communities is essential to advancing HCQIP. Our approach assumes that most health care providers need and welcome both information and, where necessary, help in applying the tools and techniques of quality management. HCFA seeks to serve as a catalyst for improving care so that all beneficiaries receive the best possible care and good providers become even better.

HCFA's approach rests on our experience that a provider's own internal quality-management system is the key to good performance. Although a purchaser such as HCFA can impose its requirements or standards for outcomes and processes of care, the management of care needed to

<sup>2</sup> HCFA also administers the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (Public Law 100-578), which require laboratories to meet Federal standards and be certified in order to perform laboratory tests. CLIA does not rest on Medicare and/or Medicaid participation and is, therefore, not specifically discussed in this article. Nonetheless, the goals and basic approach of HCQIP do apply to the CLIA quality-management program.

meet those standards must come from within the organization.

The "purchaser" rationale for HCFA's QA programs surprises many in the health care community who view the agency as regulatory and akin to State licensure. Indeed, the Medicare certification program has established and enforced health and safety standards where none existed previously. These activities have generally been viewed as appropriate government services. Additionally, due to the great purchasing power of the Medicare and Medicaid programs, meeting these standards is, for many health care providers, essential to their financial well-being and even their survival. While the roles of regulator and purchaser are not contradictory, they do require HCFA to achieve a balance between its public service and purchaser responsibilities.

## HEALTH CARE QUALITY

### Environment

Several environmental changes contributed to HCFA's decision to reinvent its QA programs:

- The health care system is changing rapidly. The growing complexity of arrangements among providers and the need to reduce costs while maintaining quality puts special pressures on payers to manage quality. Additionally, greater medical knowledge, new medical technologies, advances in communication systems, and increased patient expectations make health care today very different from that provided when Medicare and Medicaid were enacted. Too much of our QA program has been based in the world of 10 and 20 years ago.
- There is growing agreement in the health care community that the quality of care can be defined and measured.

Research has led to scientifically-based practice guidelines, and to the development of quality indicators. Much development remains to be done, but agreement that the quality of care can be measured compels managers to use such measures as they become available. HCFA must apply these new tools in our quality-assurance programs and in our activities as a purchaser.

- Data systems have changed immensely. Technology permits us to gather and manipulate data more intelligently and inexpensively than was possible just a few years ago, and further advances will occur. This enables the assessment and measurement of care both within and across health care settings.
- Finally, the Total Quality movement incorporating the concepts of customer satisfaction, Continuous Quality Improvement, and employee empowerment is present in all sectors of the economy. It has gained a foothold in health care, and has spurred an increasing number of health care providers to measure and improve their performance. HCFA can build on that movement. External quality-monitoring programs can be used to support and enhance internal quality-improvement and management programs.

### Improvement Program

HCFA's HCQIP is still evolving, and will continue to unfold as we learn from providers,<sup>3</sup> consumers, PROs, survey and certification State agencies, ESRD networks, and our own experience. Yet the focus will remain on improving outcomes, promoting quality measurement, informing and educating beneficiaries and providers, and enforcing health and safety standards.

<sup>3</sup> For the remainder of this article "provider" refers to all health care providers, physicians, and other practitioners, as well as health care plans and networks.

The following section describes the current program and some future plans.

## IMPROVING OUTCOMES

We are refocusing attention from the structures and processes of health care to outcomes, as well as creating an expectation and strategy for improvement.

### Focus on Outcomes

- We are replacing the structure and process requirements in Medicare survey and certification with outcome measures wherever possible. At the same time, we are focusing the PRO and ESRD network programs on outcomes and on processes of care that have been shown to directly affect better outcomes.
- We are revising the conditions of participation for hospitals, HHAs, and ESRD facilities. The revisions will place greater emphasis on the provider's responsibility to monitor outcomes and on effective internal quality-management systems. For example, standards that specify the format and content of medical records or the availability of dietary manuals are requirements that need not be mandated and monitored by an external body if the provider's quality-management system is effective in doing so. It is our intent to eliminate, wherever possible, process and structure requirements as methods for measurement of outcomes become more effective and are used by health care providers.
- Revised survey processes that reinforce these changes are now in place for HHAs, dialysis facilities, and nursing homes. We will retrain surveyors across the country to strengthen their ability to focus on patient outcomes. In dialysis facilities, for example, they will focus on the adequacy of dialysis, measuring the condition of beneficiaries relative to established norms. In nursing homes, they will focus on the resident's health and quality of life. The surveyor will identify existing patterns of deficiencies and report them in terms that identify a system failure. The focus on outcomes considerably strengthens external quality-management efforts by giving important information to providers for use in their quality-improvement programs.
- McClellan et al. (1995) describe the Core Indicator Project for ESRD, which reorients HCFA's QA program for renal disease to focus on adequate dialysis, anemia, nutritional status, and blood pressure.
- Jencks (1995) describes the cooperative cardiovascular project, a national PRO project to improve hospital management of acute myocardial infarction. It focuses on outcomes through a set of processes of care that have been well demonstrated to be directly linked to improved outcomes by strong scientific evidence.
- For both HHAs and nursing homes, we are developing quality indicators that focus very heavily on patient outcomes rather than the organization and activities of the provider (Zimmerman et al., 1995; Shaughnessy, 1994).

