The "Why" of Conditions of Participation in the Medicare Program

JOHN W. CASHMAN, M.D., PEARL BIERMAN, M.A., and BEVERLEE A. MYERS, M.P.H.

Medicare's Effects on Medical Care

THE MEDICARE LAW authorizes the Secretary of Health, Education, and Welfare to establish conditions of participation for hospitals, extended care facilities, home health agencies, and independent laboratories. The statute defines each of these providers of services and, in addition, states that they must "meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution."

Standards, whether for licensure, accreditation, or Medicare certification, are definitions of (*a*) the services that should be available in a specific type of health care facility or program, (*b*) the professional personnel who should provide the services, including their qualifications and numbers adequate for patient loads, (*c*) how personnel should be organized to provide the services and maintain quality controls (for example, medical staff committees and bylaws in a hospital), (*d*) the policies and administrative organization and procedures that facilities should have, (*e*) required equipment and physical facilities for and definitions of adequate safety, cleanliness, and sanitation, and (*f*) definitions of other areas of importance to health and safety, such as dietary service, drugs, and medical records.

Thus, standards serve as indicators of the level of quality of medical care an institution or service program is capable of providing.

The authors are with the Division of Medical Care Administration, Health Services and Mental Health Administration, Public Health Service. Dr. Cashman, Assistant Surgeon General, is director of the division. Miss Bierman is chief, Policy and Standards Branch. Mrs. Myers is special assistant to the chief, Health Services Organization Branch.

The paper is adapted from a speech Miss Bierman gave at the Federal Bar Association Briefing Conference on Medicare on April 20, 1967, held in Washington, D.C.

History of Hospital Standards

Although some States were pioneers in standard setting, widespread application of standards through State or local licensing is relatively recent and has been largely limited to care given in institutions. It has developed substantially over the past 20 years under the stimulus of the Hill-Burton Hospital Planning and Construction Program.

However, as early as 1916, the American College of Surgeons undertook its first quality survey of hospitals in the United States and Canada. At that time, there were less than 700 hospitals in the two countries with 100 beds or more and 2,000 with 25–99 beds. The criteria employed in that first survey, and its findings, were never published and have not been preserved in the files of the American College of Surgeons. It is known, however, that only 89

of the 700 hospitals with more than 100 beds could meet any reasonable standards of that time, and it has been said that the facts elicited from the first survey were so shocking that the survey committee ordered the individual survey reports destroyed forthwith.

Subsequently, the American College of Surgeons adopted a watered-down version of the quality survey activity which had as objectives, "first, to define a Minimum Standard, second, to enlist the cooperation of the hospitals in the fulfillment of the Standard, this work to be accomplished through personal visits to the hospitals by staff members of the College, and third, to publish from time to time the list of hospitals throughout the two countries (Canada and the United States) which fulfilled the Minimum Standard" (*1*).

The list was not to be published, however, until the hospitals themselves generally approved of such publication and each hospital had been given full opportunity to meet the standard under normal conditions. The Minimum Standard Program of the American College of Surgeons continued until the early 1950's, when functions of professional accreditation of hospitals were taken over by the Joint Commission on Accreditation of Hospitals (JCAH).

Accreditation programs, such as JCAH's, State licensure programs, and Medicare with its conditions of participation, have as basic objectives measurement of the capacity to provide at least minimum levels of quality of medical care and assistance to the providers to maintain and improve their ability to achieve even better levels of quality of care.

In recent years, licensure and accreditation standards have been given a legal function by the courts, which have ruled that State licensing regulations, together with accreditation standards and hospital medical staff bylaws, may be introduced into evidence and considered by the jury in determining whether a hospital has breached duties owed to the patient. It has been ruled, for example, that the standards perform the same function as evidence of custom and may result in denying the defense that the attending physician was an independent contractor. The effect of these decisions is to give further legal support to the standard-setting activities of both regulatory and professional organizations and to state that the hospital has a direct duty to the patient to provide medical services consistent with regulatory and professionally accepted standards (*2*).

In the Medicare program at least four questions underly the definition and application of standards:

1. What is the justification for establishing standards controlling quality in this public program?
2. What is the justification for giving a private organization such as the Joint Commission on Accreditation of Hospitals, which is not accountable to the public, authority to make determinations that institutions qualify for a public program?
3. How high can standards be set in a national program?
4. Can the desire for high quality be balanced against a need to have services available?

