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# HEALTHY PEOPLE 2010

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**Understanding and  
Improving Health**

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REPORT TO THE SECRETARY  
TASK FORCE ON BLOOD SAFETY

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## INTRODUCTION

In July, 1993, at the request of Senators Kennedy and Graham and Representative Goss, Secretary Donna Shalala asked the Institute of Medicine (IOM) to review the events of the early 1980s, relating to the transfusion of HIV through blood products to more than half of the 16,000 hemophiliacs in the U.S. While recognizing that the blood supply in the United States is among the safest in the world, the Secretary believed that the results of such a study could be helpful in strengthening capacities to ensure the safety of the Nation's blood supply against new challenges in the future. The IOM convened an expert panel, which released its report on July 13, 1995.

Consistent with the HHS request, the panel did not review the existing blood safety program or the current safety of the blood supply, but rather, studied the events and public health organizational and decision-making structures of the early 1980s as they affected blood safety. Based upon this historical review, the panel developed 14 recommendations "that might have moderated some of the effects of the AIDS epidemic," and urged government and private organizations responsible for blood safety "to evaluate their current policies and procedures to see if they fully address the issues raised" by the recommendations. To conduct such an evaluation, including an overall review of HHS blood safety activities, Secretary Shalala appointed this Task Force.

After reviewing the IOM recommendations in the context of the existing blood safety system, the Task Force concluded that most of the recommendations had been addressed by improvements introduced since the mid-1980s. In light of the goals embodied in the IOM recommendations, however, the Task Force identified aspects of the Department's organizational structure surrounding blood safety decision making that could be strengthened. The proposed improvements involve broadening the formal avenues of advice available to FDA for certain decisions and improving high-level coordination among PHS agencies on blood safety issues. The Task Force also agreed with the IOM that FDA needs better information on blood availability and supply issues, but believed more study would be necessary before proposals could be made in that regard.

The Task Force's comments and recommendations follow the format of the IOM recommendations 1-14. In preparing this report, the Task Force met with representatives of a variety of organizations interested in blood safety issues. The Task Force believes that the report fully addresses the issues raised in the IOM report, and contains proposals that will further improve the safety of the U.S. blood supply.

Recommendation 1:

The Secretary of Health and Human Services should designate a Blood Safety Director, at the level of a deputy assistant secretary or higher, to be responsible for the federal government's efforts to maintain the safety of the nation's blood supply.

The Task Force recommends that the Secretary designate the Assistant Secretary for Health to serve as the Blood Safety Director. The Task Force notes that the Assistant Secretary for Health has been broadly responsible for coordination and oversight of the blood safety program among the many responsibilities of this position; however, the Task Force believes it would be valuable to support and enhance this important function by clearly highlighting this responsibility within the Department's administrative structure. The Blood Safety Director would be responsible for coordination and oversight of the overall blood safety program of DHHS, and would serve as Chair of the Blood Safety Committee (see Recommendation #2). The Blood Safety Director would periodically report to the Secretary on issues of importance regarding blood safety and availability.

The Assistant Secretary for Health brings accountability at a senior level within the Department, and extensive professional experience and administrative expertise in coordinating interagency issues. Established working relationships between the Assistant Secretary for Health and PHS agencies around blood safety issues would facilitate quick implementation of the goals of this recommendation.

Recommendation 2:

The PHS should establish a Blood Safety Council to assess current and potential future threats to the blood supply, to propose strategies for overcoming these threats, to evaluate the response of the Public Health Service to these proposals, and to monitor the implementation of these strategies. The Council should report to the Blood Safety Director (see Recommendation 1). The Council should also serve to alert scientists about the needs and opportunities for research to maximize the safety of blood and blood products. The Blood Safety Council should take the lead to ensure the education of public health officials, clinicians, and the public about the nature of threats to our nation's blood supply and the public health strategies for dealing with these threats.

Prior to the organizational changes now pending within the Department, the Assistant Secretary for Health had general responsibility for coordination and oversight of the Department's overall blood safety program, with the FDA Commissioner as the final decision maker on all regulatory matters. Surveillance efforts have been led by CDC and research on blood and blood products has been shared by the NIH, FDA and CDC. An interagency group, with representatives of FDA, CDC, NIH, HRSA, and the Department of Defense, constitutes the Public Health Service Interagency Working Group on Blood Safety and Availability. This group meets monthly by conference call. The conference call is an effective mechanism for sharing information and coordinating activities among the various government agencies involved in blood safety issues. Each agency is represented on the Working Group by public health officials with expertise in these issues.

FDA receives outside advice through its Blood Products Advisory Committee (BPAC), a scientific advisory group that includes representatives from interest groups in the blood safety arena. Outside groups also communicate informally with FDA and the other agencies, all of which maintain ongoing relationships with interested outside groups, including some formal liaisons.

While this arrangement has worked well and helped produce one of the safest blood supplies in the world, the goals embodied in the IOM's first two recommendations could be furthered by certain changes.

First, the Task Force recommends the formation of a PHS Blood Safety Committee, chaired by the Blood Safety Director and made up of the FDA Commissioner, the CDC Director, and the NIH Director, with the Public Health Service Interagency Working Group on Blood Safety and Availability reporting to this committee.

Under the Department's new organizational structure, the Public Health Services agencies will not routinely report to the Assistant Secretary for Health. The PHS Blood Safety Committee, with the Assistant Secretary for Health as its chair, will ensure the necessary coordination of policy and actions by the PHS agencies.

The PHS Blood Safety Committee would strengthen the interagency efforts that constitute the PHS blood safety program. Currently, the monthly interagency conference calls provide an effective forum for communication of information and ideas between PHS agencies. The Task Force believes it is important to create a forum for decision-making, priority setting, and high-level interagency coordination on key issues. The Blood Safety Committee would accomplish this.

The PHS Blood Safety Committee would meet several times each year on a scheduled basis, and would also meet at the request of any individual member, to accommodate quick action on priority issues. It would consider issues arising out of the monthly PHS Interagency Working Group on Blood Safety and Availability conference calls, assure that issues raised there were addressed, and allow for high-level, expeditious, interagency action on such issues where appropriate. The Interagency Working Group would routinely provide a report of the proceedings of this Group to the Chair of the Blood Safety Committee.

The Blood Safety Committee would serve the following functions outlined by the IOM in Recommendation 2: assessing threats to the blood supply, proposing strategies to address these, and evaluating the implementation and effectiveness of these strategies over time. Primary responsibility for identifying research needs and opportunities and conveying these to the scientific community would continue to remain with individual agencies. However, the Blood Safety Committee would ensure that new research questions regarding blood safety (such as emerging infectious agents) and availability raised by the PHS Interagency Working Group or the PHS Advisory Council on Blood Safety and Availability (see following page) are directed to the appropriate agencies for further exploration.

The Department would continue to carry out the responsibility for communicating information about risks in the blood supply to the public.

The Task Force believes that the functions outlined by the IOM for the Blood Safety Council are governmental functions that should be performed by the Department, not by outside private parties. The Task Force makes the following recommendation to address the important role and contributions of those outside of government.

**Second, a PHS Advisory Council on Blood Safety and Availability representing the range of interests in the blood safety area, including industry, consumers, and ethicists, should be appointed to advise the Committee.**

As demonstrated by the events of the 1980s, decisions concerning blood safety may implicate basic societal values or highly politicized public health issues. Currently, HHS receives advice on blood safety and availability through the FDA's Blood Products Advisory Committee (BPAC). The primary mission of the BPAC is to provide expert scientific advice to the FDA on regulatory matters relating to the blood supply. For example, the BPAC is asked to evaluate the quality and sufficiency of data which are submitted to the Agency as a basis to validate either safety or efficacy of a novel product which is pending licensure. Such issues typically are brought before the BPAC when there is

controversy over the applicable scientific standard, the interpretation of clinical trial data, or the net benefit of product approval despite limited effectiveness or potential toxicities. Additionally, the BPAC is used to obtain outside scientific input into policy decisions affecting the blood supply, to assess the importance of emerging threats and to evaluate the potential benefits of new technologies.

While FDA can and does seek advice from a wide range of sources, a more standardized, formal mechanism for seeking advice from sources outside the FDA on sensitive issues would strengthen the process. The Task Force concluded that there are advantages to having a broader range of advisory viewpoints available when issues inherently raise broader societal concerns that cannot be resolved through the evaluation of scientific data alone. The PHS Advisory Council on Blood Safety and Availability would provide a forum in which to examine the broad public health and societal implications of issues impacting on the safety and availability of the blood supply. The Task Force recommends inclusion of industry representatives on the Advisory Council because of importance of input and expertise from this sector; however, no industry representative would vote on particular issues in which they have a conflict of interest.

The range of issues considered by the Advisory Council would be: implications for blood safety and availability of various economic factors affecting product cost and supply; defining societal parameters around safety of the blood supply; broad ethical and legal issues, including discussion of appropriate informed consent; and the setting of global priorities such as allocation of research resources.

The Task Force is aware that this recommendation may appear to add additional layers of complexity and bureaucracy to the blood safety program at the Department, however the Task Force believes it does not. The Advisory Council would have the specific charge of advising on broad societal issues affecting blood safety and availability, not those requiring immediate Departmental action. The Task Force sees an important role for providing decision-makers with broad-based consumer input to establish a societal context within which to consider blood safety and availability issues. In contrast, the role of the BPAC would remain as a forum in which complex scientific regulatory issues could be rigorously considered, keeping decision-makers fully informed around developing scientific and technical matters. The Task Force believes the Advisory Council would be valuable in conjunction with the BPAC to maximize the Department's ability to address all areas of concern in maintaining a safe blood supply.

**Recommendation 3:**

The federal government should consider establishing a no-fault compensation system for individuals who suffer adverse consequences from the use of blood or blood products.

The IOM report provided as a basis for this recommendation a concern for the ability of individuals to seek legal remedies due to blood shield laws. There are a wide range of legal issues involved here, such as the degree to which sufficient remedies or alternative resources are available to persons with blood-product related injuries. These issues are beyond the purview and expertise of public health officials at the Department of Health and Human Services and should be considered in a broader context.

Although the IOM report did not address issues of cost and availability of care as the basis for a compensation proposal, the Task Force recognizes the substantial needs faced by many individuals with HIV disease who are also affected by hemophilia. Both conditions are chronic, devastating illnesses requiring complex and costly medical care over time. The availability of insurance to meet these costs is often predicated upon the ability to work, and many individuals with HIV eventually require federal support through the Medicaid program. The Department has a number of programs targeted to address this burden, such as the hemophilia treatment centers and Ryan White CARE Act, recognizing that resources are straining to meet the need. The Task Force acknowledges the important role of these programs but could not undertake to re-examine them in the context of this report.

**Recommendation 4:**

Other Federal agencies must understand, support, and respond to CDC's responsibility to serve as the nation's early warning system for threats to the health of the public.

The Task Force agrees with this recommendation, and all of the HHS agencies understand the value and quality of CDC's work. The key to assuring that this recommendation is carried out is interagency communication, so that CDC's information about potential threats is widely known and understood. CDC has pursued this goal by, for example, participating in the monthly interagency conference calls of the PHS Interagency Working Group on Blood Safety and Availability and participating in meetings of the FDA Blood Products Advisory Committee. CDC's participation in the recommended PHS Blood Safety Committee would further assure that CDC's views are well known to all HHS agencies responsible for the safety of the blood supply.

CDC has also developed an internal working group to address issues of blood safety. The working group ensures better coordination of the different groups at CDC that work on individual pathogens, by focusing attention and effort on blood safety issues related to these different pathogens. This group is also able to consider and evaluate any new or newly recognized known or potential threats.

**Recommendation 5:**

The PHS should establish a surveillance system, lodged in the CDC, that will detect, monitor, and warn of adverse effects in recipients of blood and blood products.

The Task Force agrees that surveillance is vital. PHS now has comprehensive surveillance systems in place, and refinements are continuing. CDC has a number of different systems for surveillance of current or potential threats related to transfusion of blood/blood products. These include disease-specific surveillance systems (e.g. hepatitis viruses and AIDS), donor-based systems (for HIV), and recipient population-based systems (e.g. among hemophiliacs). Identification of previously unknown agents may occur through epidemic investigations or Emerging Infection projects. The CDC routinely provides input to the FDA's Blood Products Advisory Committee, affording the Committee the benefit of this surveillance expertise.

Special studies have also been used to assess the magnitude of the risk, if any, for transmission of agents by blood/blood products, such as variant HIV strains, idiopathic CD4+ T-lymphocytopenia (ICL), and hepatitis C from intravenous immunoglobulin (IVIG). Surveillance studies are enhanced by use of quantitative decision analyses which can contribute to appropriate evaluation of potential threats to the blood supply. In addition, applied research that enhances the safety of the blood supply is conducted both at FDA and at CDC. At NIH, the Retrovirus Epidemiology in Donors Study plays an important role in the Department's surveillance efforts.

The Task Force notes that the success of certain components of HHS' surveillance system is dependent in part upon the public health infrastructure at the state, local and provider level. This public health infrastructure for the reporting of new events maximizes the effectiveness of existing surveillance networks.

**Recommendation 6:**

Where uncertainties or countervailing public health concerns preclude completely eliminating potential risks, the FDA

should encourage, and where necessary require, the blood industry to implement partial solutions that have little risk of causing harm.

The Task Force agrees with this recommendation with reservations. FDA has already utilized the stated principle in its decision-making since 1986. For example:

- Since 1987, FDA has approved product amendments for viral inactivation of clotting factor concentrates and immune globulins using solvent-detergent incubation procedures despite the fact that these methods are effective only for enveloped viruses, which account for all major known transmitted diseases.
- In 1990, FDA approved the first donor screening test for antibodies to hepatitis C virus (HCV) despite estimates that the test could at best prevent only about 70% of non-A, non-B post-transfusion hepatitis.
- In 1992, the FDA recommended donor screening for HIV-2 despite the rarity of HIV-2 infections in North America. This measure was taken when the availability of combination HIV-1/HIV-2 antibody tests made it possible to provide a preventive measure of uncertain benefit without the addition of risk.

The Task Force notes, with reservation, that risk analyses are not always possible, because of missing data or a lack of complete scientific understanding. It may be extremely difficult to develop a quantitative assessment of low risks. Also, it is not always possible to assure lack of harm from any intervention, and it can be dangerous to presume absence of harm where data are lacking.

Recommendation 7:

The FDA should periodically review important decisions that it made when it was uncertain about the value of key decision variables.

The Task Force agrees with this recommendation. FDA has implemented such periodic review for numerous decisions made since 1986. For example:

- FDA has recently reexamined the question whether to screen the blood supply for HIV-1 antigen. A decision against such screening was made in 1989 when the available data showed a lack of efficacy. Based on new information, the issue was

brought to public discussion again in 1995. On the basis of this discussion, FDA now has decided to recommend donor screening for HIV-1 antigen, once the test becomes available for blood screening.

A test for antibodies to HIV-2 was first approved in 1990, but was not recommended for use in donor screening due to the rarity of HIV-2 infections in North America and the predicted negative impacts of adding a donor screening test. This decision was reexamined in 1991 after combination tests for HIV-1/HIV-2 antibodies, as well as results of additional surveillance studies, became available.

In 1978 an FDA Advisory Panel recommended discontinuation of the donor screening test for syphilis. FDA was about to publish a proposed rule to discontinue the test in 1985. This action was reconsidered in face of the AIDS epidemic, and the test was retained as a surrogate marker for risk of sexually transmitted diseases, including AIDS. The latter decision is now being reexamined.

#### Recommendation 8:

Because regulators must rely heavily on the performance of the industry to accomplish blood safety goals, the FDA must articulate its requests or requirements in forms that are understandable and implementable by regulated entities. In particular, when issuing instructions to regulated entities, the FDA should specify clearly whether it is demanding specific compliance with legal requirements or is merely providing advice for careful consideration.

The Task Force agrees that FDA's communications should be clear, and believes that FDA has made many improvements in this regard since 1986. For example, FDA has increased its use of Advisory Committees, public meetings and workshops as means to communicate its expectations through public discussion, and has issued increasingly specific guidance to regulated industry through Guidelines, Points to Consider and Recommendations. In addition, FDA has made increasing use of compliance policy guidance documents to clarify its positions on enforcement. Guidance documents are used to provide clarification and education but are not legally binding on either the industry or the agency.

Under existing authorities, FDA can promulgate regulations either through notice and comment rulemaking or directly under its emergency authorities should an urgent public health need exist. Alternatively, FDA may issue guidance documents as a vehicle of rapid communication. As long as guidance documents are treated as non-binding, the federal Administrative Procedures Act does

not require notice-and-comment rulemaking. FDA uses these alternative approaches as appropriate.

In the past, FDA communication to the blood industry has often taken the form of recommendations, rather than regulations, in part because of the length of the regulations development process and the resources required. It is also impractical for FDA to rely on its emergency rulemaking authorities routinely. The Task Force is aware of concerns within the blood products industry regarding FDA guidance issued outside of the rulemaking process. Industry views the rulemaking process as a comprehensive one with clear parameters for evaluation. One area for further consideration is whether the rule-making process could be expedited to allow more timely, formal FDA guidance on blood safety issues.

FDA will continue to strive to communicate the most recent information available, in the clearest manner possible, and specifically identify those requirements that are binding. Where the agency does not engage in formal rulemaking, the FDA will remain mindful of the need for public discussion and input.