### Improvement

Traditional QA sought to ensure that all care met standards. HCQIP promotes improvement in care above those standards. As HCFA rewrites conditions of participation, it emphasizes that institutions furnishing Medicare and Medicaid financed services must track and improve their own performances, not simply meet HCFA's standards. In addition, the work of the PROs in cooperative projects, such as the cooperative cardiovascular project and

the ESRD networks Core Indicators Project, establishes a model for furnishing comparative information and technical support to help providers meet these standards. The basic model of these improvement projects is straightforward. It: defines one or more quality indicators; measures current performance to see if there is an opportunity for substantial improvement; supports providers in improving their systems of care; and measures subsequent improvement using the same indicators.

## **PROMOTING QUALITY MEASUREMENT**

The critical tools in promoting quality measurement are quality indicators and data systems to support their application.

### **Indicators**

Indicators are critical to HCQIP because we cannot have a systematic program for improving the quality of health care unless quality can be measured in a systematic way. When HCFA's quality-indicator system is fully developed, it will cover a full range of Medicare services. It will include not only acute care, but also preventive care, chronic conditions, and care provided in the various settings in which HCFA pays for care—hospitals, nursing homes, HHAs, dialysis facilities, and office settings. We are beginning to link indicators so that we can assess care for patients across settings rather than by provider-based episodes. For example, we are studying systems of indicators that can be applied to diabetic patients in a variety of settings.

The indicators are heavily oriented to outcomes or to processes that have been shown to be critical to outcomes, and they are designed to support quality improvement. Thus, part of their importance is organizing data into actionable information for improvement.

## **Data Systems**

A second key tool in quality measurement is improved data systems. We have used hospital records and bills for the inpatient setting; for nursing homes, HCFA has developed a Minimum Data Set (MDS). We are also developing MDSs for use in Medicare home care and by managed-care plans that enroll Medicare and Medicaid beneficiaries. We are beginning a dialogue with employers and managed-care organizations on the data that health plans need in order to assess the quality of care they are providing.

As a major purchaser of care, HCFA will specify its data requirements in various ways, focusing on what data must be reported or delivered. We have no plan to specify internal data systems for providers. Whenever possible, HCFA will make its requirements consistent with those of other purchasers and will work collaboratively with the health care community to enhance standardization.

HCFA's success in this area will depend on the value of the data to the provider. The provider must see the data as an integral component of its larger effort to improve care. The nursing home and HHA MDSs, for example, are designed in collaboration with providers to be useful in routine patient management. Unless the data that HCFA requires can be demonstrated to be useful, data will not be collected and reported reliably and the system will not work. Thus, we will encourage providers to build management systems around the MDSs.

Finally, these same data systems play a vital part in helping us demonstrate the value of quality improvement efforts to beneficiaries, providers, and ourselves, and measure the effectiveness of what we do.

## **INFORM PROVIDERS AND PROMOTE USE OF PRACTICE GUIDELINES**

Indicators turn data into information, and information is power. Providing comparative data to providers can be very valuable to them. We have started to do this with the ESRD core indicator project and within 3 years we will be able to do it for nursing homes nationwide. Furthermore, HCFA will develop a system to provide each nursing home with data about its performance in relation to standards, its peers, and State and national averages. Ultimately, HCFA will provide performance data in relation to benchmarks, to the extent that benchmarks exist.

This approach is already working well in one State. Since the third quarter of 1993, the Vermont Division of Licensing and Protection has provided nursing homes with comparative information on performance indicators each quarter. Each nursing home is able to review its performance on a range of about 40 indicators, compared with the statewide averages for those indicators. The indicators are based on MDS+ data and reflect resident conditions. Prior to 1993, nursing home administrators and staffs had not seen such information. They report finding it useful because it places their performance in a realistic framework. The data encourage them to study their processes of care, when the data indicates performance substantially variant from the statewide average or from what the better performers are achieving. In the 6 quarters for which data is available, trends reflecting improved nursing home care are shown for several of the indicators: development of stage III and IV pressure ulcers, daily use of limb and trunk restraints, use of antidepressants, and development of toileting plans. The nursing homes had a mar-

velous opportunity to improve care, and took it because the State was able to provide useful information to them.

