

THE PATIENTS' BILL OF RIGHTS IN MEDICARE AND MEDICAID

Overview: *On March 26, 1997, President Clinton created the Advisory Commission on Consumer Protection and Quality in the Health Care Industry and charged it with recommend[ing] such measures as may be necessary to promote and assure health care quality and value and protect consumers and workers in the health care system." As part of that charge, the President asked the Commission to develop a "Patients' Bill of Rights" in health care.*

In February 1998, President Clinton directed the Department of Health and Human Services (HHS), along with the departments of Labor, Defense, and Veterans' Affairs and the Office of Personnel Management, to use their regulatory and administrative authority to bring their health programs into compliance with the Bill of Rights and Responsibilities.

HHS' Health Care Financing Administration (HCFA) has begun the work to establish new requirements for managed care plans participating in the Medicare program. It is also working to strengthen protections for beneficiaries enrolled in Medicaid managed care. In November 1998, HHS issued a report to the Vice President showing that it is moving aggressively to strengthen existing patient protections under Medicare and Medicaid.

When these regulations are fully implemented, Medicare and Medicaid will have among the strongest patients' protections in the country. The proposed regulations give HHS a variety of monitoring and enforcement tools, including suspension of payments, civil monetary penalties, and termination from the Medicare and Medicaid programs.

BACKGROUND: THE PRESIDENT'S ADVISORY COMMISSION ON CONSUMER PROTECTION AND QUALITY IN THE HEALTH CARE INDUSTRY AND THE PATIENTS' BILL OF RIGHTS

In November 1997, President Clinton's Advisory Commission on Consumer Protection and Quality on the Health Care Industry, in an Interim Report, issued the Patients' Bill of Rights and Responsibilities. The Commission's Final Report, "Quality First: Better Health Care for All Americans," was issued in March 1998.

Co-Chaired by Secretary of Health and Human Services Donna E. Shalala and Secretary of Labor Alexis M. Herman, the Commission had 34 members, including broad-based representation from consumers, businesses, labor, health care providers, health plans, and health care quality and financing experts.

The Patients' Bill of Rights and Responsibilities has three goals: to strengthen consumer confidence that the health care system is fair and responsive to consumer

needs; to reaffirm the importance of a strong relationship between patients and their health care providers; and to reaffirm the critical role consumers play in safeguarding their own health. The Commission articulated seven sets of rights and one set of responsibilities:

- **The Right to Information.** Patients have the right to receive accurate, easily understood information to assist them in making informed decisions about their health plans, facilities and professionals.
- **The Right to Choose.** Patients have the right to a choice of health care providers that is sufficient to assure access to appropriate high-quality health care including giving women access to qualified specialists such as obstetrician-gynecologists and giving patients with serious medical conditions and chronic illnesses access to specialists.
- **Access to Emergency Services.** Patients have the right to access emergency health services when and where the need arises. Health plans should provide payment when a patient presents himself/herself to any emergency department with acute symptoms of sufficient severity "including severe pain" that a "prudent layperson" could reasonably expect the absence of medical attention to result in placing that consumer's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.
- **Being a Full Partner in Health Care Decisions.** Patients have the right to fully participate in all decisions related to their health care. Consumers who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators. Additionally, provider contracts should not contain any so-called "gag clauses" that restrict health professionals' ability to discuss and advise patients on medically necessary treatment options.
- **Care Without Discrimination.** Patients have the right to considerate, respectful care from all members of the health care industry at all times and under all circumstances. Patients must not be discriminated against in the marketing or enrollment or in the provision of health care services, consistent with the benefits covered in their policy and/or as required by law, based on race, ethnicity, national origin, religion, sex, age, current or anticipated mental or physical disability, sexual orientation, genetic information, or source of payment.
- **The Right to Privacy.** Patients have the right to communicate with health care providers in confidence and to have the confidentiality of their individually-identifiable health care information protected. Patients also have the right to review and copy their own medical records and request amendments to their records.

- **The Right to Speedy Complaint Resolution.** Patients have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.
- **Taking on New Responsibilities.** In a health care system that affords patients rights and protections, patients must also take greater responsibility for maintaining good health.