**Recommendation 9:**

**The FDA should ensure that the composition of the Blood Products Advisory Committee reflects a proper balance between members who are connected with the blood and blood products industry and members who are independent of industry.**

The Task Force agrees with this recommendation, and notes that FDA has been attentive in recent years to the issue of representation on its advisory committees. Responding in part to an earlier IOM report, FDA restructured the Blood Products Advisory Committee in 1994, expanding consumer representation through voting consultants. This status was reserved by FDA for individuals who bring specific expertise on an issue and who have no conflict of interest bearing on the issue under consideration. In 1995, the charter was revised to expand the possibility for voting representatives with consumer interests. Also, in 1995, FDA removed advisory committee members with any appearance of a conflict of interest, except for a single, designated, non-voting industry representative. The scientific expertise and input of industry are available to BPAC through invitations to industry representatives to participate as non-voting consultants on an ad hoc basis, and through industry participation in Open Public Hearings at all BPAC meetings.

The Task Force reviewed criticism of blood industry organizations that there is now insufficient technical expertise on the BPAC.

While FDA is considering changes in this regard, the Task Force believes that BPAC can fulfill its obligations in its current format, using industry consultants where necessary. Whereas the role of industry in voting on BPAC proceedings has been eliminated as a result of reforms, industry input in terms of scientific data and expertise must remain strong.

Recommendation 10:

The FDA should tell its advisory committees what it expects from them and should independently evaluate their agendas and their performance.

The Task Force agrees with this recommendation, and notes that FDA, not BPAC itself, provides the agendas for discussion at the meetings. The Task Force believes that FDA currently manages the Blood Products Advisory Committee well and communicates expectations clearly. In particular:

- FDA routinely provides members of the Advisory Committee with a summary of each issue to be discussed at the upcoming meeting, including all relevant publications and summaries of presentations. Additionally, FDA provides its own analysis of each issue, its policy position, and a set of options and/or questions for committee consideration. FDA formats such discussion items in a manner likely to sharpen the committee focus, such as by asking "yes or no" questions on critical points affecting FDA decisions.
- FDA evaluates its committee members first through a selection process, and then through a review of their performance at the time of renewal of appointment. FDA considers such factors as participation in the meetings, contribution to the discussion of issues and other engagement with the business of the Agency, such as service on site visit teams.

Recommendation 11:

The PHS should develop reliable sources for the information that it needs to make decisions about the blood supply. The PHS should have its own capacity to analyze this information and to predict the effects of regulatory decisions.

The Task Force agrees with the premise of this recommendation, but believes that additional study is necessary to determine whether, or to what degree, it is feasible to implement. Although FDA gathers and analyzes data as needed to enhance

decision making, the agency still lacks independent information in certain key areas bearing on product supply, distribution and cost which may affect the safety, efficacy or availability of products. The availability of such information to FDA and the rest of PHS would enhance decision making in the realm of blood safety. However, new data collection could be expensive and difficult for HHS.

One option to obtain this information would be through expanded PHS authority to access data, or through additional record keeping requirements. Another alternative would be to leave data collection on economic aspects of the blood industry to outside organizations, with PHS participation in the analysis and interpretation of such data. A third option is to rely on voluntary reporting of data by industry. A fourth option is for the Secretary to ask the Office of the Inspector General to do compliance audits to determine the accuracy of the data provided to FDA.

CDC has expressed interest in collaborating with FDA to assess the feasibility of implementing this recommendation. Such an assessment will continue over the next six months, and will include an evaluation of benefits to be obtained through additional information collection, weighed against the burdens and costs such activity would impose upon HHS and upon the blood industry.

Recommendation 12:

When faced with a decision in which all options carry risk, especially if the amount of risk is uncertain, physicians and patients should take extra care to discuss a wide range of options.

The Task Force agrees, and believes that the level of informed discussion occurring between doctors and patients has risen since the early 1980s.

Recommendation 13:

The Department of Health and Human Services should convene an expert panel to inform the providers of care and the public about the risks associated with blood and blood products, about alternatives to using them, and about treatments that have the support of the scientific record.

While a standing expert panel might not be the most effective means available, the Task Force agrees that this type of

clinically useful information should be communicated as it becomes available. As issues of importance arise, the PHS Blood Safety Committee and the Advisory Council on Blood Safety and Availability will evaluate the government's communication efforts, including the activities of the Agency for Health Care Policy and Research and its clinical guidelines program, to determine what additional efforts are needed.

**Recommendation 14:**

Voluntary organizations that make recommendations about using commercial products must avoid conflicts of interest, maintain independent judgment, and otherwise act so as to earn the confidence of the public and patients.

The Task Force agrees with the premise of this recommendation.



SEP 17 1993

TO: The Secretary  
Through: DS \_\_\_\_\_  
COS \_\_\_\_\_  
IB \_\_\_\_\_

FROM: Assistant Secretary for Health

SUBJECT: Decision Memorandum on Blood Quality Assurance  
Supplemental for Food and Drug Administration (FDA)  
--ACTION

ISSUE

FDA has requested a supplemental appropriation for its blood program, in order to establish a blood quality assurance initiative aimed at ensuring the safety of the blood supply and upgrading the operational quality of blood banks, specifically the voluntary whole blood sector.

BACKGROUND

Over the past few years, FDA has mandated annual inspections of all blood centers and has substantially revised its guidelines and requirements for the blood industry. The Agency has found increasing evidence that some components of the industry have been unable, on their own, to develop and implement the Good Manufacturing Practices (GMPs), follow the Standard Operating Procedures (SOPs), and validate the information systems needed to ensure the safety of the blood supply. Mandatory error and accident reports multiplied tenfold from 1,036 in 1989 to 10,456 in 1992 for licensed establishments, representing a fourth of the 2,400 registered blood banks. The violative rate for these same licensed blood banks was 23% in 1988. In recent years it has gone even higher, peaking at 25% in 1990 before easing to 24% in 1991 and 1992. For licensed ARC blood banks excluding donor centers, the 1992 violative rate was estimated conservatively at 27%. If pending cases (which are usually violative) are included, ARC's rate could be as high as 32%. This means that in 1992, one in every four licensed blood banks overall was significantly out of compliance; in ARC's case, one out of every three. These compliance problems for the high volume, complex operations need to be addressed urgently if FDA is to ensure the safety of the nation's blood supply.

FDA has developed a proposal for a five-year program to accomplish this by strengthening its capability to diagnose blood center operational deficiencies and to provide appropriate guidance to the blood banking industry, to educate and assist

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blood centers in conforming to this guidance, to provide more timely decisions on licensing applications and amendments, and to carry out inspections that will assess the progress of the industry in bringing its operations to a higher standard.

The five-year projected cost for the proposed program is \$135.0 million. This will be added to the existing base of \$52.1 million for the entire blood program, including blood therapeutics, in the FY 1994 budget appropriation, with a base increase in FDA's annual appropriation of \$24.4 million beginning in 1994, and adjusted for inflation at an annual rate of 5% in subsequent years. The components of the program are shown in Exhibit 1.

Fiscal Year	BASE		ANNUAL INCREMENTAL RESOURCES			
	1994	1994	1995	1996	1997	1998
FTE (#)	504*	142	85	15	0	0
Total (\$000)	52,104*	24,425	1,221	1,282	1,346	1,413

\* Includes resources for the Blood Therapeutics Program, not addressed in this supplemental. These needs are addressed separately by the Prescription Drug User Fee Program.

By the end of 1998, FDA expects that most blood banks will have made significant progress toward reliable quality assurance in their systems. Some will have achieved the ability to monitor their own operations, through the information provided in error and accident reports, and to make needed corrections. As blood centers come into compliance, FDA time spent on site should diminish but the Agency will continue to diagnose recalcitrant problems and to provide guidance and assistance in remedying them.

### DISCUSSION

Over the past decade, and in particular since the emergence of the AIDS epidemic, ensuring the safety of the blood supply has become far more complex and difficult than before. To meet the challenge, the blood industry has instituted more thorough screening of potential donors, introduced numerous laboratory tests, and developed comprehensive record systems to prevent the transmission of blood-borne disease. At the same time, it has introduced successive waves of new technology. While these have produced many new products that contribute significant benefits to public health, they also require extensive quality assurance procedures. During this same period, FDA has mandated annual inspections of all blood centers to ensure compliance with these new safety procedures and more complex operational requirements.

It has also substantially revised its guidelines and requirements for the blood industry.

While donor screening, increased testing and record keeping have done much to reduce the risk, they have not eliminated it. More importantly, the systems on which public safety rests are themselves highly fragile. Unlike the pharmaceutical industry, which manufactures products in large "lots," with thousands of identical units, each of the 12 million units of blood collected annually is a separate lot of one unit. The blood banking industry must shoulder responsibility for ensuring that each one unit lot meets all safety and quality standards. Each separate unit of whole blood drawn has potential safety concerns, and its processing into separate blood products such as red blood cells, platelets and plasma results in a number of further products that are also subject to these concerns, e.g., contamination with HIV, hepatitis or some other blood borne disease. The situation is made more difficult by the fact that expiration dates for blood products are days and, for some, just hours. This forces quick decisions that must be accurate.

FDA does not and cannot test samples of each blood product. The only quality assurance available is through rigid adherence to GMPs by each blood center. These practices are what ensure that donors are screened properly, that HIV and other screening tests yield accurate results, and that each and every unit of processed blood can be identified and connected with a donor and a set of test results. The adequacy of the system is increasingly dependent on computerization which must have reliable and validated software. GMPs also require comprehensive SOPs and employee training.

The recalcitrance of quality assurance problems has much to do with the nature of the industry itself. First, blood banking has traditionally been a highly fragmented industry comprised mostly of independent community blood banks reporting to local boards, voluntary hospitals and the American Red Cross (ARC). The community blood banks and hospitals have created a loose federation under the umbrella of the American Association of Blood Banks (AABB), which invests most of its limited resources in training. Locally, the banks are often managed by professionals with clinical credentials, but no background in manufacturing or exposure to the sort of GMPs that were instituted long ago in the pharmaceutical industry. ARC, because of its scale, might seem to be the exception: a strong, centralized force in a fragmented industry. However, even with the ARC, the FDA has had to resort to a consent decree to ensure that these issues are addressed in a timely manner.

Second, operational improvements require both development funding and implementation costs. The whole blood sector is not-for-profit and, ARC aside, dominated by small to medium scale

operations. This translates into serious financial hurdles for needed investments in systems development and the ability to amortize them over a large enough base of operations. Here, ARC does have an advantage. It has undertaken a major initiative to improve the quality and efficiency of its operations and, as part of the consent decree agreement, must pursue aggressive implementation. While ARC anticipates a long-term reduction in operating costs of at least 10%, this will be achieved only after investing about \$150 million to consolidate its operations and bring them under centralized control. As part of this program, ARC expects to spend \$34.5 million to consolidate its 47 testing laboratories into 10 regional laboratories by the end of 1994, \$72.4 million to create a single integrated information system to replace the 10 separate systems now in place, and \$19 million to train staff to use uniform SOPs.

Implementation costs pose additional financial hurdles. ARC estimates that the break-even volume for centers making these changes will be about 100,000 units of blood per annum. Only a handful of its centers fall below this threshold, but a large percentage of the 1,800 unlicensed bloodbanks are apt to do so. For large independents, financing for needed systems infrastructure will prove a challenge. Although smaller blood banks have less complex operations, adequate systems and training remain costly.

Prior to introducing new technology or operational changes, licensed blood centers must file amendments to their establishment licenses and new product license applications (FLAs). The volume of these applications is rising steadily (at a rate of from 10% to 16% per annum, depending on type), and the backlog of pending applications is also increasing at nearly an exponential rate. In FY 1990 for example, the Division of Transfusion Transmitted Diseases, which handles applications for in vitro diagnostic tests, had 12 pending at the end of the year. By the end of FY 1992, this number had risen to 40 and by the end of 1993 it is expected to reach 59. Based on work load measures, the Office of Blood estimates that it would need 37 additional FTEs just to erase the 1994 backlog of this and other divisions, which handle all applications for new blood products and medical devices as well as applications for new establishments and amendments to old licenses.

Left alone, this situation can only get worse. Decision times now stretch out to 18 to 24 months, a major frustration for the industry. The issuance of new regulations and guidelines, such as the Quality Assurance Guideline that is slated for final release in FY 1994, requires that blood banks make changes, sometimes of a fundamental nature, to their operations. Yet, absent timely review and approval by the FDA, operational improvements will come to a standstill.

FDA has held preliminary discussions with the leadership of ARC, AABB and the Council of Community Blood Centers (CCBC), whose members jointly account for nearly all whole blood collections in the U.S., about the support the industry will require to upgrade operations and stay abreast of technology changes. The blood banking community, particularly through the AABB and CCBC, has emphasized that it needs more support from FDA in terms of guidance, leadership (e.g., in bringing together the industry to agree to uniform standards and SOPs), and responsiveness to licensing requests. The industry acknowledges a lack of knowledge about GMPs, and believes that FDA is its best resource for learning what is needed to upgrade operations. At the same time, it is dependent on FDA to support its operational changes by processing its licensing requests, either amendments to existing establishment licenses or for new products, in a timely fashion. Otherwise, it cannot move forward to upgrade its operations and manufacture new products demanded by the clinical community.

FDA lacks the resources to provide this support across nearly all components of its program. In January 1993, CBER created a new Office of Blood Research and Review, as part of its comprehensive reorganization, to focus its resources and activity on its blood safety mission. The Office of Blood has insufficient staff to develop all of the new product guidance that blood centers need. The Office of Compliance faces similar problems in trying to integrate all the information coming in from the field as a first step toward identifying where the need for new policy and guidance is most urgent, in trying to develop the specific guidances needed (e.g., for computer software validation procedures), in distributing them and in assisting blood banks with compliance.

FDA's field staff is the primary organization responsible for on-site inspections and enforcement of GMP requirements. Without additional resources, the field will be unable to enforce new quality assurance guidelines and to attend to the systems flaws pointed to in errors and accidents reports. Perhaps most importantly, it does not have the resources required to do adequate software systems validation or to inspect the 50 or so vendors that develop and sell software to the industry. Since the integrity of the record keeping system linking products to donors and tests depends on this software, proper validation is essential to any quality assurance program. Further, since inspections are where the Agency directly interacts on site with blood centers, field staff de facto perform much of the education and assistance needed by the industry. They uncover problems, suggest ways to rectify them, and hold the blood centers accountable for making the changes. In this sense, they force change in situations that, left to themselves, would settle into patterns of denial and inertia. Their activity is vital to moving the industry forward.

Undergirding FDA's entire blood program are multiple automated systems, whose lack of integration impedes the flow of information between the field and headquarters, and among program areas within headquarters. This system needs to be integrated on a relational data base that would permit field, compliance, policy and review staff to share information quickly. Such a system, once in place, would permit the integration of information into a program for monitoring the blood banking industry's performance relative to quality assurance goals, the diagnosis of areas requiring guidance and policy formulation, and a more proactive approach to helping the industry prevent accidents rather than recover from them.

Two options are presented below. The first is the enhanced blood initiative that FDA proposes, which will require additional resources; the second is the blood program that FDA expects to follow without a supplemental appropriation.

Option 1: Proposed Blood Quality Assurance Initiative

In order to guide and support the blood industry through the changes it needs to undergo, FDA proposes an initiative that will have four main components. These are:

1. INDUSTRY EDUCATION AND ASSISTANCE (15 FTEs IN 1994, RISING TO 25 FTEs IN 1995 AND BEYOND)

In order to increase the guidance available to industry and integrate it with the best available information about their needs, FDA will:

- Assign dedicated policy staff to ensure the timely development of guidance for product applications and for the development of procedures to ensure compliance with FDA regulations. These staff will be responsible for creating a single, unified guidance document to serve as a reference document both to industry, to FDA headquarters and to field personnel. While it is difficult to quantify its impact, such a document should improve the quality of license applications and amendments, expedite application review and help industry resolve policy issues more quickly, thus contributing to their ability to upgrade their operations.
- Through the Office of Compliance, establish mechanisms to identify problem areas in blood bank operations, e.g., the review of error and accident reports to identify trends and develop appropriate "early warning" guidance to industry.

- Train both investigators and inspectors from headquarters, the field and HCFA in regulatory policy, quality assurance, and the effects of technology change on systems integration and validation.
  - Establish a staff of dedicated personnel whose mission will be similar to that of the Division of Small Manufacturer Assistance (DSMA) in the Center for Devices and Radiological Health: to provide industry workshops in GMP, to publish guidance, and to establish a telephone "hot line" for rapid response to industry questions. This kind of program has been highly successful in helping small device firms come into compliance and is expected to be an equally successful outreach to blood banks.
  - Fund a one-year study of the donor deferral data base infrastructure now in place in the blood banking industry, with a view to two goals: (1) assessing the adequacy of that infrastructure relative to the demands placed on it by the local operation, and (2) scoping the requirements of a national donor deferral registry. Such a national system would of necessity have to be built on a local information base. Hence, it is important to assess the adequacy of what exists today, both to develop guidance in support of that area and to determine the feasibility of the national system.
  - Work with the industry to identify collaborative approaches to helping blood centers improve their operations. In FY 1994, the Agency will begin a series of industry exchange meetings to elicit the views of all members of the blood banking community on quality assurance issues. These efforts will be complemented by the Blood Forum, an initiative that will provide an opportunity for the exchange of ideas about blood safety not only to FDA and the blood banking community, but also to members of the academic and clinical communities.
2. ACCELERATED LICENSE REVIEW (25 FTEs IN 1994, RISING TO 50 IN 1995, TO 65 IN 1996 AND BEYOND)
- To ensure that product and establishment license approval does not become the rate limiting factor in upgrading blood banking operations, the Office of Blood will bring on board 25 new FTEs in FY 1994, another 25 in FY 1995, and another 15 in FY 1996 to stabilize and then eliminate the backlog. These FTEs will be needed on an ongoing basis to address the increasing volume of applications. The five-year objective is to decrease

the average time that a blood bank must wait for approval of a licensing application.