Justification for Establishing Standards

As mentioned previously, there is a statutory base for establishing the conditions of participation in Medicare. In fact, with Medicare, for the first time specific statutory authority was established to define and apply national standards in a Federal program to assure the quality of medical care purchased for beneficiaries. Other Federal or Federal-State medical care statutes have either been silent on such authority or have specifically denied the administrative agency authority to control quality. For example, the program of medical care for dependents of military personnel—the first Medicare—was authorized to purchase care for these dependents from private hospitals which were to be reimbursed through contracts made by the Secretary of Defense. The Department of Defense Medicare program is administered under contract with Blue Cross and private insurance companies, similar in some respects to the Medicare intermediary relationship. However, the military dependents Medicare program lacks provisions like those in the health insurance for the aged program which authorize the administrative agency to define quality standards, even though the program is national in scope and serves Federal beneficiaries.

Under the Federal-State programs of public

assistance, where medical care may be included, authority is provided for the States to set standards, but the Federal Government has such authority in very limited degree.

Some have suggested that Medicare should have followed these precedents: that there should have been no statutory base for quality control or that the statutory base has been interpreted too broadly and thus the regulatory conditions of participation conflict with that section of the law that prohibits Federal supervision or control over the practice of medicine. There are arguments that the purpose of Medicare is simply to purchase for the aged certain kinds of medical services that are available to the population in general, and therefore assurance of standards through State licensure programs should be sufficient. Some argue that the only justification for discriminating among eligible providers should be to use only those that can provide the services at the cheapest price. In another vein, it has been said that, since it is not the stated purpose of the law to give Government responsibility to use its purchasing power to upgrade and improve medical services generally, then the services available to the beneficiary population should be no different than those available to the general population.

However, the Congress did see fit to authorize quality controls, and in the long history of the legislation are clues to why Congress felt this authorization was justified. As early as the 1950's when health insurance proposals of various kinds were under consideration, a report prepared by the Department of Health, Education, and Welfare at the request of the House Ways and Means Committee suggested that, with such a vast program proposed, the question was not whether there would be controls of the individual hospital and the quality of care furnished but whether there should be uniform Federal standards or reliance on State controls, with or without the upgrading required to meet at least minimum Federal conditions (*3*).

In the end, the Congress chose to authorize uniform national standards as a minimum and to require the Secretary to use State agencies where possible to certify that providers met and continued to meet the conditions. Congressional committee reports were quite specific that the intent was to pay only for medical services that met professionally acceptable standards. In effect, Congress insisted that if reasonable costs were to be paid to providers, then reasonable services must be rendered. The principle established by this authorization is perhaps one of the most significant aspects of the legislation from the point of view of medical care administration and the benefit that accrues from it for the population generally.

Giving JCAH Public Responsibility

If the rationale and need for uniform national standards in a program of this scope are accepted, the next question is who should have responsibility for establishing standards? As mentioned, responsibility was given to the Secretary of Health, Education, and Welfare, and also to a private organization, the Joint Commission on Accreditation of Hospitals. The law specifically provides that hospitals accredited by the JCAH shall be deemed to meet all conditions of participation except for the special requirement for utilization review. In addition, Congress stated that the Secretary could not establish conditions of participation higher than those of the JCAH.

That action raises the issue, not of whether to use private organizations to assist in administering a public program, but of how much authority and responsibility should be delegated to organizations that cannot be held accountable to the public. The action seems to carry out the basic intent of Congress that Medicare should purchase only care that meets professionally accepted standards. The joint commission, going back through its predecessor organization to the early part of the century, is clearly accepted as the professional leader in hospital standard setting. The commission itself describes its present standards as the minimum necessary to assure acceptable quality, and it is currently planning to upgrade its hospital standards.

Setting National Standards

How high can standards be set in a national program? The Department of Health, Education, and Welfare turned first to the legislative history for an indication of intent. Congress thought of extended care facilities as satisfying "a number of conditions necessary for an insti-

tutional setting in which high-quality convalescent care and rehabilitation care can be furnished" (*4*, *5*). The sense of active treatment implied by these words contrasts markedly with the custodial care given in so many nursing homes. In its discussion of home health agencies, the Congress was not as detailed with respect to the level of quality, perhaps because there had never been a serious public concern about the quality of care in these programs. When authorization for standard setting for laboratories was added to the bill, somewhat far along in the legislative process, the Senate Finance Committee cited a need for assurance of acceptable quality in laboratory services.