MEDICARE AND MEDICAID COMPLIANCE WITH THE PATIENTS' BILL OF RIGHTS

While many of the protections articulated in the Bill of Rights are most relevant to individuals in managed care, such as those related to choice of providers and access to specialists, other protections such as complaints and appeals apply to beneficiaries not enrolled in managed care.

Medicare covers nearly 40 million individuals, of whom approximately 6.5 million, or 17 percent are currently enrolled in managed care arrangements. Medicaid covers an estimated 40 million people, of whom about half are in a managed care arrangement for some or all of their health care at some point during a year.

HHS has moved aggressively to strengthen existing patient protections under Medicare and Medicaid. On June 26, 1998, the Health Care Financing Administration (HCFA) published an Interim Final rule establishing new requirements for managed care arrangements participating in Medicare. On September 29, 1998, HCFA published a Notice of Proposed Rulemaking (NPRM) strengthening protections for Medicaid beneficiaries enrolled in managed care arrangements. Generally, the Medicare protections became effective on or before January 1, 1999, and will be fully implemented by no later than December 31, 1999. States will be required to implement all new protections within one year from the effective date of the final regulation for Medicaid, which is expected to be issued by mid-1999.

When these regulations are fully implemented, Medicare and Medicaid will have among the strongest patients' protections in the country. Specifically, HHS has been able to come into compliance for managed care enrollees with critical patient protections such as information disclosure, access to emergency services, patient participation in treatment decisions, and complaints and appeals. These regulations also expand patients' ability to choose their health care providers and to have ready access to specialists.

In a few areas, however, both Medicare and Medicaid currently lack the statutory authority to achieve full compliance with the Patients' Bill of Rights. For example, current legislative authority also does not permit full implementation of the right to medical record confidentiality. HHS has, however, separately submitted a report to

the Congress laying out the parameters for federal legislation to protect the confidentiality of health records. Additionally, while Medicare and Medicaid managed care enrollees are currently protected to the full extent of the Patients' Bill of Rights with regard to respect and non-discrimination, the rules that prohibit discrimination under fee-for-service address some, but not all, categories of protection and providers included in the right as recommended by the Commission.

The proposed regulations give HHS a variety of monitoring and enforcement tools including suspension of payments, civil money penalties, and termination from the Medicare and Medicaid programs. HHS will take all necessary actions to enforce the protections included in the Medicare and Medicaid regulations.

Specific Rights

Information Disclosure. Under proposed regulations, Medicare and Medicaid will require plans to provide critical information to consumers, both annually and upon request, that will enable them to make more informed choices about their health plans. Medicare's web site, www.medicare.gov, offers the "Medicare Compare" database to help beneficiaries evaluate different plans and decide which options are best, including comparative information about the quality of care provided to patients and about the level of satisfaction among patients with the care that they receive.

Choice of Providers and Plans. The Interim Final rule for Medicare and the proposed Medicaid managed care regulations assure provider network adequacy, by requiring that medically necessary services be available 24 hours a day, 7 days a week to enrollees. The Interim Final rule and the proposed rule also reflect the recommendations of the Commission by requiring that participating plans offer women access to qualified women's health specialists for routine preventive care, and provide consumers with complex or serious medical conditions an adequate number of direct access visits to specialists under a plan of treatment. As has been the case since the start of these programs, Medicare and Medicaid beneficiaries who obtain their care on a fee-for-service basis can choose any provider who agrees to participate in these programs.

Access to Emergency Services. The Interim Final rule for Medicare and the proposed regulations for Medicaid guarantee that emergency services will be covered when and where the need arises, in exact compliance with the Patients' Bill of Rights. Plans would not be permitted to require preauthorization in order for an enrollee to obtain emergency services. In addition, the regulations articulate a standard for post-stabilization services that is applicable to both Medicare and Medicaid managed care enrollees. This policy identifies the obligation of the plan to pay for care provided after an emergency situation is stabilized, particularly when the plan fails to authorize such care on a timely basis.