- Beyond this, the Office of Blood will establish a task force to consider ways in which applications that are simple and routine might receive a faster review, either by the use of computer support, or by alternative approaches to the review. Where possible, the Office of Blood will seek to develop simpler and faster review tracks for applications that would warrant them.

3. **COMPREHENSIVE INSPECTION OF BLOOD BANKS AND OF SOFTWARE VENDORS (100 FTEs IN 1994, RISING TO 150 IN 1995 AND BEYOND)**

- The field will undertake much more extensive inspections of software systems, quality assurance programs, and error and accident reporting than it has hitherto been able to perform. For the most part, this will not necessitate additional inspections, but it will lengthen routine inspections on average from 30 hours to 48 hours. The first few years will be particularly labor intensive as inspections reveal new problems, and are followed to determine whether the blood centers have come into compliance. While most centers are expected to move to compliance, it is impossible to estimate the rate with which they will be able to do so until the severity of their problems is known.
- In addition to its work with blood banks, the field will begin inspection of all software vendors, to ensure that the software has been validated at source. This program will address problems that occur at the user site, but are difficult to remedy there.
- The field needs 49 FTEs to carry out ongoing critical AIDS related inspections and validation of new viral marker tests.
- Finally, the field will begin inspection of foreign licensed blood banks, and both domestic and foreign unlicensed blood banks in FY 1994.

While this is a significant investment in the field, the Agency considers it vital to bringing about real change in industry operations. Today, many blood banks know too little about quality assurance systems even to be able to recognize their own deficiencies. Many are unable to define their systems and to establish critical control points. The field takes on the challenging assignment of teaching them, in concrete "shop floor" terms, what quality assurance is and where their systems are

lacking. At the beginning stages of implementing quality assurance programs, there is no substitute for the "hands on" support that the field can bring to bear in diagnosing systemic problems and suggesting ways that the blood centers can be brought into compliance.

4. INFORMATION SYSTEM SUPPORT (2 FTEs IN 1994 AND BEYOND, 54 MILLION IN 1994 FOR HARDWARE AND SOFTWARE SUPPORT IN 1994; HARDWARE PROCUREMENT DROPS IN FUTURE YEARS.)

CBER's blood program is impeded by dependence on a set of antiquated and incompatible information systems. To ensure that information can be shared quickly and readily by field and headquarters staff, the Center needs to consolidate its data bases into a single relational data base on a single hardware and software platform. Doing so will facilitate the exchange of information between field and headquarters staff. It will also provide the base for new tracking systems that will permit CBER to move toward monitoring blood bank performance, identifying trends and problems in early stages of development, and issuing guidance to prevent errors and accidents.

Option 2: Proposed Blood Program Using FY 94 Base Resources Only

Should FDA not receive the requested supplemental resources, it will attempt to maintain its current blood program and, wherever possible, reallocate resources toward the most critical program elements. In practice, it has limited flexibility in redirecting resources, for several reasons. First, the blood inspection program is now being carried out at the expense of other FDA programs, particularly devices. FDA's Office of Regulatory Affairs estimates that in order to accomplish all of the critical AIDS-related inspection work in FY 1992, it "borrowed" 37 FTEs from other programs. Option 1 returns the "borrowed" resources to the device program. Therefore, while some resources can be saved by moving to a streamlined inspection model and to a biennial rather than annual inspection cycle for selected blood banks, all of the resources "saved" would be needed to replace those that already are being consumed at the devices' program expense.

Second, while CBER is actively engaged in a report reduction effort, the Center would require a major overhaul of regulatory policy to reduce its applications review workload enough to prevent the continued accumulation of a backlog. The reallocation of resources from other program within CBER and from the Blood Therapeutics Program is essentially blocked by the user fee program, which protects the base resources for user fee funded applications. The only remaining option would be to reprogram the new FY 1994 vaccine resources, which is contrary to the President's priority vaccine initiative. This would also come on top of a recent cutback of resources from the National

Vaccine Program. As a result of these limitations, opportunities for reallocating FTEs are marginal.

With the resources provided in the 1994 budgeted base, FDA would expect to drop the effort to develop a unified information system to support the blood program, and focus on only a limited number of compliance and inspection initiatives. Specifically, it has the following options:

• Industry Education and Assistance; Field Inspections

The only way to continue the current level of inspections is to "borrow" FTEs from other inspection programs. At best, the Agency can move aggressively to streamline the inspection programs for non-violative centers to meet some additional needs, as discussed below:

- Continue annual inspections of all 2,410 licensed and unlicensed blood banks.
- However, use a streamlined inspection approach for facilities with a history of compliance, and reallocate the resource saved to perform inspections of software vendors. These inspections will promote the solution of some software problems at source, and thus mitigate the need to deal with them at the user site.
- Focus CBER resource on producing the most critical guidance, especially for software validation and quality assurance. Other guidance will be forthcoming but on an extended schedule.
- Forego an industry education program, similar to DSMA in the Center for Devices and Radiological Health, that would provide blood banks with seminars on GMPs, publications and a telephone hot line to respond to their questions.

It is clear that this approach provides no support to the blood centers in improving the quality of their operations.

• Application Review

FDA has even less flexibility in applications review. Streamlining the review process would require both development of needed guidance for industry and changes in regulatory policy. Currently, CBER lacks the staff to approach either effort, or indeed even to keep up with the volume of applications. Work load measures show that the current staffing complement is sufficient to complete about 400 blood components and establishment applications or amendments, 100 in vitro diagnostics and medical device

applications, and 56 INDs. This processing capacity falls well below the level needed to complete the actual volume of applications. In consequence, there is a rapidly growing backlog and not time for review staff to develop the product guidance needed.

Since the volume of applications is increasing by 10% to 16% annually, depending on type, the situation will certainly become much worse without additional resources. In 1994, CBER will face a backlog of 443 pending applications, requiring 37 FTE years of work to eliminate. If the current staffing level is held constant, this backlog will grow to 715 applications in 1995, and 1,074 in 1996. By then, 95 FTE years will be needed just to eliminate the backlog, and the operation will for practical purposes have come to a standstill, making it impossible for blood banks to make needed changes in their own operations.

RECOMMENDATION

I recommend Option 1, specifically that you include a request for \$24.4 million for FDA for an urgent supplemental appropriation for FY 1994 in the budget that you will send to OMB by October 1.

DECISION

OPTION 1.

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Date \_\_\_\_\_

OPTION 2.

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Date \_\_\_\_\_

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Philip R. Lee, M.D.

Attachment

**EXHIBIT 1**

<b>BLOOD QUALITY ASSURANCE PROGRAM</b>								
<b>Estimated FDA Resource Requirements by Fiscal Year</b>								
<b>Activity</b>	<b>Resource Type</b>	<b>FY 94 Base</b>	<b>Additional Resources Being Requested</b>					
			<b>FY 94</b>	<b>FY 95</b>	<b>FY 96</b>	<b>FY 97</b>	<b>FY 98</b>	
<b>1. Industry Education and Assistance</b>	HQ FTEs Oper/Cont \$(000)	33	15 \$1,515	10	(\$500)			
<b>2. Application Review</b>	HQ FTEs Oper/Cont \$(000)	79	25 \$2,751	25 (\$2,094)	15			
<b>3. Inspectional Activities</b>	HQ FTEs FD FTEs FD Oper \$(000)	23 176	5 95 \$3,565	50 (\$2,200)	(\$500)			
<b>4. Data Systems</b>	HQ FTEs Oper/Cont \$(000)	2	2 \$3,956	(\$2,956)	(\$323)			
<b>Subtotal for activities subject to this request</b>	FTEs Oper/Cont \$(000) FTE Cost \$(000) Total Cost \$(000)	315	142 \$11,787 \$12,638 \$24,425	55 (\$7,252) \$8,473 \$1,221	15 (\$1,323) \$2,005 \$1,282	\$1,346	\$1,413 \$1,413	
<b>5. Other Blood and Blood Product activities not subject to this request, e.g., therapeutic blood products</b>	FTEs	189						
<b>Total Blood and Blood Product Program</b>	FTEs Oper/Cont \$(000) FTE Cost \$(000) Total Cost \$(000)	504 \$7,248 \$44,856 \$52,104	<b>Additional resources will be supplied from prescription drug user fees and will be added to the above resources and the base to adjust these two rows.</b>					

**NOTE:** In FY 94 Oper/Cont cost refers to initial setup, housing, equipment, and contracts.

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# MEDICARE

*A Profile*

25  
*Celebrating*

MEDICARE



# Medicare 2000: 35 Years of Improving Americans' Health and Security

*Health Care Financing Administration  
July 2000*



President Lyndon B. Johnson at the signing ceremony July 30, 1965, at the Truman Library in Independence, Missouri.

*"No longer will older Americans be denied the healing miracle of modern medicine. No longer will illness crush and destroy the savings they have so carefully put away over a lifetime so they might enjoy dignity in their later years. No longer will young families see their own incomes, and their own hopes, eaten away simply because they are carrying out their deep moral obligations."*

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## Preface

Medicare's enactment on July 30, 1965, followed several decades of debate over ways to meet the health care needs of vulnerable Americans. In 1952, President Harry S. Truman became the first President to ask Congress to enact a program to insure elderly Americans against the cost of medical care. The Medicare banner was taken up again by President John F. Kennedy in 1963 but did not pass the Congress until 1965, two years after Kennedy's death, under the leadership of President Lyndon B. Johnson. Recognizing the enormous role that President Truman had played in placing the Medicare idea on the national agenda, President Johnson traveled to Independence, Missouri, to sign the Medicare bill into law and present the first two Medicare cards to former President and Mrs. Truman.

*"Medical care will free millions from their miseries. It will signal a deep and lasting change in the American way of life. It will take its place beside Social Security, and together they will form the twin pillars of protection upon which all our people can safely build their lives and their hopes."*

— President Lyndon Baines Johnson in June 1966, just before implementation of the Medicare program, speaking to the National Council of Senior Citizens

Without question, Medicare has altered the lives of seniors and Americans living with disabilities. In the words of a Medicare beneficiary:

*Well, I think it's one of the greatest things we have. You know, used to be we didn't have things like that to help pay bills years ago.*

During the past 35 years, Medicare has provided health care coverage to more than 93 million elderly and persons with disabilities, assuring them access to high-quality medical care and protecting their often-meager income and savings from the frequently devastating cost of illness. Today, more than 39 million men and women are enrolled in Medicare and that number is projected to nearly double to 77 million by 2030. In its 35-year history, Medicare has made important improvements in the health status of elderly and disabled beneficiaries whose health needs are greater than those of the general population. And, because of its significant role in the U.S. health care system, Medicare has made major contributions to the improvement of that system.

In commemorating Medicare's 35th anniversary, this report examines the role that Medicare has played in improving the health and well-being of America's senior citizens and those living with disabilities. It looks at the impact Medicare has had on the U.S. health care system and the changes that have been made to the program to improve benefits, eligibility, and finances. Finally, the report examines the challenges Medicare faces in meeting the needs of future beneficiaries. It is my hope that, as we debate the future of the Medicare program, we pause to reflect upon the 35 years that Medicare has provided health security to our nation's seniors and disabled.

*Nancy-Ann Min DeParle*

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## Executive Summary

One of the crowning accomplishments of the Great Society programs of President Lyndon Baines Johnson was the 1965 enactment of the Medicare program, providing health insurance to Americans over the age of 65 and, eventually, to Americans living with disabilities. As he signed the Medicare program into law, President Johnson said:

*"No longer will older Americans be denied the healing miracle of modern medicine. No longer will illness crush and destroy the savings they have so carefully put away over a lifetime so they might enjoy dignity in their later years. No longer will young families see their own incomes, and their own hopes, eaten away simply because they are carrying out their deep moral obligations to their parents, and to their uncles, and to their aunts . . . No longer will this nation refuse the hand of justice to those who have given a lifetime of service and wisdom and labor to the progress of this progressive country."*

In the 35 years since President Johnson spoke, Medicare has provided access to affordable high-quality health care to more than 93 million elderly and disabled Americans. Today, Medicare

serves more than 39 million beneficiaries, or 1 in 7 Americans. In 30 years, the number of Americans covered by Medicare will nearly double to 77 million, or 22 percent of the U.S. population.

Beneficiaries born in 1900, who enrolled in Medicare in its first year, 1966, are celebrating their 100th birthday this year. There are families with two generations, parent and child, both of whom are enrolled in Medicare today; some families have three generations enrolled in Medicare.

Medicare's importance to Americans will grow. Today, the Census Bureau estimates that there are about 70,000 Americans age 100 or older, virtually all of whom are enrolled in Medicare. Over the next 30 years, improved access to health care and continuing scientific breakthroughs are expected to result in more than 300,000 Americans living until the age of 100 or longer (Census Bureau, 1999).

## I. A Profile of Medicare and its Beneficiaries

In 2000, Medicare serves 39 million elderly and disabled Americans. Because of longer life expectancy and other factors, 57 percent of elderly Medicare beneficiaries are women. Among the disabled, however, men are 59 percent of the beneficiaries. The majority of elderly Medicare beneficiaries are white (84 percent), 7 percent are African-American, 6 percent are Hispanic, and 3 percent are members of other racial or ethnic minority groups. Minorities are a larger share of the disabled beneficiary population.

- **Economic Status.** Most Medicare beneficiaries have relatively modest incomes, and Social Security benefits often constitute a significant portion of that income. The reliance on Social Security is considerably greater for single seniors living alone.

- **Health and Functional Status.** Nearly 30 percent of beneficiaries report that they are in fair or poor health compared with 17 percent of Americans age 45 to 64. Health status is poorer among those over age 85 and members of minority groups. Nearly one in three seniors reports limitations in one or more activities of daily living (e.g., eating, bathing, and going to the bathroom).

- **Health Spending.** In fiscal year 1999, Medicare spent an average of \$5,410 per beneficiary, significantly more than is spent by those under 65. Medicare spending is concentrated on a small group of beneficiaries: more than 75 percent of Medicare spending is spent on the 15 percent of beneficiaries who incur costs of more than \$10,000.

## II. Improving the Lives of Seniors and the Disabled

President Johnson's predictions about the impact of Medicare on America's seniors and society as a whole have proven to be remarkably accurate. Medicare provides a crucial role in:

- **Guaranteeing insurance coverage.** Medicare has made a dramatic difference in the number of seniors who are insured against health care costs. In 1964, nearly half of all seniors were uninsured, making the elderly among the least likely Americans to have health insurance. Today, with 97 percent of seniors covered by Medicare, the elderly are the most likely to have insurance.

- **Lengthening life expectancy.** The average life expectancy of elderly Americans has increased, in part, because of Medicare. A 65-year-old woman on Medicare today will live 20 percent longer than her counterpart in 1960.

- **Providing access to care.** Medicare had an immediate and substantial impact on seniors' access to high-quality medical care. In 1964, hospital discharges averaged 194 per 1,000 elderly Americans. By 1973, that number had jumped to 350 per 1,000.

- **Improving quality of life.** More important than simply adding more years to a senior citizen's life, Medicare has helped to improve the quality of those years. By providing access to medical procedures such as cataract surgery, hip replacement, cardiac bypass, and organ transplants, Medicare has enabled millions of seniors to remain healthier longer, and to participate more fully in the lives of their families and their communities. For example, the number of beneficiaries undergoing knee replacement surgery

more than doubled, from 2.0 per 1,000 beneficiaries to 5.2 per 1,000, from 1986 to 1998. The number of beneficiaries undergoing angioplasty to clear blockage in their arteries and prevent a heart attack rose more than 600 percent, from 1.3 per 1,000 to 8.4 per 1,000, in the same period. Access to these and other services helped to reduce mortality rates and improve seniors' ability to function.

• **Protecting seniors' financial health.** Medicare keeps millions of seniors from becoming impoverished as a result of illness or disability. Before Medicare, senior citizens were disproportionately poor compared with the rest of the population. In 1959, for example, 35.2 percent of Americans over 65 were living below the poverty line, compared with 17 percent of those under 65. Today, about 10 percent of seniors are living in poverty. Before Medicare was enacted, the elderly paid 53 percent of the cost of their health care. That share dropped to 29 percent in 1975 and to 18 percent in 1997. The elderly's health costs consumed 24 percent of the average Social Security check shortly before Medicare; by 1975, that share dropped to 17 percent (Gornick, 1976).

• **Helping minority seniors.** One in seven Medicare beneficiaries is a member of a racial or ethnic minority. Prior to Medicare's enactment, many U.S. hospitals discriminated against African Americans and other racial and ethnic minorities. Most minority Americans were denied access to these facilities and had to rely on separate and often inferior hospitals and clinics to receive care. By requiring hospitals accepting Medicare funding to be integrated for all patients, Medicare played a powerful, but often overlooked, role in expanding access to high-quality care for minority seniors, and for all Americans who are members of minority groups. In 1963, minorities 75 years and older averaged 4.8 visits to the doctor; by 1971 their visits grew to 7.3, comparable to Caucasian utilization rates (NCHS, 1964 and 1971).

• **Improving access to health care for the disabled.** In 1972, Medicare expanded to include Americans living with disabilities and those with end-stage renal disease (ESRD). Today, more than five million people with disabilities are enrolled in Medicare. Since 1973, more than one million Americans have received life-saving renal replacement therapy, either dialysis or transplantation. Currently 350,000 Americans are alive on renal replacement therapy, and 90,000 of these persons have a better quality of life due to a successful kidney transplant (including some 20,000 whose medical condition improved so much that they left the Medicare program).

### III. Improving and Modernizing the Medicare Program

When Congress created Medicare in 1965, it deliberately modeled the new program after the existing private health insurance market, allowing for a remarkably quick and efficient implementation of the program just 11 months later. Medicare's benefit package, administration, and payment methods were modeled on the Blue Cross and Blue Shield plans then prevalent in the private market. Private insurance companies were hired to administer much of the program as contractors.