National MDS data collected during this same period of time show no similar positive trend, perhaps because these data were not made available to nursing homes. In July 1995, HCFA will begin providing MDS data to nursing homes. Each home will receive its self-reported data together with the statewide data, thus facilitating comparison.

### **Guidelines**

The pioneering work of Wennberg and Gittelsohn (1982) has led to extensive work directed at developing practice guidelines. There is a rapidly growing knowledge base (American Medical Association, 1994), and we will help providers apply that knowledge. HCFA does not develop guidelines or conduct effectiveness research; it disseminates guidelines, translates them into quality indicators, and will use them as a basis for conditions of participation when appropriate.

We distributed Agency for Health Care Policy and Research guidelines on pain management, pressure ulcer treatment, depression in primary care, and urinary incontinence to nursing homes. We also plan to distribute the Renal Physicians Association's *Clinical Practice Guidelines on the Adequacy of Hemodialysis* to all dialysis facilities.

HCQIP operated by the PROs is currently HCFA's most important, broad-based effort in translating guidelines into indicators. In HCQIP, PROs use Medicare data and professional knowledge to examine processes of care in relation to guidelines, identifying variations that exist, and providing this data to health care providers for their analysis and use. When necessary, PROs help providers in this analysis.

## **INFORM AND EDUCATE BENEFICIARIES**

HCFA seeks to give beneficiaries information that will support more informed personal health choices and more informed choice of providers.

### **Personal Health Choices**

There are a number of activities underway to educate beneficiaries about their own health care. This fall, HCFA will issue a brochure for ESRD patients to help them pose questions concerning the adequacy of their dialysis so they know what to ask their physician and what to ask the caregivers at the dialysis facility. This activity builds on the work previously described on the core indicator project.

Vladeck (1994) describes how HCFA is working to increase the use of preventive services. For example:

- We carried out an influenza immunization promotion campaign targeted at Medicare beneficiaries in 1994 and will extend it in 1995.
- HCFA is also engaged in a screening mammography campaign to increase the use of the Medicare mammography benefit by women.
- Additional topics are being developed and piloted to ensure that the most effective messages and communication approaches are used.

In nursing homes and HHAs, survey procedures place growing emphasis on interviews with residents and clients, and the interviews focus on the resident's understanding of their rights and on quality of life issues. For hospitals, a HCFA task force is rewriting and clarifying the message that every patient gets outlining their rights so that patients will have more effective knowledge.

## **Choice of Provider**

A health care provider not only wants to do a good job, but also wants the public to know it is doing a good job. Little comparative performance information is available to health care consumers. That which is available has been criticized as difficult to understand. We want to change this because informed, educated, discriminating consumers will make more appropriate choices about some aspects of their care and their providers. If we can inform and educate beneficiaries, we will be serving the community well and will be enhancing both internal and external quality improvement efforts. We will focus our efforts on real choices that consumers are able to make in a considered way. For example, consumers can't usually choose their hospital for emergency treatment, but otherwise can choose between several managed-care plans or nursing homes.

HCFA is pursuing several initiatives in this area. In managed care, we plan to build on private sector efforts. The National Committee on Quality Assurance (NCQA) has developed the Health Plan and Employer Data Information System (HEDIS) for use by health plans to provide key performance information. As described by Armstead, Elstein, and Gorman (1995), HCFA and NCQA are developing a Medicaid version of HEDIS, which builds on the original HEDIS. A Medicare HEDIS is under discussion. We decided to build on the private sector HEDIS because the proliferation of information requirements runs the danger of unnecessarily burdening providers and of confusing the consumers they are intended to inform.

Within a few years, we expect to be able to report the characteristics and key performance of nursing homes, thus facilitating consumer comparison among facilities. This effort will present a number of

challenges, because we will have to compare nursing homes in ways that take into account the differences in caring for residents with varying levels of need. While these comparisons will be complex, and presenting them clearly will also be complex, the information should be valuable to consumers and their families.

## **ESTABLISH AND ENFORCE STANDARDS**

Establishing and enforcing standards is the bedrock on which beneficiary protection is based.

### **Establishing Standards**

As a major purchaser of health care services, HCFA has an obligation to protect beneficiaries from poor care, and as a purchaser for vulnerable populations it must act aggressively. As the primary purchaser for several types of care—nursing home care, dialysis, home health care—HCFA effectively establishes and enforces standards for the community. This community-wide impact is the reason we establish requirements through public notice with fair opportunity for comment.

HCFA's goal is to limit its requirements to those that tie to outcomes in one of three ways:

- Directly (we measure the outcome).
- Through critical processes (we measure a process that is known to produce a desired outcome).
- Through physical or organizational structures that are strongly believed to support outcomes that cannot reasonably be measured.