Participation in Treatment Decisions. The Interim Final rule for Medicare and the NPRM for Medicaid reflect existing and new policies that are consistent with this right, including information about treatment options and advance directives, physicians' financial disclosure and prohibition against "gag rules." Health plans will be required to provide patients with easily understood information and the opportunity to decide among all treatment options--including no treatment--consistent with the informed consent process. Managed care organizations and providers are required to discuss the use of advance directives, or "living wills" with patients and their families and to abide by the wishes as expressed in an advanced directive, except where state law permits a provider to conscientiously object. Physicians are required to disclose to Medicare and Medicaid any financial arrangements that create incentives for limiting care. Plans are prohibited from penalizing or otherwise restricting the ability of health care providers to communicate with and advise Medicare and Medicaid patients about medically-necessary treatment options.

Respect and Nondiscrimination. Under the Interim Final rule for Medicare and the proposed regulations for Medicaid, managed care enrollees are protected to the full extent of this right as articulated in the Bill of Rights, with regard to services, marketing and enrollment. Under fee-for-service, however, Medicare and Medicaid protections against discrimination are largely a function of federal anti-discrimination rules that apply to recipients of federal funds. These rules address some, but not all, categories of protection and providers included in the Bill of Rights. As a result, the fee-for-service aspects of Medicare and Medicaid are in only partial compliance with this right.

Confidentiality of Health Information. The Interim Final regulations for Medicare and the proposed regulations for Medicaid require Medicare+Choice and Medicaid health plans to safeguard the privacy of any information that identifies a particular enrollee by ensuring that information from the plan (or copies of records) be released only to authorized individuals, that unauthorized individuals cannot gain access to or alter patient records, and that original medical records must be released only in accordance with federal or state law, court orders or subpoenas. In Medicaid, plans are required to establish procedures to address the confidentiality and privacy of minors, subject to applicable federal and state law.

While current federal laws and related regulations protect certain written records from disclosure outside of Medicare and Medicaid, such protections do not extend to all written records, nor to verbal communications between enrollees and providers. Protection of communication between patients and providers is a matter of state law, many of which do not afford the protections included in this right. Moreover, not all providers under Medicare and Medicaid are subject to federal laws on privacy. The Secretary's Privacy Recommendations to Congress (September 1997), if enacted, would bring all beneficiary information obtained by Medicare and Medicaid providers

and plans, as well as the programs and their contractors, into compliance with this right as articulated in the Bill of Rights.

Complaints and Appeals. The Interim Final rule for Medicare and the proposed regulations for Medicaid managed care require establishment of meaningful processes for resolution of complaints and appeals. Similar processes already exist for resolution of disputes arising in fee-for-service settings.

Internal Appeals. Both the Interim Final rule for Medicare and the NPRM for Medicaid define rigorous standards for the establishment of internal (plan-level) appeal processes, with explicit timeframes for both prior authorizations and resolution of appeals at the plan level. Both the Medicare and Medicaid regulations establish a process for expedited review of prior authorizations and resolution of appeals by plans in emergency or urgent care situations. Extensions for both the standard and expedited timeframes are possible only under limited circumstances.

External Appeals. The Bill of Rights proposes that an appeal process include an independent system of external review, in order to ensure its fairness and accuracy. Medicare has long had this protection which includes a provision for expedited decisions in time-sensitive areas. Individuals who are dissatisfied with the determination of the independent external review entity have the right to pursue their claim for Medicare benefits further through an administrative review, including review by the Departmental Appeals Board and, ultimately, federal court.

The appeals process for Medicaid, as articulated in the NPRM, differs from the Bill of Rights in two significant ways. The Bill of Rights calls for the establishment of a sequential process of internal (plan-level) and external review. Under the proposed rule, however, states would be permitted to design their appeals systems so that individuals would appeal either sequentially or simultaneously to the state's fair hearing process, which otherwise serves as the independent external review entity. Second, the state fair hearing process, which serves a docket of programs and issues much broader than Medicaid managed care, currently has timeframes that are not consistent with the timeframes established by the NPRM for internal review by Medicaid managed care plans; in addition, there is no provision for expedited review.