A health insurance program designed to meet the needs of seniors in 1965 needs regular updating to keep pace with and set the pace for change in the private market. Since 1965, Congress and the President have made numerous changes to Medicare to continue to modernize the program. For example:

• **Eligibility.** The original Medicare program only covered those Americans age 65 and older. Recognizing the significant health

care needs, and the lack of access to private insurance of other groups of Americans, Congress expanded eligibility (in 1972) to include Americans with disabilities and those with end-stage renal disease.

- **Benefits.** Medicare's original benefit package was consistent with medical practices in 1965 with a strong emphasis on inpatient hospital care. Since then, Congress has expanded Medicare several times to include coverage of hospice care and preventive benefits. For example, in 1997, Congress expanded Medicare to include coverage of certain preventive benefits including prostate cancer screening, bone mass density measurement, diabetes self-management, and other services.
- **Payment reforms.** Medicare's original payment mechanisms based on actual costs proved to be highly inflationary because providers were paid for their costs, regardless of their efficiency. Medicare has initiated a series of payment reforms for hospitals, physicians, home health agencies, nursing homes, and HMOs. Many of these innovations have been replicated by the private insurance market to help rein in health costs, making Medicare a widely recognized leader in developing payment systems.
- **Patient protections.** Medicare is a leader in protecting the health, safety and financial security of its beneficiaries. Medicare established strong federal standards for the quality of all hospital, nursing home, and home health care. It has set standards for the sale of private supplemental medical insurance also known as Medigap insurance. Medicare has some of the strongest patient protections for beneficiaries enrolled in HMOs and other managed care plans.

#### IV. Improving the Health Care System

In addition to the improvements Medicare has produced for America's senior citizens and people with disabilities, the program has made a significant contribution to the quality and stability of the American health care system. By providing a stable source of payment for a large segment of the population that has substantial health care needs, Medicare has made a major contribution to the recognized quality of the American health care system, including:

- **Ensuring a revenue base.** Medicare finances a growing share of the nation's health system — up from 11 percent in 1970 to 21 percent today. Medicare provides 32 percent of all hospital revenue in the United States and 22 percent of all spending on physicians' services. The program pays a substantial portion of the revenues of home health agencies, hospices, renal dialysis facilities, and other services.
- **Protecting the "safety net."** Medicare provides special financial support to urban and rural health care providers (such as \$4.6 billion on disproportionate share payments in fiscal year 2000), enabling them to provide free or discounted care to millions of uninsured and underinsured Americans while also serving the needs of Medicare beneficiaries.
- **Training for the future.** Medicare plays an important societal role in financing graduate medical education by paying nearly \$8 billion a year for the costs of training physicians and other health professionals at our nation's academic medical centers.
- **Combating fraud and abuse.** Medicare is a leader in developing systems to detect and prevent fraud and abuse, including Operation

Restore Trust. Last year, the federal government recovered nearly \$500 million as a result of health care prosecutions. Since 1996, aggressive enforcement has recovered nearly \$1.9 billion.

• **Innovative payment systems.** By adopting innovative payment mechanisms such as diagnosis-related groups (DRGs) for hospital payments and resource-based relative value scale (RBRVS) payments to physicians, Medicare has paved the way for significant cost savings and efficiencies in Medicare and in the health care system as a whole. In recent years, Medicare developed new and innovative payment systems for home health services, skilled nursing care, and other outpatient services. Medicare is also a leader in risk-adjustor research for managed care plans.

• **Reducing administrative costs.** Medicare is the single largest health insurer in the United States, yet it operates at the lowest administrative costs of any insurer. Medicare's overhead costs are less than 2 percent, far below the private insurance industry average of 12 percent. In other words, Medicare spends more than 98 cents out of every dollar it receives in tax and premium revenue on health care services for patients. Over the last decade, Medicare Part A claims have doubled and the cost for processing each claim has been cut in half. These administrative savings have been achieved in part by Medicare's leadership in working with health care providers and others to computerize claims payment, which has paved the way for other payers to also computerize their claims payment.

## V. Improving Medicare for the Future

In its first 35 years, Medicare has accomplished a tremendous amount for America's seniors and those with disabilities. In concert with Social Security, Medicare has made a huge difference in the lives of the people of this country. As President Johnson predicted, Medicare has positively affected the lives of not only those it directly serves but millions of other Americans who are the sons and daughters, grandsons and granddaughters, and even the great-grandsons and great-granddaughters of Medicare's beneficiaries.

But Medicare and the people it serves cannot continue to thrive if today's program remains stagnant. Medicare must be continually modernized to meet the needs of our seniors and those with disabilities. Medicare's benefit package is now out of sync with what is covered by today's private insurance market. In particular, the failure to pay for prescription drugs is a departure from the norms of medicine and private insurance. And while Medicare has provided peace of mind to those who are over age 65 or living with disabilities, millions of Americans with significant health care needs—especially early retirees—remain unable to buy affordable insurance.

Though Medicare coverage of preventive services has improved, it lags behind private insurance. In addition, the utilization of preventive services by Medicare beneficiaries remains low, especially among low-income and minority populations. This indicates a need to examine and eliminate any impediments to the use of these important services, including cost-sharing requirements, lack of public awareness, and the need for greater provider education and outreach.

As Medicare enters its 35th year, President Clinton has proposed a series of Medicare reforms that will prepare this vital program and the people it serves for the 21st century. The President's fiscal year 2001 budget dedicates \$378 billion over 10 years to Medicare. This plan makes Medicare more fiscally sound, competitive and efficient, and modernizes the program's benefits by including a prescription drug benefit. The overall plan includes:

- ***Making Medicare more competitive and efficient.*** Since taking office, President Clinton has worked to reduce the rate of growth in Medicare spending; eliminate waste, fraud, and abuse; and extend the life of the Medicare Trust Fund from 1999 to 2025. He has proposed to build on these efforts and save \$38 billion over 10 years by expanding anti-fraud policies and enhancing Medicare's competitiveness and quality.

- ***Dedicating \$115 billion over 10 years to Trust Fund solvency.*** It is impossible to pay for a doubling in Medicare enrollment through provider savings or premium increases alone. To address the future financing shortfall, the budget dedicates \$115 billion of the non-Social Security surplus to Medicare, helping extend the HI Trust Fund to at least 2030 and reducing publicly held debt.

- ***Establishing a voluntary prescription drug benefit.*** The drug benefit, which costs \$253 billion over 10 years, would be accessible and voluntary, affordable for beneficiaries, and competitively and efficiently administered. It would also provide high-quality, necessary medications. No beneficiary would pay more than \$4,000 in out-of-pocket costs for needed drugs.

- ***Improving preventive benefits.*** This proposal would eliminate the existing deductible and copayments for preventive services, such as colorectal cancer screening, bone mass measurements, and mammograms.

- ***Creating health insurance options for people ages 55 to 65.*** The plan would allow people age 62 through 65 and displaced workers ages 55 to 65 to buy into Medicare. It would require employers who drop previously promised retiree coverage to give early retirees with limited alternatives access to COBRA coverage until they are 65 and can qualify for Medicare. To make this policy more affordable, the President proposes a tax credit, equal to 25 percent of the premium, for participants in the Medicare buy-in and a similar credit for COBRA.

## I. A Profile of Medicare and Its Beneficiaries

Today, the Medicare program provides health insurance coverage to a diverse and growing segment of the United States population [Figure 1]. Over its history, the people who are covered under the program have not only expanded in numbers, but have grown more complex in composition and health care needs. More than 19 million elderly entered Medicare in 1966; today, Medicare provides insurance coverage for 34 million elderly, or 97 percent of older Americans. The number of elderly and disabled enrollees has more than doubled to 39.9 million. The Medicare population is expected to grow from 39.9 million enrollees (14 percent of the population) today to more than 77 million in 2030 (22 percent of the population). [Figures 1 and 2].

### Demographic Trends

Because of their longer life expectancy, elderly women outnumber men in the Medicare program by 7 percent. The proportion of female Medicare beneficiaries increases with age: women constitute more than 70 percent of the Medicare population age 85 and older (Medicare Current Beneficiary Survey). Among disabled beneficiaries, however, men outnumber women by 9 percent.

Older women are much more likely to be widowed and live alone than older men due to a number of factors, including women's longer life expectancy, the tendency for women to marry men who are slightly older, and higher remarriage rates for widowed men. Among people age 85 and older, about half of the men were still married, compared with only 13 percent of the women (Forum, 2000).

Among the elderly, 84 percent are Caucasian, 7 percent are African-Americans, 6 percent are Hispanic, and 3 percent make up all other racial and ethnic minority enrollees. Among disabled enrollees, African-Americans make up nearly 17 percent and Hispanics about 11 percent [Figure 3].

The living arrangements of the elderly vary by racial and ethnic group. Older Caucasian women are much less likely to live with other relatives than older minority women (15 percent compared to 30-40 percent) (Forum, 2000). Living alone is a risk factor for nursing home placement as the elderly grow older.

More than 13 percent, or 4.5 million Medicare beneficiaries, are over the age of 85, and more than 70,000 are over the age of 100.

### Economic Status

Although the economic status of the elderly as a group has improved over the past 35 years [Figure 4], most elderly individuals have modest incomes. Correspondingly, most Medicare spending is for beneficiaries with modest incomes: 33 percent of program spending is on behalf of those with incomes of less than \$10,000; 74 percent of program spending is on behalf of those with incomes of \$25,000 or less; but only 10 percent of program spending is on behalf of those with incomes over \$40,000 [Figure 5].

Many elderly Medicare beneficiaries depend on their Social Security benefits for much of their income. The reliance on Social Security income is greater among single seniors and increases dramatically as individuals get older. For example, Social Security benefits represent half of the average 85-year-old's income. In 1998, Social

Security benefits provided about two-fifths of the income of older persons (Forum, 2000).

Nearly 30 percent of Medicare beneficiaries live alone, and beneficiaries who live alone are disproportionately female and poor: 72 percent are women, and 60 percent have incomes under \$15,000. About 15 percent of those who live alone are over the age of 85 [Figure 6].

Because of their low incomes and high medical costs, approximately 6.5 million beneficiaries or about 16.5 percent of the Medicare population are enrolled in both Medicare and Medicaid. Dual-eligible beneficiaries are Medicare beneficiaries who also qualify for Medicaid benefits on the basis of financial need, including those that become eligible as they spend down their income because of high medical costs.

### **Health and Functional Status**

In 1999, nearly 30 percent of the elderly reported that they were in fair or poor health, compared to 17 percent of those ages 45 to 64. The percentage reporting fair or poor health was higher for minority groups and increased with age: about 35 percent of those 85 and older considered themselves in relatively poor health (Health, US, 1999).

Differences in self-reported health status are reflected in Medicare per capita spending. Beneficiaries who reported their health status as poor spent five times as much as the beneficiaries reporting excellent health. Medicare per capita spending also increases as functional status declines. Twice as much is spent on those with one or two limitations in activities of daily living (ADL),

including bathing, dressing, going to the bathroom, or eating, compared to those with no ADL limitations. Beneficiaries with three or more ADL limitations had per capita costs more than three times as high as those with no difficulties with ADLs.

Among the elderly, the incidence of chronic conditions, defined as prolonged illnesses that are rarely cured completely, varies significantly by age and racial group. For instance, about one in every 10 elderly Americans has diabetes. Both the incidence of diabetes and the mortality rates from it are higher for minority groups (Health, US, 1999).

Nearly one in three of the elderly reported limitations with one or more activities of daily living (ADLs). About 11 percent of the elderly reported limitations in instrumental activities of daily living (IADLs). About 30 percent of the disabled Medicare beneficiaries had difficulties with one or more ADLs. The contrast in functional status was more marked in the realm of IADL limitations, with 25 percent of disabled beneficiaries reporting trouble with IADLs, a rate more than twice as high as that of elderly beneficiaries [Figure 7].

### **Medicare Spending**

Medicare benefit spending for fiscal year 1999 is estimated at nearly \$212 billion [Fig. 8]. The largest shares of spending are for inpatient hospital services (48 percent) and physician services (27 percent) [Fig. 9].

In fiscal year 1999, Medicare spent an average of \$5,410 per beneficiary. The amount varied on the basis of eligibility and masked considerable variation across individuals.

A small percentage of beneficiaries account for a disproportionate share of Medicare spending. More than 75 percent of Medicare's payments for elderly and disabled beneficiaries in 1997 were spent on the 15 percent of enrollees who incurred Medicare costs of \$10,000 or more.

Medicare is the single largest source of payment for beneficiary health care costs; it covers about half of the cost of health care [Figure 10]. Many beneficiaries have other insurance (e.g., private Medigap policies, retiree coverage, or Medicaid) to supplement their Medicare benefits [Figure 11]. Supplemental insurance reduces beneficiaries' out-of-pocket expenditures, including Medicare cost-sharing. About 14 percent of Medicare beneficiaries have no supplemental coverage; groups most likely to rely solely on Medicare are the disabled, minorities and those with low incomes.

Despite Medicare benefits and supplemental coverage, health care costs remain a substantial and growing burden for the elderly. Long-term care costs, followed by physician payments and outpatient prescription drug spending, are the three largest sources of out-of-pocket expenses [Figure 12]. The elderly spend a higher proportion of their income on health than the general population, both because they have higher health care costs (on average four times that of the under age 65 population) and because they have lower incomes. Lower-income seniors spend a higher proportion of their income on health than higher-income elderly [Figure 13].

The vast majority of Medicare beneficiaries (83 percent) rely on Medicare's traditional fee-for-service benefits, while 17 percent are enrolled in Medicare + Choice plans. Nearly 70 percent of beneficiaries have the option of joining at least one managed care plan in their area [Figure 14]. Over the decade of the 1990s, Medicare enrollment grew rapidly in managed care plans; such growth has slowed in more recent years [Figure 15].

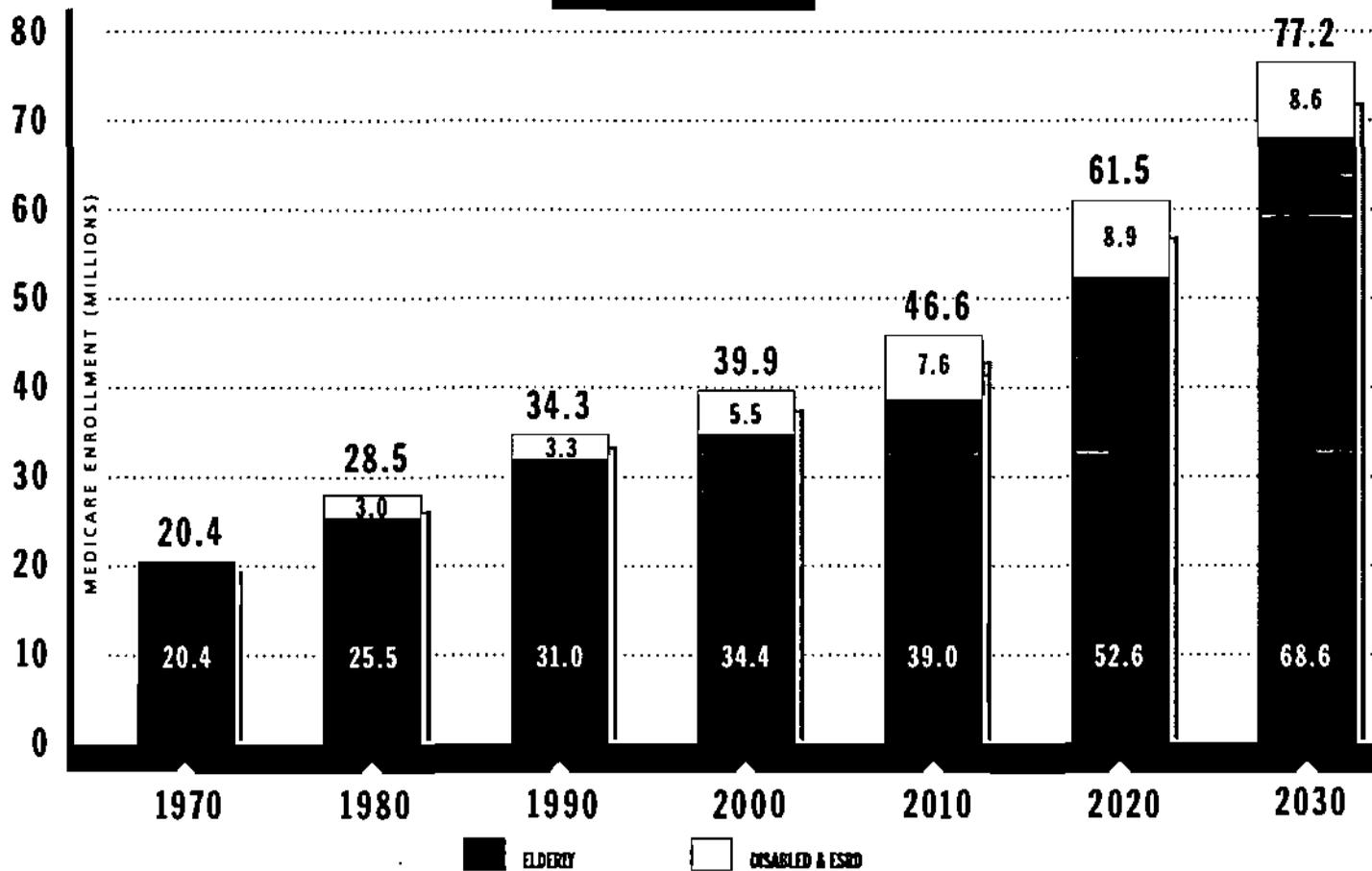
Most Medicare beneficiaries, whether enrolled in fee-for-service or a Medicare + Choice plan, say they are satisfied with their medical care [Figure 16].