There was not, therefore, a great deal of specific guidance from Congress on the level of the standards to be set, although the desire for quality was evident. The administrators turned then to professional leaders. The Public Health Service was delegated responsibility to develop the conditions of participation, in cooperation with the Social Security Administration. In addition, many hundreds of knowledgeable persons participated as consultants in standards development. Obviously, all the advice offered could not be accepted, since it varied. In general, however, when unanimity was not achieved, program decisions were usually based on a consensus or majority opinion.

Medicare offered the opportunity to define national standards for four different classes of providers of services, and there was an opportunity to break new ground with at least three classes. The ceiling for hospital standards was spelled out in the law as being the requirements of the Joint Commission on Accreditation of Hospitals, and an administrative decision was made that these would also be the floor. There was no statutory accreditation floor or ceiling, however, with respect to standards for extended care facilities, home health agencies, or independent laboratories, and indeed very little in the way of licensing or accreditation standards to serve as guidelines for the home health agencies or the laboratories.

With the home health agencies, standard setting was compounded by the fact that relatively few agencies existed. The principal difficulty was to set standards initially at a level which would encourage the organization and participation of new agencies and at the same time encourage the rare hospital-based or community-based comprehensive home care program. This aim was difficult to achieve with one set of standards applicable to all home health agencies. In the future it may be possible to experiment with different standards for different kinds of agencies.

With extended care facilities, there was a unique problem since Congress, by coining the term, had conceived of an entirely new kind of institution. An extended care facility is neither a hospital nor a nursing home but is somewhere in-between, since the benefits were designed to provide an extension of hospital care, not the usual long term care. All licensing programs and the embryonic accreditation programs that existed before Medicare were directed to the usual nursing home, and these were used, therefore, only as a floor.

The development of standards for independent laboratories has been the most controversial standard-setting activity in Medicare. Currently thousands of laboratories throughout the nation serve their communities, make profits in most instances, and rarely encounter any control over their activities. A very small number of States have licensure laws for clinical laboratories or laboratory personnel, yet all studies indicate a serious need for standards. The sudden challenge of Federal standards was extremely threatening, and our problems with the laboratories are not yet fully resolved.

Balancing Quality and Availability

With respect to the final basic issue—that of balancing the desire for high quality against a need to have services available—we in the Department of Health, Education, and Welfare were keenly aware that any public program has a responsibility for administration which results in the promised benefits being adequately delivered. In a contributory health insurance program, this responsibility is even greater, because all but a small number of beneficiaries have contributed to the cost of their care. All have a statutory right to specific benefits. But the lack of certain health services and of health manpower, deficiencies outside the control of Medicare, prevents the benefits from being universally available. The availability of services,

however, can be ameliorated according to the level at which standards are set.

Both licensure and accreditation programs have faced the quality-availability dichotomy by using provisional licenses or 1-year accreditation to allow time for institutions to correct deficiencies. The expedient solution in Medicare was the concept of "substantial compliance," so that hospitals and other providers of service can be certified for participation even though they have significant deficiencies with respect to one or more standards. To be certified as being in substantial compliance in the presence of significant deficiencies, the provider must be in general conformity with the initial statement of each condition and must develop an adequate plan to correct the deficiencies. Furthermore, the deficiencies themselves must not be in statutory requirements or be so serious as to interfere with adequate care or represent hazards to health and safety. If a provider so certified does not make adequate efforts to correct the deficiencies, certification is withdrawn.

The Department did not, however, stop with the concept of substantial compliance. A special certification category was introduced. State agencies were permitted to certify, for a limited period, providers that could not be found in substantial compliance with the conditions of participation, but "where by reason of isolated location or absence of sufficient facilities in an area, the denial of eligibility of an institution to participate would seriously limit the access of beneficiaries to participating institutions. . . ." In this special certification category are many of the small isolated hospitals with minimal nursing services, one or two physicians on the staff, and few, if any, specialized services.

The Department is analyzing the overall experience in the application of the standards, and we hope to reach some objective judgments as to the validity and pertinence of our approach to balancing quality against availability.

Conclusion

In the first year of Medicare, the interpretation and application of standards has been uneven. The standards will need evaluation and revision during the coming years. It is true, however, that they have had an upgrading effect in many places, that they have stimulated improvement or initiation of several voluntary accreditation programs, and that the Medicare program has caused changes, even though indirect and involuntary, in the manner in which medical services are provided to the entire population and in the operation and administration of medical facilities and personnel. In the years ahead, this effect will become ever more apparent as institutions and agencies continue to strive to comply with the program's requirements.

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