A recent example of the powerful positive effect that standards can have on care is the dramatic reduction in the use of physical restraints in nursing homes following

the publication of new nursing home standards in 1992. The standards state that "the resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms" (Code of Federal Regulations, 1991). In 1989, restraints were used to physically hold 4 in 10 nursing home residents; today restraint use hovers around 20 percent. This reduction is the result of new societal expectations embodied in the law and conditions of participation, providers' understanding the need to meet expectations, education on alternatives to the use of restraints, and consistent enforcement of the standard.

The restraint rules also illustrate the evolving character of standards. As we develop better understanding of successful strategies, what was once impractical becomes practical and our expectations and standards rise. We believe that we can promote continuing reduction in the use of restraints in coming years through a dual strategy of strengthening and enforcing standards and promoting internal quality-improvement activities.

### **Enforcement**

Enforcement comes last in HCQIP because, while enforcement is one of HCFA's most critical responsibilities, the need for an enforcement action means that other strategies have failed. Enforcement has two purposes: to protect beneficiaries against continuing substandard care and to ensure that skimping care for our beneficiaries is not profitable to providers. Consistent with our role as a purchaser of care, our basic enforcement action terminates Medicare and Medicaid program participation. In recently acquired authority, HCFA may also impose monetary penalties in clinical laboratories and nursing homes



and, when residents are at immediate risk in nursing homes, may require specific actions to improve care (Omnibus Budget Reconciliation Act of 1987, Public Law 100-203; CLIA, 1988).

In fulfilling its responsibilities, HCFA, when possible, gives providers who are not meeting health and safety standards opportunities to improve. Nevertheless, the inspection process and the enforcement of sanctions are key parts of HCFA's HCQIP. The challenge is to administer this part of the program fairly, efficiently, effectively, and in support of the provider's own quality-improvement efforts.

## SUMMARY

HCQIP is an approach to improving outcomes for HCFA beneficiaries through measurement, improvement projects, information dissemination, and enforcement. The fundamental theme is working in partnership with providers and beneficiaries and improving quality by supporting internal quality assurance and quality improvement efforts—strengthening and, in some cases, developing for the first time, purchaser/supplier relationships. We are integrating our conditions of participation, our cooperative projects, our survey methods, and our outreach to consumers.

## ACKNOWLEDGMENTS

The approach to HCFA's quality-management programs described in this article is the product of many HCFA staff members and reflects the input of numerous provider and consumer advocates, as well as the PROs, ESRD networks, and survey and certification agencies. This article benefited greatly from the contributions of Harvey Brook, Steve Jencks, Michael McMullan, and Tony Tirone, all of the Health Standards and Quality Bureau, HCFA.

## REFERENCES

- Armstead, R., Elstein, P., and Gorman, J.: Toward a 21st Century Quality-Measurement System for Managed-Care Organizations. *Health Care Financing Review* 16(4):25-37, Summer 1995.
- Code of Federal Regulations: Public Health. Title 42, Part 483.13 [a]. *Resident Behavior and Facility Practices*. Office of the Federal Register, National Archives and Records Administration. Washington, DC. U.S. Government Printing Office, September 26, 1991.
- American Medical Association: *Directory of Practice Parameters: Titles, Sources, and Updates, 1994 Edition*. Chicago. 1994.
- Institute of Medicine, Committee on Nursing Home Regulation: *Improving the Quality of Care in Nursing Homes*. Washington, DC. National Academy Press, 1986.
- Jencks, S.F.: Measuring Quality of Care Under Medicare and Medicaid. *Health Care Financing Review* 16(4):39-54, Summer 1995.
- Lohr, K., ed.: *Medicare: A Strategy for Quality Assurance*. Washington, DC. Institute of Medicine, Division of Health Care Services, National Academy Press, 1990.
- McClellan, W.M., Frederick, P.R., Helgerson, S.D., et al.: A Data-Driven Approach to Improving the Care of In-Center Hemodialysis Patients. *Health Care Financing Review* 16(4):129-140, Summer 1995.
- Shaughnessy, P.W.: Measuring and Assuring the Quality of Home Health Care. *Health Care Financing Review* 16(1):35-69, Fall 1994.
- Vladeck, B.C.: From the Health Care Financing Administration, The Consumer Information Strategy. *Journal of the American Medical Association* 272(3):196, July 20, 1994.
- Wennberg, J., and Gittelsohn, A.: Variations in Medical Care Among Small Areas. *Scientific American* 246:120-135, 1982.
- Zimmerman, D.R., Karon, S.L., Arling, G. et al.: Development and Testing of Nursing Home Quality Indicators. *Health Care Financing Review* 16(4):107-128, July 1995.

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