Medicare spending growth has often been compared to that of the private sector. Over the life of the program, both Medicare and private health insurance have grown at similar rates [Figure 17]. However, during selected periods, they have often grown at different rates [Figure 18].

# Number of Medicare Beneficiaries, CY 1970-2030

*The number of Medicare beneficiaries will nearly double by 2030.*

**FIGURE 1**

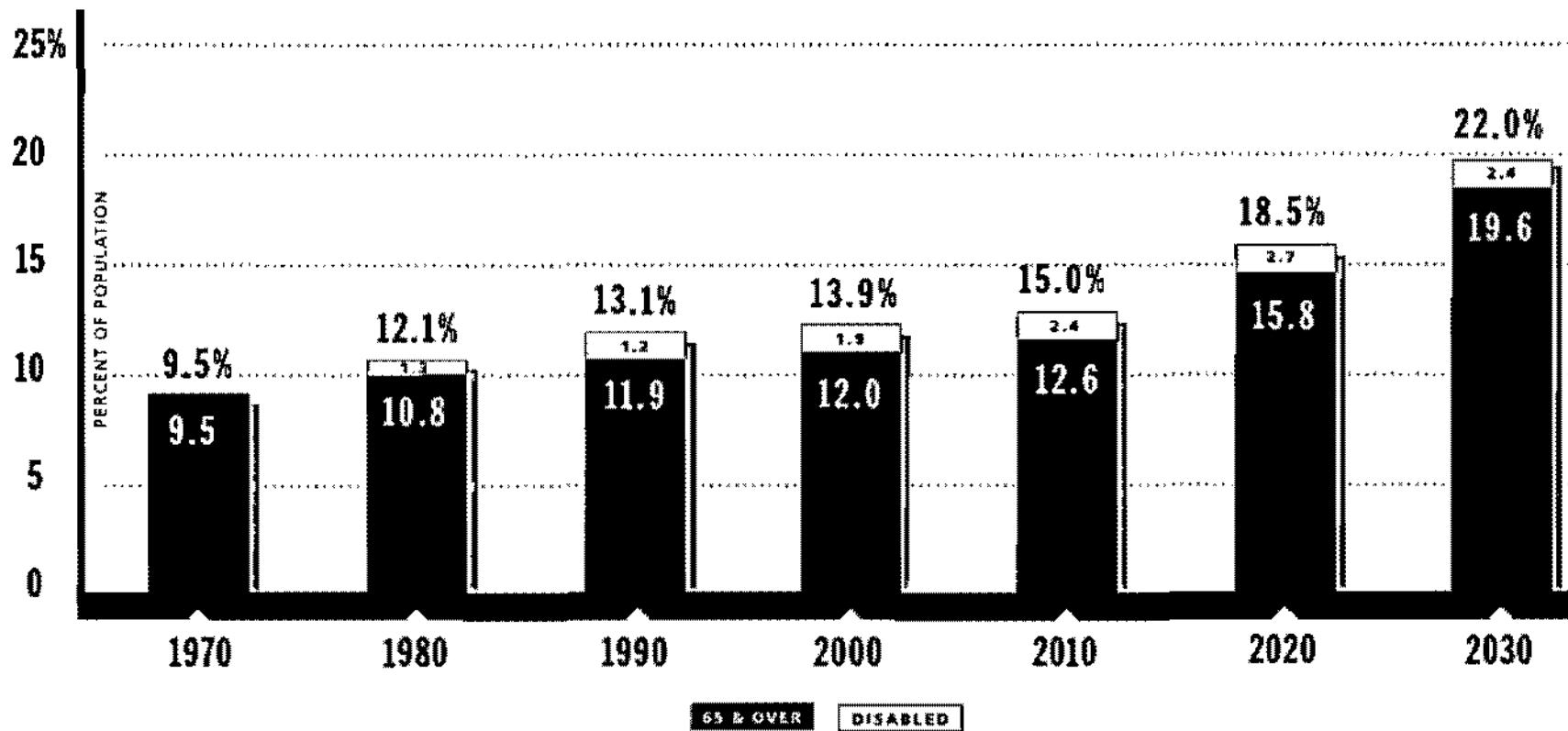


SOURCE: HCFA/OFFICE OF THE ACTUARY.

# The Aging of the U.S. Population, 1970 - 2030

*The U.S. population will age rapidly through 2030, when 22 percent of the population will be eligible for Medicare.*

FIGURE 2

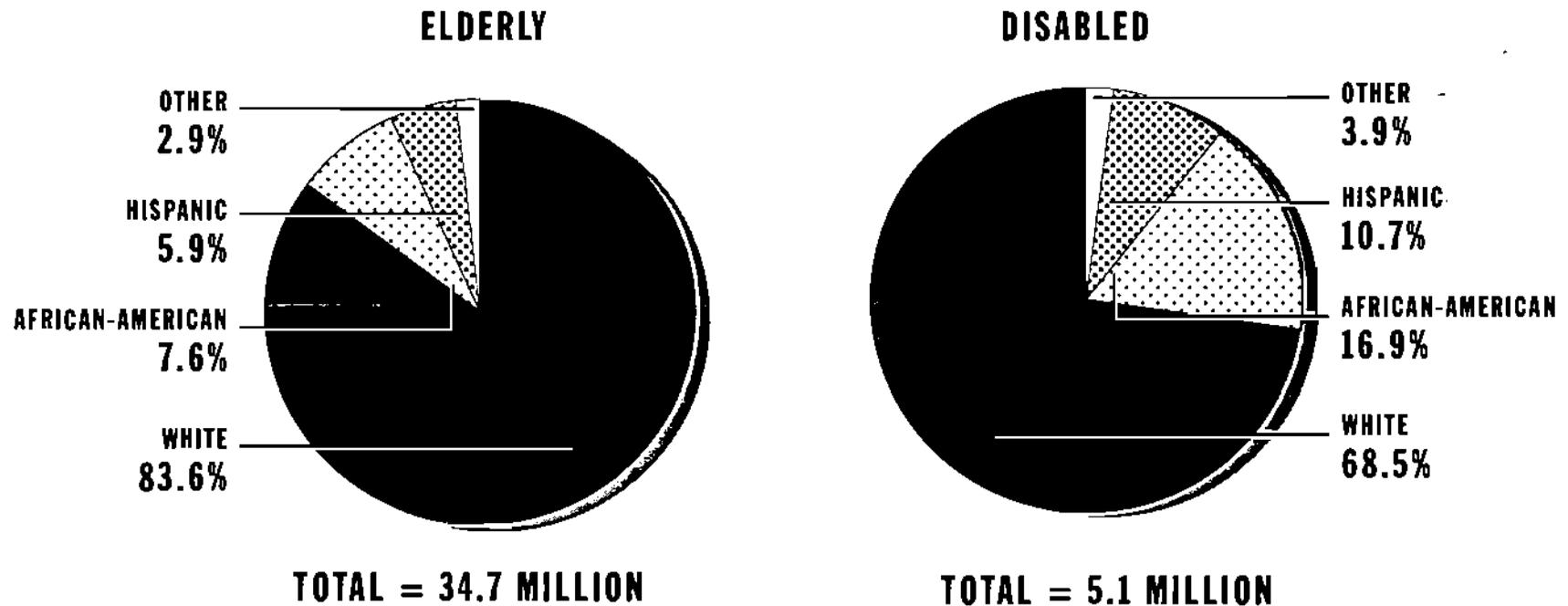


SOURCE: SOCIAL SECURITY ADMINISTRATION/OFFICE OF THE ACTUARY.

# Race/Ethnicity Distribution of Medicare Beneficiaries, 1998

*African-American and Hispanic beneficiaries are disproportionately represented among the disabled.*

FIGURE 3

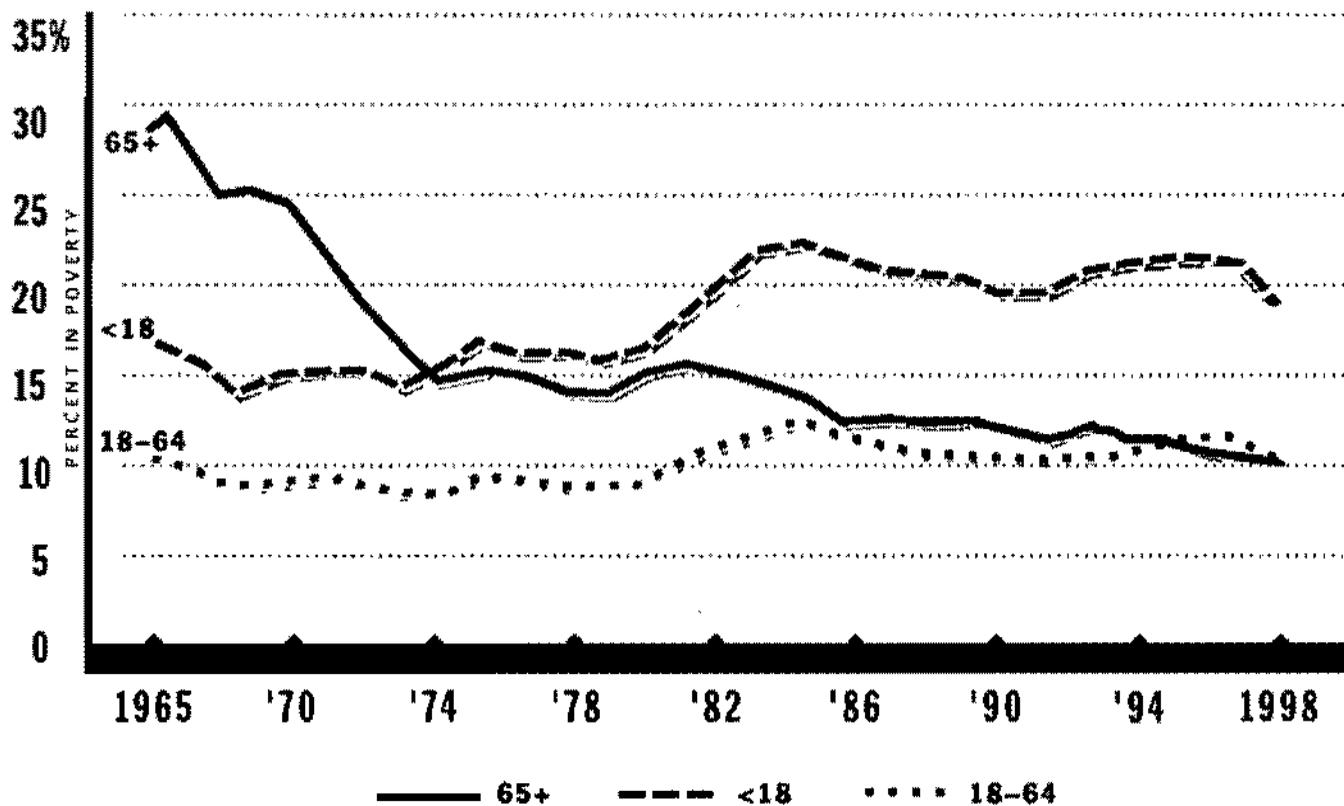


SOURCE: NCFA/OFFICE OF STRATEGIC PLANNING: DATA FROM THE MEDICARE CURRENT BENEFICIARY SURVEY.

# Poverty Rates by Age, 1965-1998

*Improvements in Social Security and private pension coverage are important factors in the decline of the elderly's poverty rate.*

**FIGURE 4**

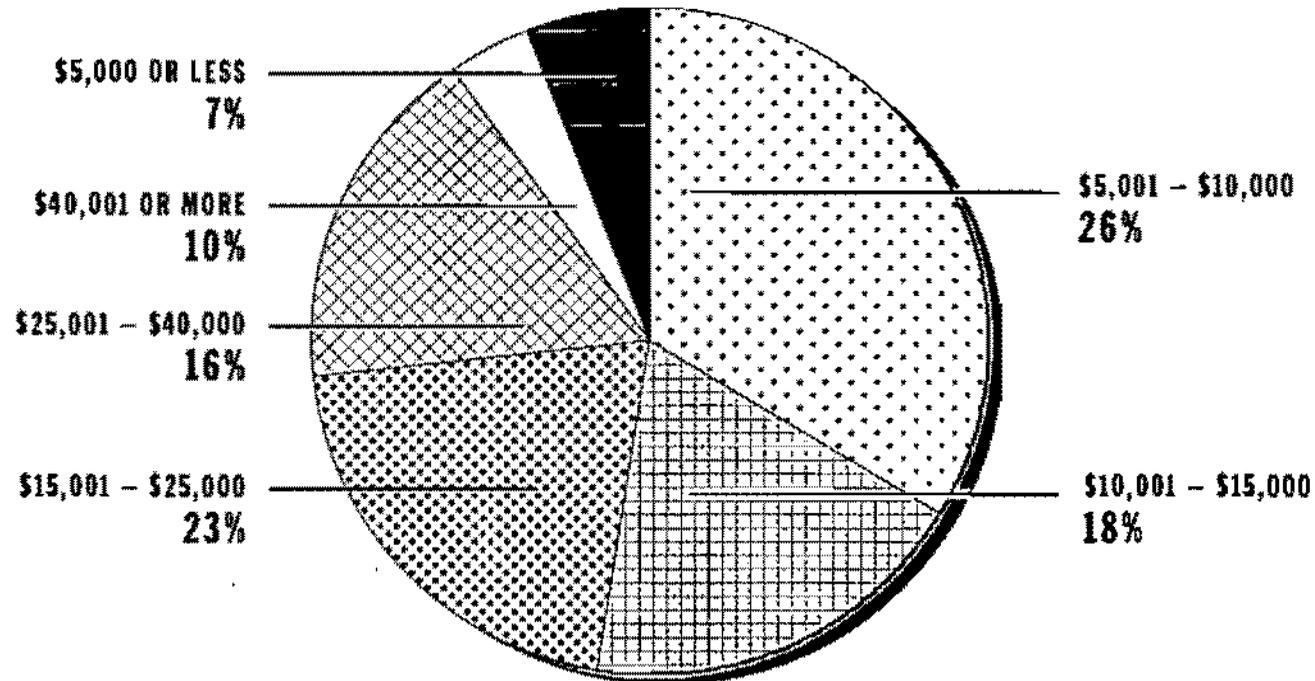


SOURCE: US DEPARTMENT OF COMMERCE/BUREAU OF THE CENSUS, 1999.

# Medicare Spending for Fee-for-Service Beneficiaries by Income, 1997

*Seventy-four percent of Medicare expenditures are on behalf of individuals with annual incomes of \$25,000 or less.*

**FIGURE 5**

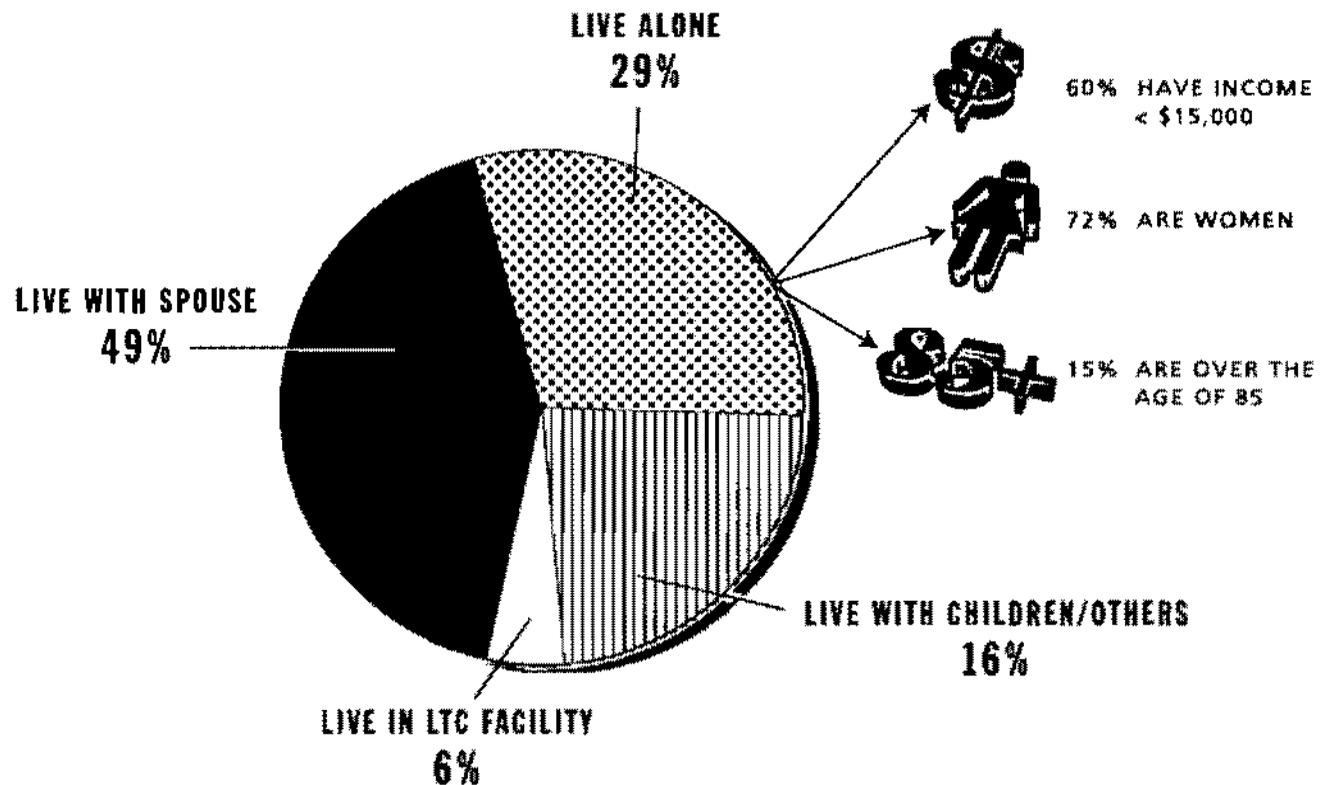


SOURCE: HCFA/OFFICE OF STRATEGIC PLANNING; DATA FROM THE MEDICARE CURRENT BENEFICIARY SURVEY.

# Living Arrangements of Medicare Beneficiaries, 1998

Nearly 30 percent of Medicare beneficiaries live alone.

FIGURE 5

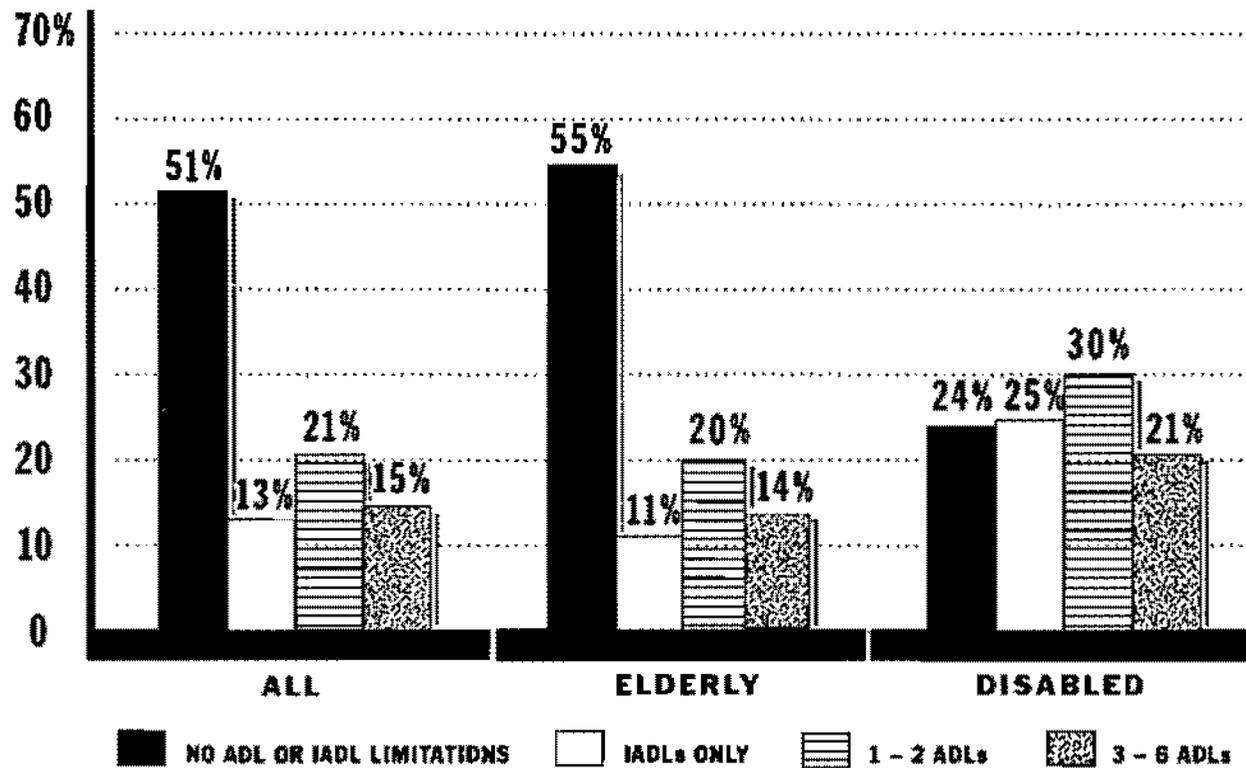


SOURCE: HCFA/OFFICE OF STRATEGIC PLANNING: DATA FROM THE MEDICARE CURRENT BENEFICIARY SURVEY.

# Distribution of Medicare Enrollees by Functional Status, 1998

*More than one-third of the Medicare population needs assistance with at least one "activity of daily living."*

FIGURE 7

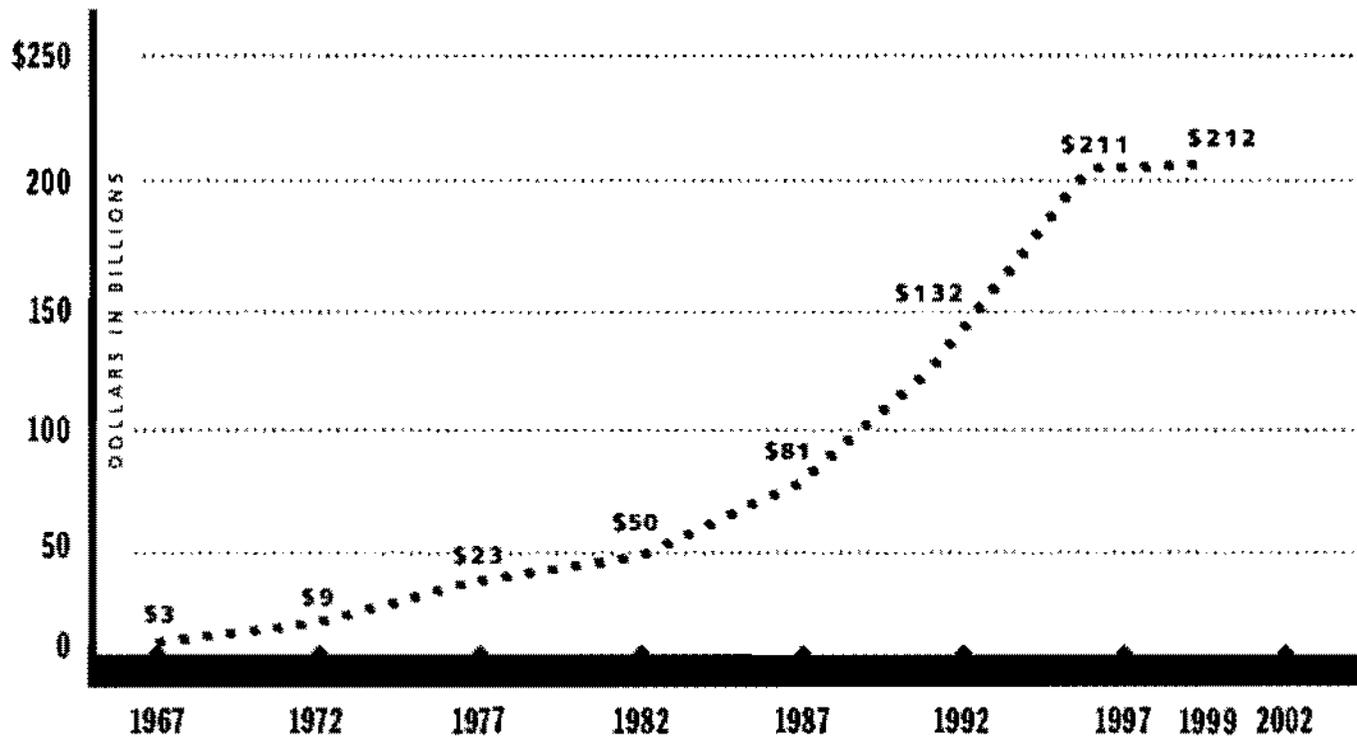


NOTE: ADL—ACTIVITIES OF DAILY LIVING (E.G., EATING, BATHING)  
 IADL—INSTRUMENTAL ACTIVITIES OF DAILY LIVING (E.G., SHOPPING, USE OF PHONE, CLEANING)  
 SOURCE: HCFA/OFFICE OF STRATEGIC PLANNING: DATA FROM THE MEDICARE CURRENT BENEFICIARY SURVEY.

# Medicare Spending, FY 1967 - 1999

Medicare spending grew from \$3.3 billion in 1967 to nearly \$212 billion in 1999.

FIGURE 8

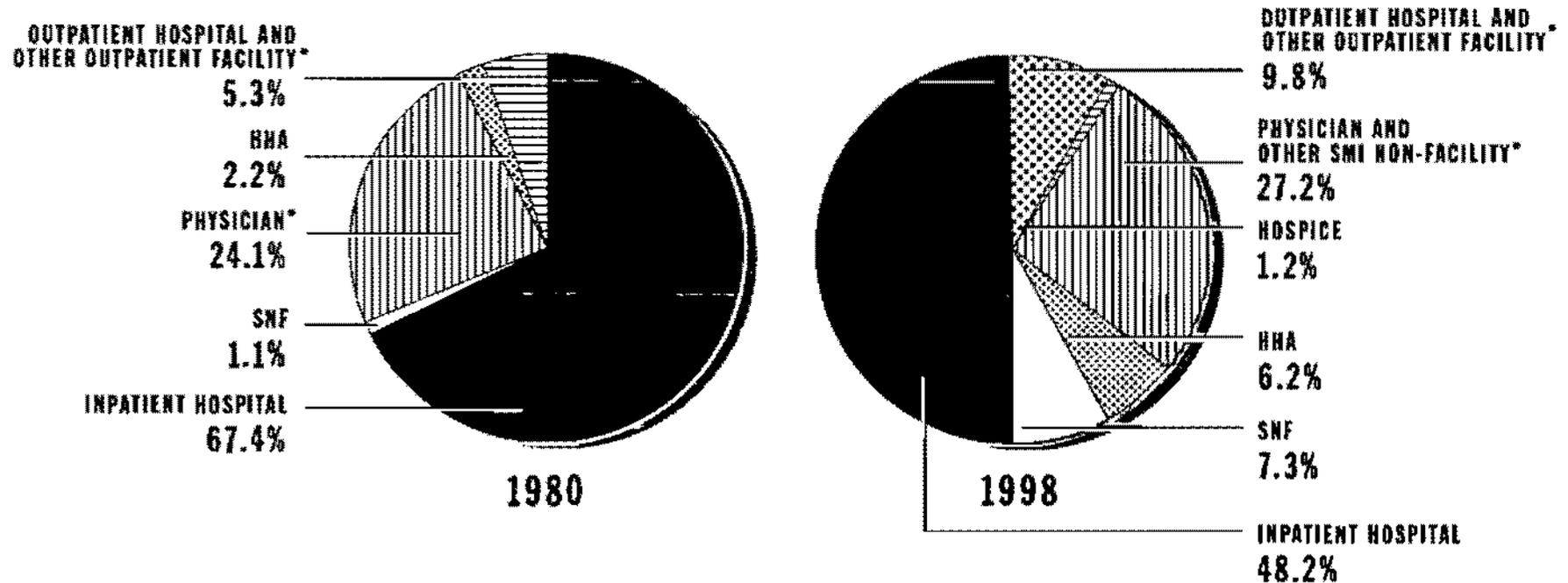


SOURCE: HCFA/OFFICE OF THE ACTUARY

# Where the Medicare Dollar Went, 1980 and 1998

Medicare spending is shifting away from inpatient hospital services toward outpatient services and other providers.

FIGURE 9



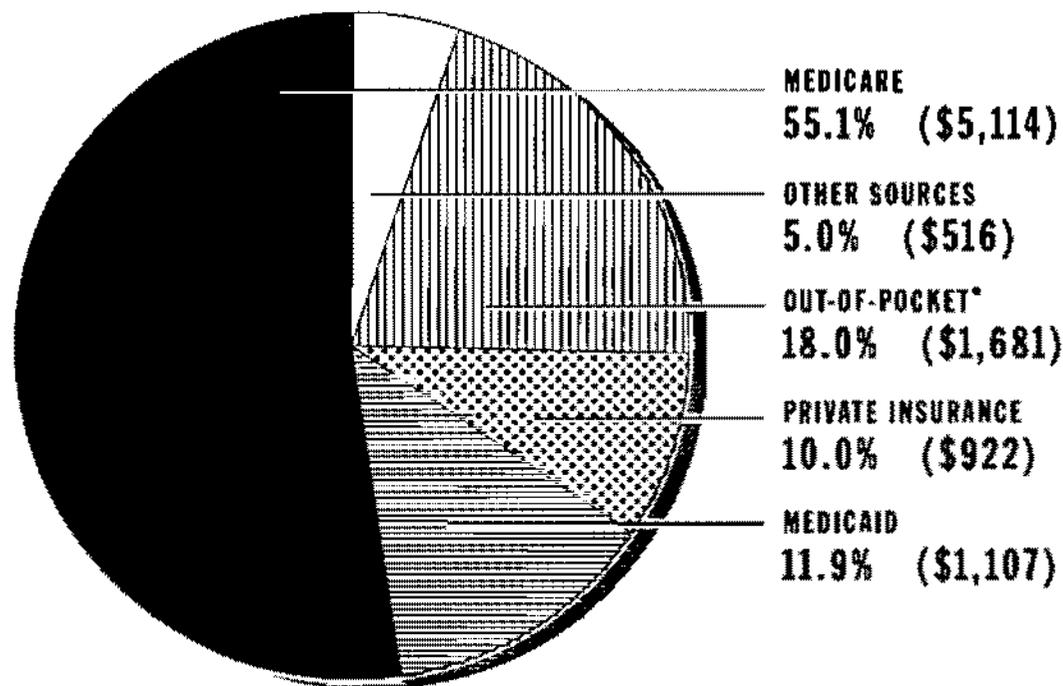
\* THE DEFINITION OF THESE CATEGORIES HAS CHANGED OVER TIME, SO THEY ARE NOT DIRECTLY COMPARABLE OVER THE PERIOD.

SOURCE: HCFA/OFFICE OF THE ACTUARY. MANAGED CARE SPENDING IS INCORPORATED WITHIN THE CATEGORIES.

# Sources of Payment for Medicare Beneficiaries' Use of Medical Services, 1997

*Medicare pays more than half of the total cost of beneficiaries' medical care.*

FIGURE 10



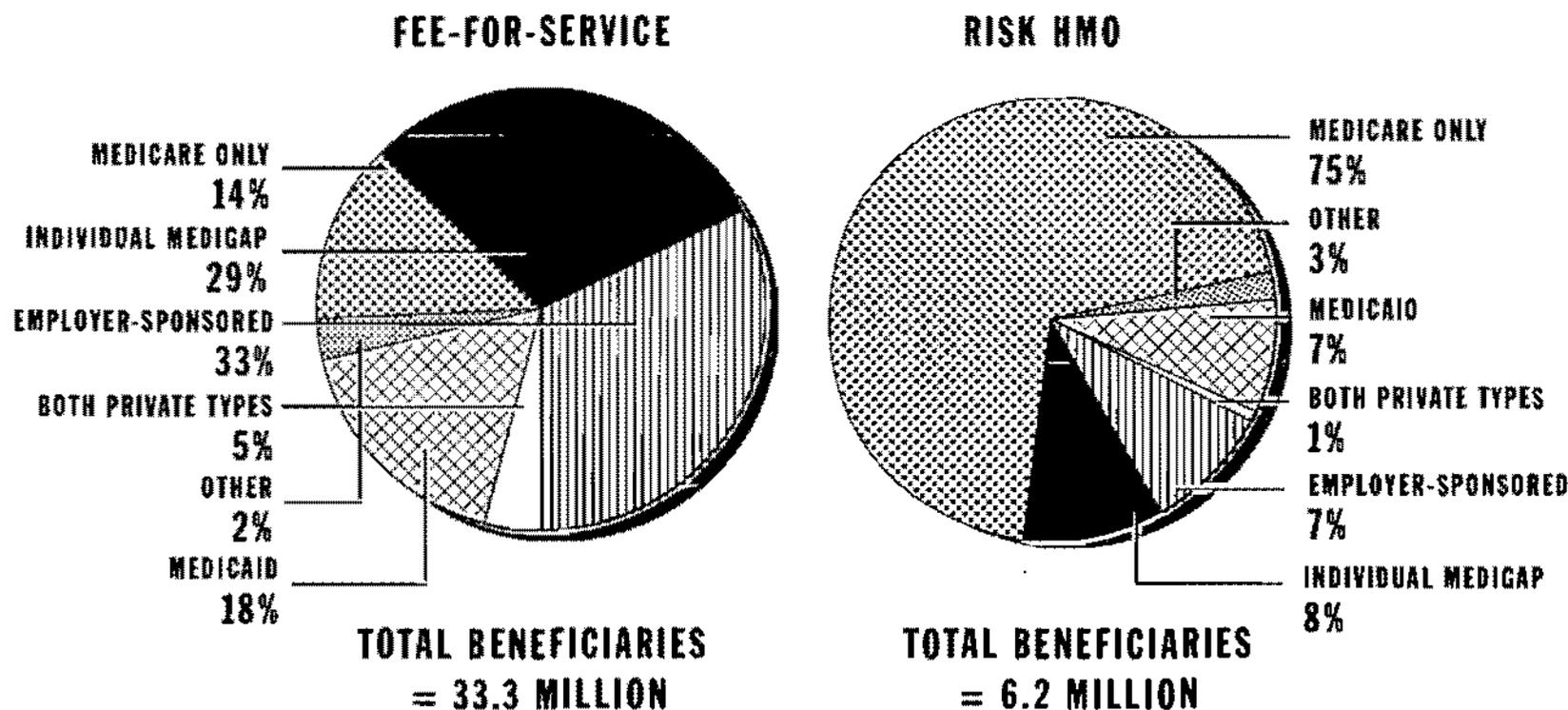
**TOTAL AVERAGE SPENDING PER BENEFICIARY – \$9,340**

\*NOTE: BENEFICIARY OUT-OF-POCKET SPENDING DOES NOT INCLUDE THEIR PAYMENTS FOR MEDICARE PART B PREMIUMS, PRIVATE INSURANCE PREMIUMS, OR HMO PREMIUMS.  
SOURCE: HCFA/OFFICE OF STRATEGIC PLANNING; DATA FROM THE MEDICARE CURRENT BENEFICIARY SURVEY.

# Type of Supplemental Health Insurance Held by Medicare Beneficiaries, 1998

*Most beneficiaries using fee-for-service Medicare have private, supplemental health plans; however, most elderly beneficiaries enrolled in managed care plans have no other supplemental coverage.*

**FIGURE 11**

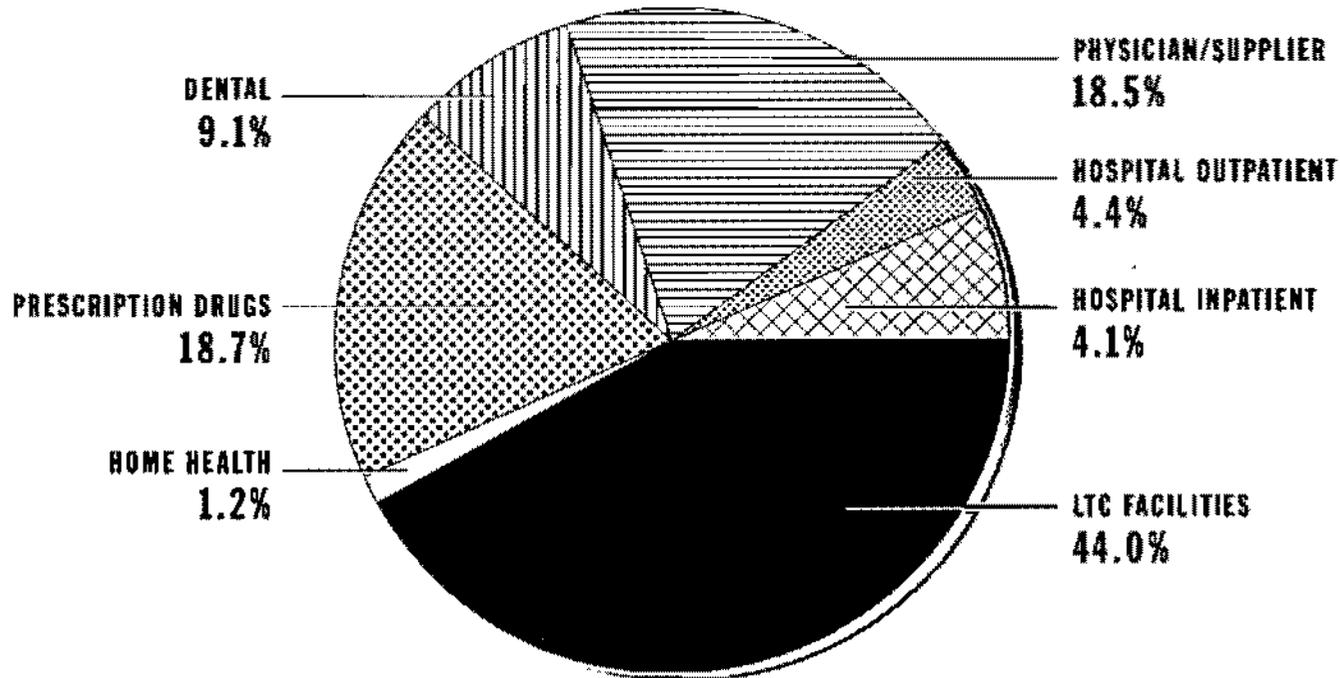


SOURCE: HCFA/OFFICE OF STRATEGIC PLANNING: DATA FROM THE MEDICARE CURRENT BENEFICIARY SURVEY.

# Distribution of Beneficiary Out-of-Pocket\* Expenses, 1997

*Institutional long-term care (LTC) services account for the highest share of beneficiary out-of-pocket payments, followed by outpatient prescription drugs and physician services.*

FIGURE 12



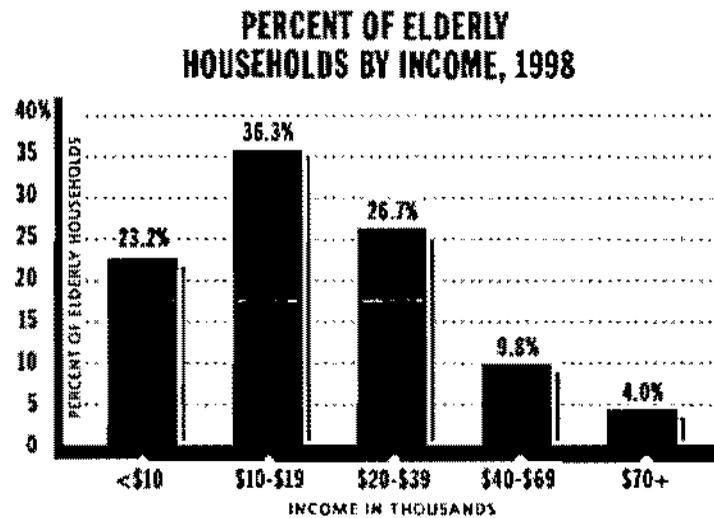
**TOTAL OUT-OF-POCKET EXPENDITURES = \$66.8 BILLION**

\*NOTE: BENEFICIARY OUT-OF-POCKET SPENDING DOES NOT INCLUDE THEIR PAYMENTS FOR MEDICARE PART B PREMIUMS, PRIVATE INSURANCE PREMIUMS, OR HMO PREMIUMS.  
SOURCE: HCFA/OFFICE OF STRATEGIC PLANNING: DATA FROM THE MEDICARE CURRENT BENEFICIARY SURVEY.

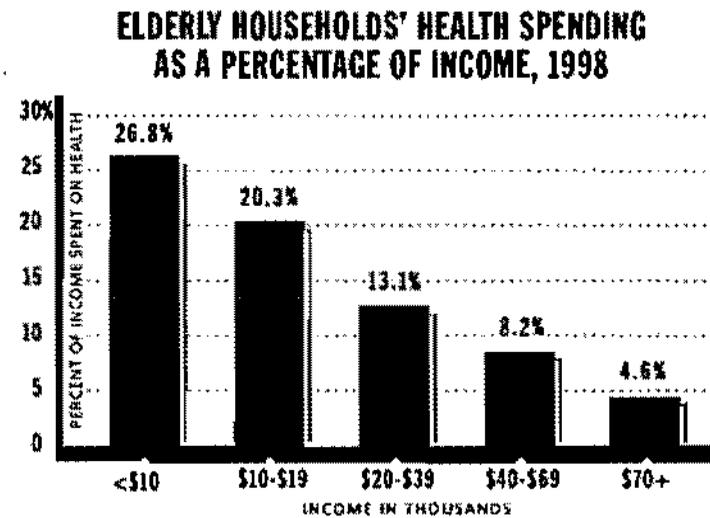
# Elderly Health Spending as a Percentage of Income, 1998

*Most elderly households have incomes below \$40,000 and spend a greater percentage of their income on health than more affluent elderly households.*

FIGURE 13



**MOST ELDERLY HOUSEHOLDS HAVE INCOMES BELOW \$40,000**



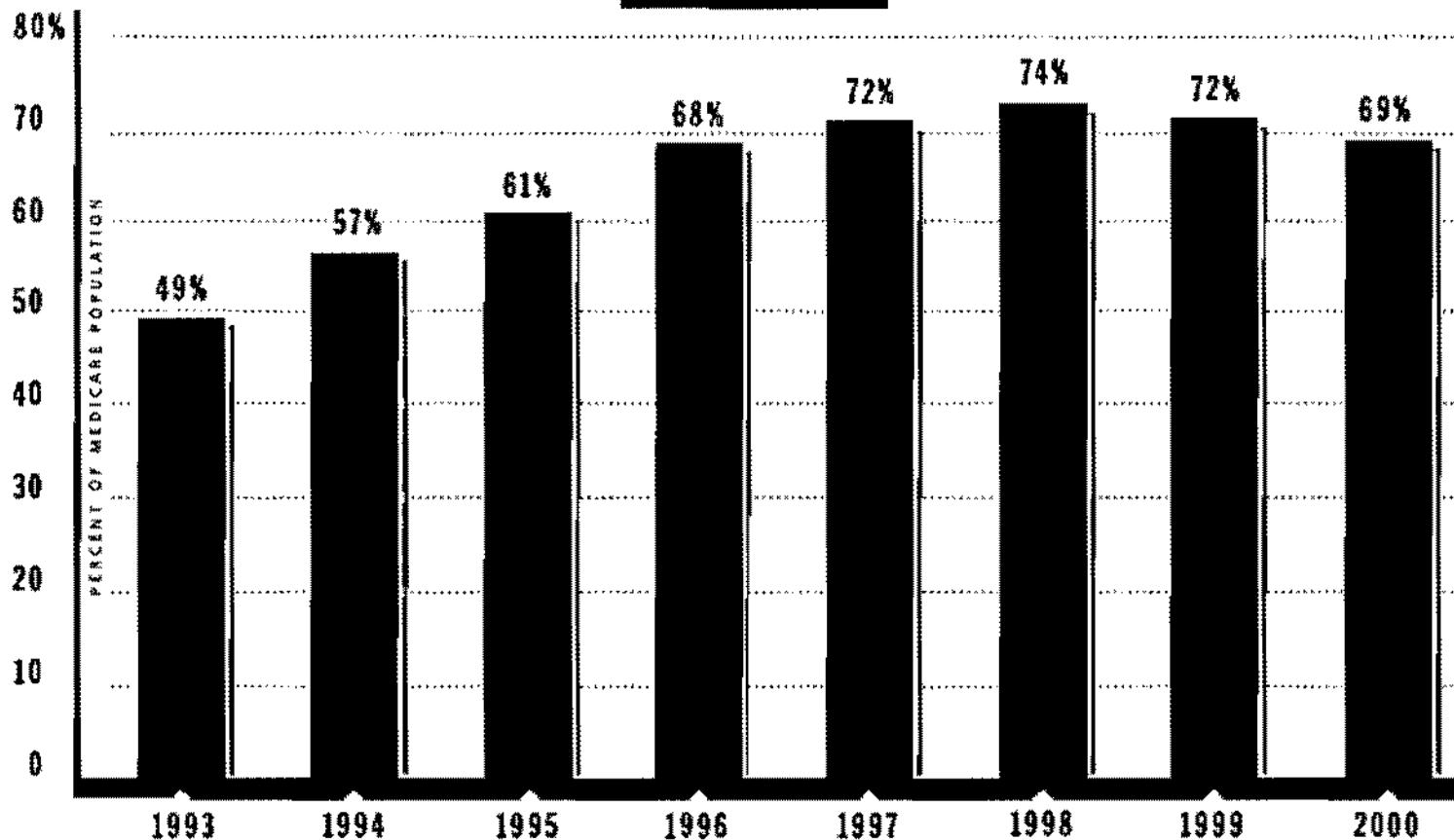
**THE ELDERLY POOR SPEND A GREATER PROPORTION OF THEIR INCOME ON HEALTH**

SOURCE: HCFA/OFFICE OF THE ACTUARY: DATA FROM THE BUREAU OF LABOR STATISTICS, CONSUMER EXPENDITURE SURVEY, 1997-98.

# Percent of Medicare Population with Access to At Least One Medicare Risk/M+C Plan, 1993-2000

Medicare beneficiary access to health plans increased by 20 percentage points from 1993 to 2000.

FIGURE 14



SOURCE: OMF ANALYSIS OF ENROLLMENT AND SERVICE AREA; DATA FROM MCHA PLAN INFORMATION CONTROL SYSTEM. MAY DIFFER FROM ANALYSES BASED ON MEDICARE COMPANY DATA.

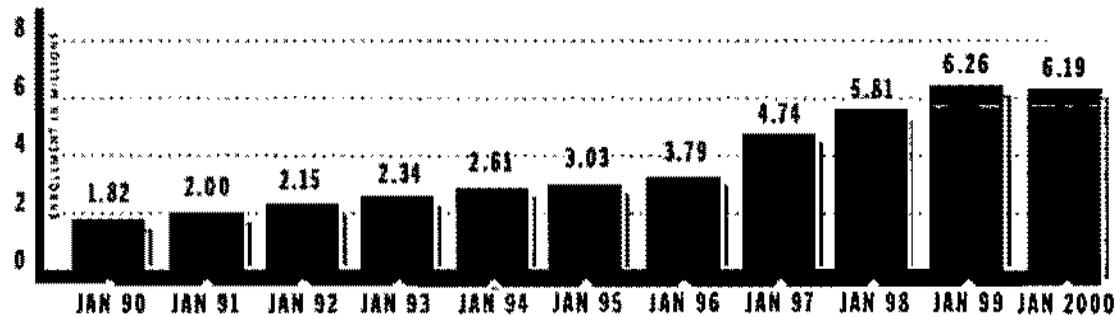
NOTE: ACCESS IS DEFINED AS AT LEAST ONE AVAILABLE PLAN IN THE COUNTY WHERE THE BENEFICIARY RESIDES.

# HMO Enrollment Growth, Medicare and Non-Medicare, 1990-1999

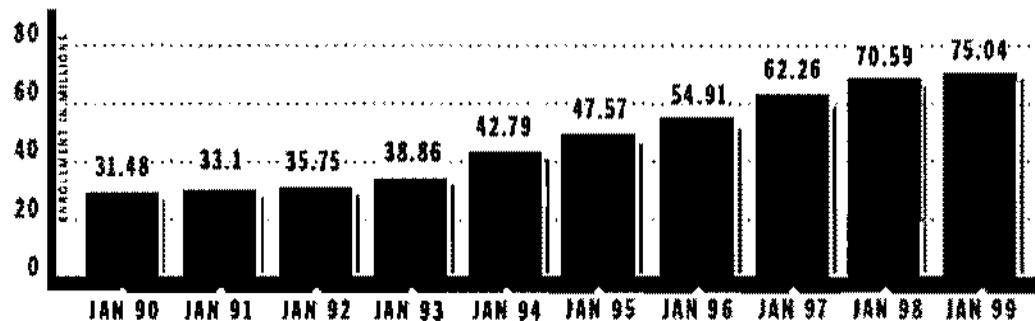
*Enrollment in each sector grew in this decade. Medicare enrollment increased rapidly through 1998 and in most of the 1990s, but has declined slightly since then.*

**FIGURE 16**

## MEDICARE ENROLLMENT IN HMOs



## NON-MEDICARE ENROLLMENT IN HMOs

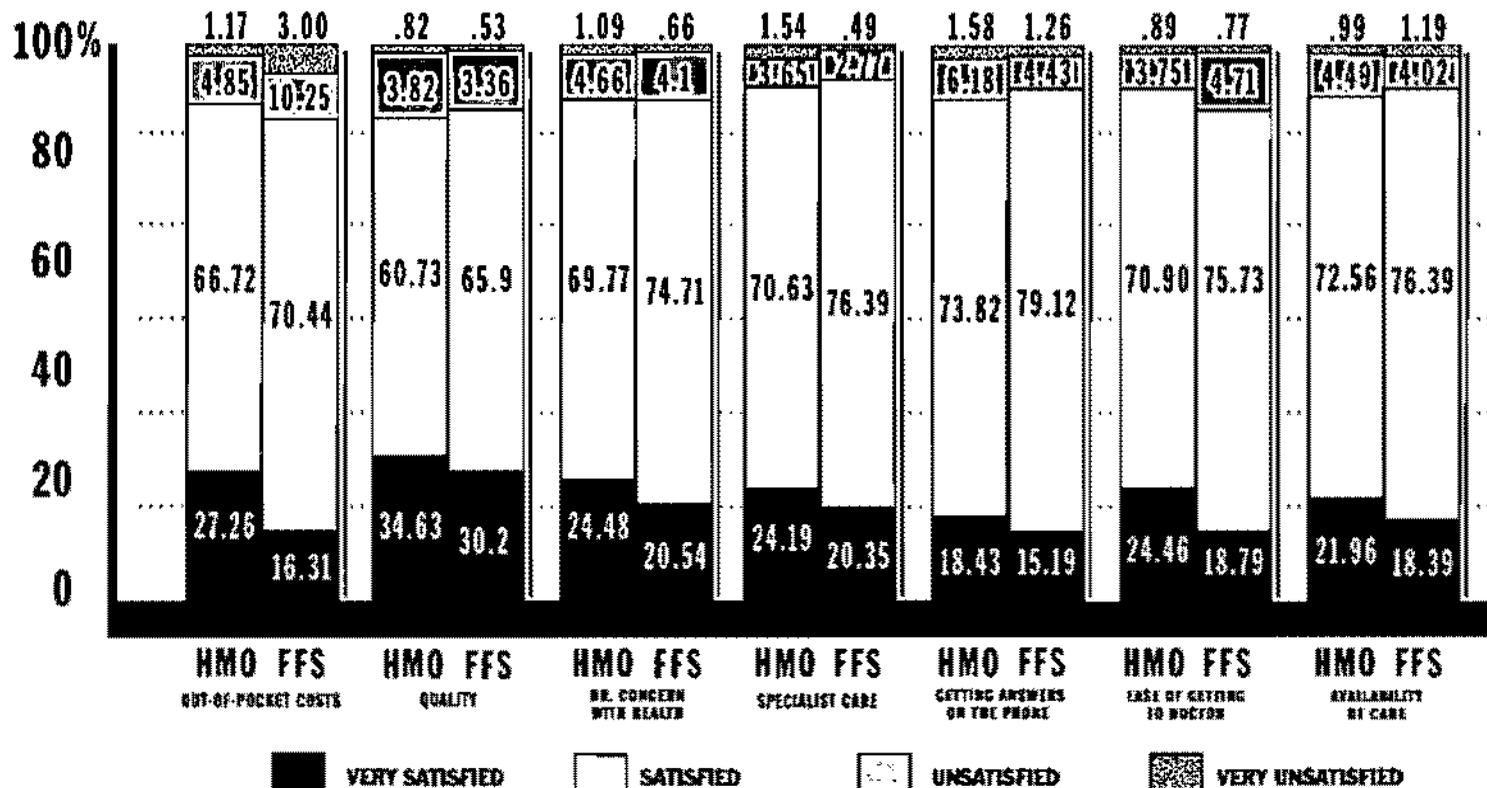


**SOURCE:** INTERSTUDY; HCFA ENROLLMENT DATA. MEDICARE ENROLLMENT NUMBERS ARE FOR DECEMBER OF THE PRECEDING YEAR, EXCEPT IN 1999, WHEN JANUARY 1999 DATA ARE USED. NON-MEDICARE NUMBERS ARE INTERSTUDY JANUARY NUMBERS, LESS MEDICARE NUMBERS.

# Beneficiary Attitudes Toward HMOs and Fee-for-Service, 1998

Medicare beneficiaries in managed care and fee-for-service have high levels of satisfaction with their health care.

FIGURE 16

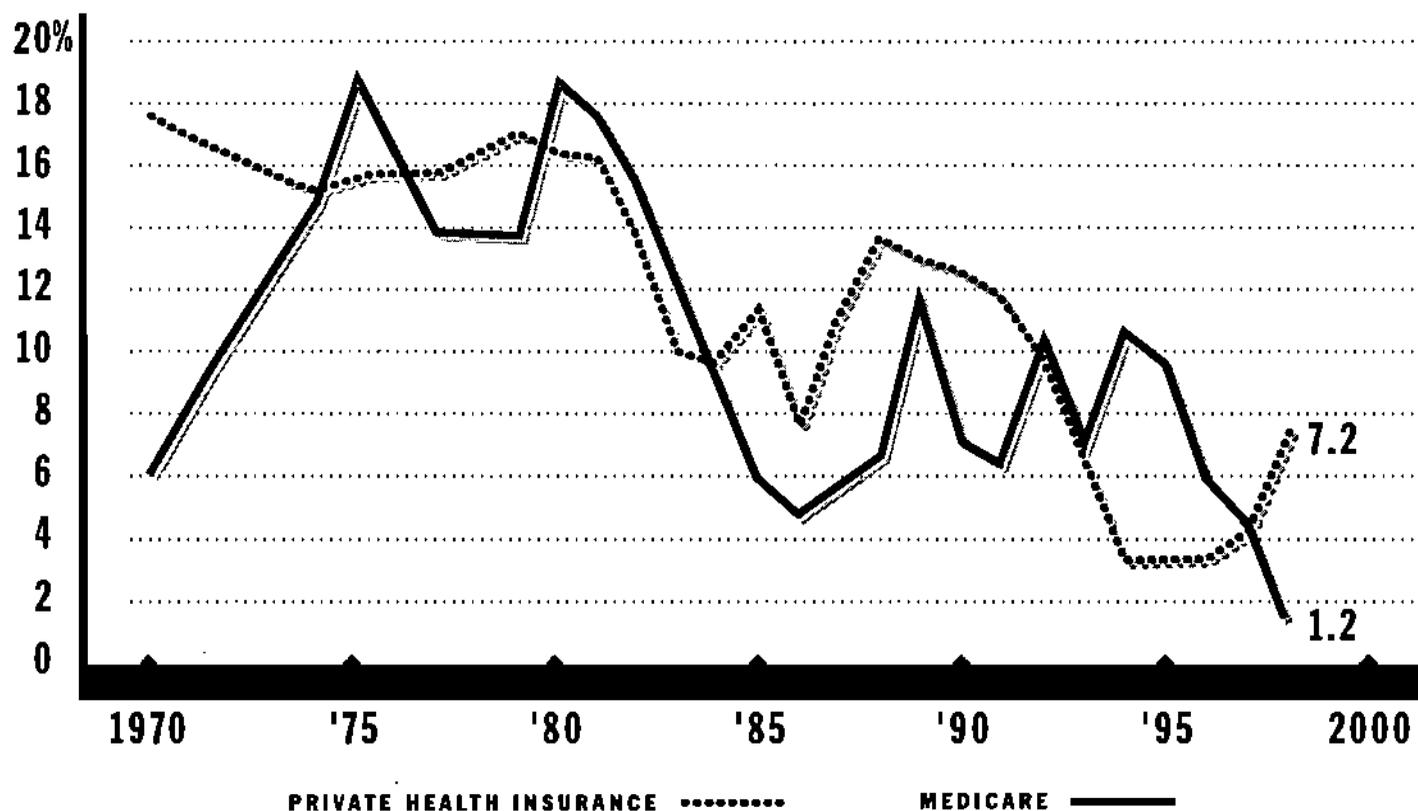


SOURCE: HCFA/OFFICE OF STRATEGIC PLANNING; DATA FROM THE MEDICARE CURRENT BENEFICIARY SURVEY.

# Rate of Growth in Per Enrollee Medicare and Private Health Insurance Benefits Spending, 1970-1998

Medicare and private health insurance are the two largest payers of health care. In 1998, benefits per enrollee under Medicare increased 1.2 percent, while those under PHI increased 7.2 percent. This represents a reversal of trends experienced from 1992-1997.

FIGURE 17

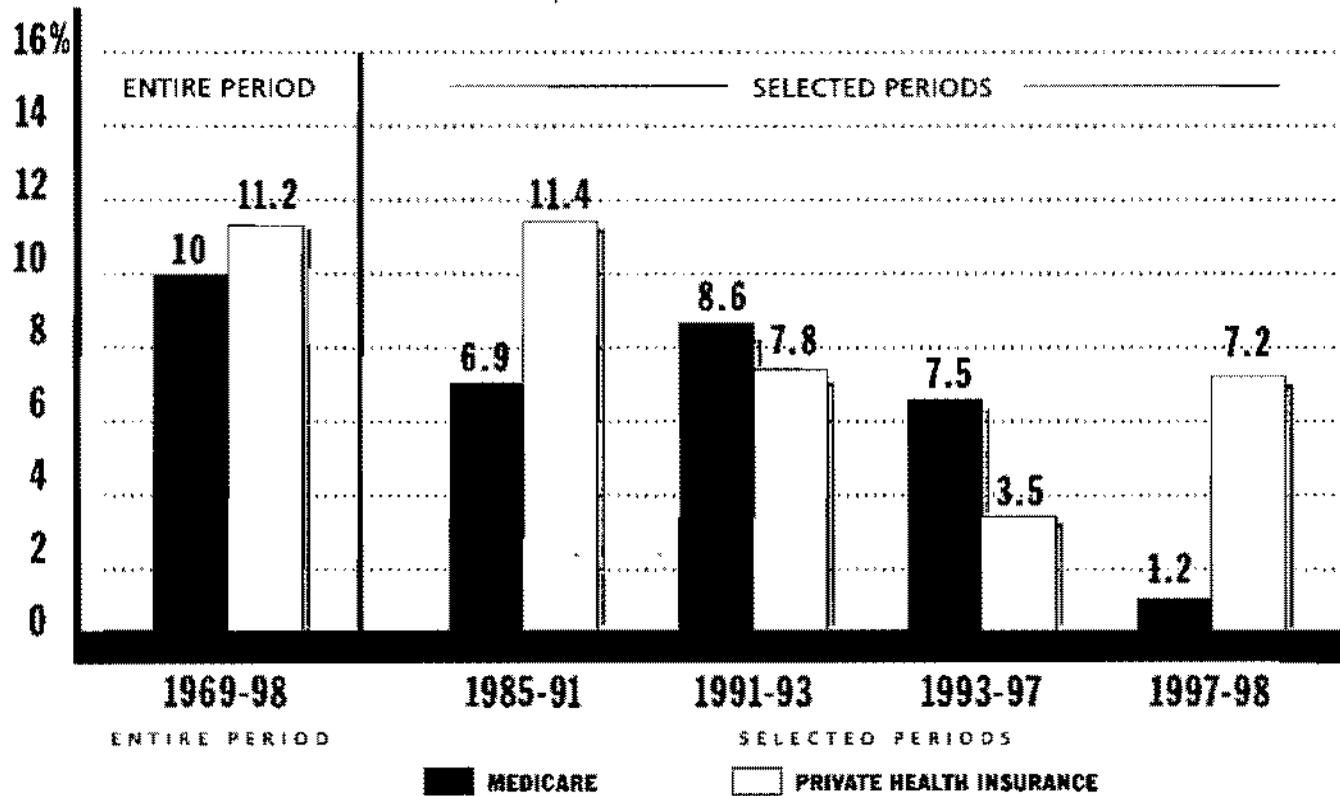


SOURCE: HCFA/OFFICE OF THE ACTUARY.

# Average Growth in Per Enrollee Medicare and Private Health Insurance Spending, Selected Periods

Over the 1969-98 period, Medicare and PHI benefits have grown at similar rates, 10 percent and 11.2 percent respectively. During selected periods, however, the growth rates have differed dramatically.

FIGURE 16



SOURCE: HCFA/OFFICE OF THE ACTUARY.

## ii. Improving the Lives of Seniors and the Disabled

*"If it was not for Medicare, I could not go to the doctor."*

Medicare beneficiary, Medicare Current Beneficiary Survey, 1999

### Medicare Has Dramatically Increased Insurance Coverage

Prior to Medicare's enactment, about half of America's seniors did not have hospital insurance. By contrast, 75 percent of adults under 65 had such coverage, primarily through their employer. For the uninsured, needing hospital services could mean going without health care or turning to family, friends and charity to cover medical bills. More than one in four elderly were estimated to have gone without medical care due to cost concerns (Harris, 1966). Today, Medicare covers nearly all of the elderly (approximately 97 percent), making them the population group most likely to have health insurance coverage.

### Medicare Has Helped to Increase Life Expectancy

In 1960, a 65-year-old American woman could expect to live an additional 15.9 years to reach the age of 80.9 years. In that same year, a 65-year-old man could expect to live an additional 12.9 years to the age of 77.9. Today, the average life expectancy of an American woman over the age of 65 has grown nearly 20 percent to 84.2 years and the average 65-year-old man can live to the age of 80.9 [Figure 19].

### Medicare Has Improved Access to Care

Medicare quickly expanded access to care for the elderly. Hospital discharges averaged 190 per 1,000 elderly in 1964 and 350 per 1,000 by 1973; the proportion of elderly using physician services jumped from 68 to 76 percent between 1963 and 1970. Currently, more than 94 percent of elderly beneficiaries receive a health care service paid for by Medicare.

### Medicare Has Improved Quality of Life

Medicare coverage has allowed the elderly to have access to many of the improvements made in medicine over the past 35 years. For example, cataract surgery means that vision can be restored, artificial hips and other joints mean that mobility can be retained, cardiac bypass and transplant surgery mean that life itself can be extended. Medicare's coverage of expensive procedures means that they are widely available. Rates for certain procedures have grown rapidly: angioplasty rose from 1.3 per 1,000 in 1986 to 8.4 per 1,000 in 1998; heart bypass surgery grew from 2.7 per 1,000 in 1986 to 4.8 per 1,000 in 1998. Mortality following a hospital admission for a heart attack has dropped from 24 percent in 1986 to 16 percent in 1998.

### Medicare Has Saved Millions from Poverty

In 1965, the elderly were the group most likely to be living in poverty—nearly one in three seniors were poor [Figure 4]. Today, the poverty rate for the elderly is similar to that of the 18-64 year old group—about one in 10 is poor. Before Medicare was enacted, the elderly paid 53 percent of the cost of their health care. That share dropped to 29 percent in 1975, and 18 percent in 1997. The

elderly's health costs consumed 24 percent of the average Social Security check shortly before Medicare was enacted; by 1975, that share dropped to 17 percent (Gomiek, 1976).

### **Medicare Has Improved Access to Care for Minorities**

Before Medicare, segregation policies and practices in many parts of the country denied African-Americans and members of other racial and ethnic minority groups access to the same health care as Caucasians. Medicare required hospitals participating in the program to be open to people of all races, and more than 1,000 government officials worked with hospitals to ensure that discrimination practices ceased before hospitals were allowed to participate in Medicare. In 1963, minorities age 75 years and older averaged 4.8 visits to the doctor; by 1971, their visits grew to 7.3, comparable to Caucasian utilization rates. Today, Medicare serves 7.3 million African-American, Hispanic, Asian and other minority seniors, and people with disabilities.

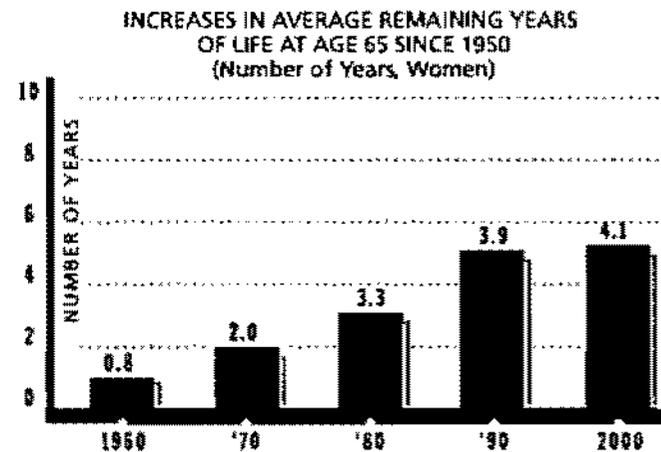
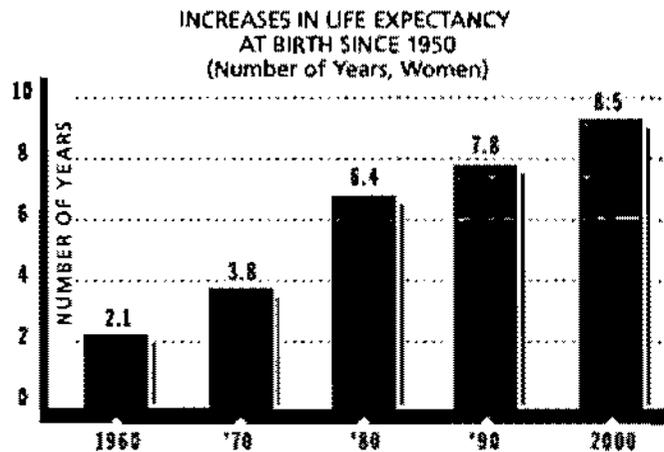
### **Medicare Has Helped Disabled Americans**

In 1972, Congress extended Medicare coverage to disabled people on Social Security Disability Insurance (SSDI) and those with end-stage renal disease (ESRD). In 1973, nearly 2 million persons with disabilities were enrolled in Medicare. Today, more than 5 million such Americans are enrolled in Medicare. Since the beginning of the ESRD program in 1973, over 1 million Americans have received life-saving renal replacement therapy (either dialysis or transplantation). Currently there are more than 350,000 persons alive on renal replacement therapy, and 90,000 of these persons have a better quality of life due to a successful kidney transplant.

# Life Expectancy at Birth and Average Remaining Years of Life at Age 65, 1950 - 2030

Over the past three decades, there has been significant progress in increasing life expectancy in the U.S.

FIGURE 19



LIFE EXPECTANCY AT BIRTH		
YEAR	MEM	WOMEN
1950	65.8	71.1
1960	68.7	73.2
1970	67.2	74.9
1980	69.9	77.5
1990	71.8	78.9
2000	73.9	79.5
2010	75.4	80.4
2020	76.4	81.1
2030	77.4	82.0

LIFE EXPECTANCY AT AGE 65		
YEAR	MEM	WOMEN
1950	12.8	15.1
1960	12.9	15.9
1970	13.1	17.1
1980	14.8	18.4
1990	16.8	19.0
2000	18.8	19.2
2010	19.4	19.4
2020	19.8	19.8
2030	17.8	20.4

SOURCE: SOCIAL SECURITY ADMINISTRATION/OFFICE OF THE ACTUARY.

### III. Improving and Modernizing the Medicare Program

Medicare's original benefit package, administration and payment methods were modeled on the private sector insurance plans prevalent at the time, such as Blue Cross and Blue Shield plans (Ball, 1995). Private insurance companies served as intermediaries to do the actual work of bill payment and to be Medicare's contact point with health care providers. To ensure Medicare beneficiaries would have access to care on the same terms as the privately insured population, payment methods for hospitals, nursing homes and home health facilities were based on reasonable costs. Also, payments for physicians and other suppliers were based on the lower of the area's prevailing rates or their own customary or actual charge.

The health care marketplace in 1965 was quite different from that of today. For instance, managed care plans barely existed outside of the western United States. Most care was delivered in either a doctor's office or a hospital. The elderly as a group did not have access to as many health or social services, or sources of information about their health care options, as they do today. The Older Americans Act, also enacted in July of 1965, fostered the development of many local services for the elderly, including senior centers and Meals on Wheels.

The Medicare program has adjusted to changes in the private sector, developed prudent purchasing techniques, and adapted to changes in the practice of medicine. Many of the changes Medicare has made have led to similar shifts in the private health care system, leading to significant savings for consumers, employers, and other purchasers of health care services.

### Changes in Medicare Eligibility

In 1972, Medicare was expanded to include individuals with disabilities who qualified for Social Security Disability Insurance (SSDI) (made eligible after a period of 24 months) and individuals diagnosed with end-stage renal disease (ESRD). Today, more than 5 million Americans with disabilities are enrolled in Medicare.

### Changes in Medicare Benefits

Medicare's benefit package has also been changed since 1965. In 1980, Medicare's home health benefit was expanded; hospice benefits for the terminally ill were added in 1982; beneficiaries were able to enroll in HMOs, paid on a risk-basis, beginning in 1985. In 1988, Medicare was expanded to include coverage of prescription drugs and limit beneficiary out-of-pocket payments in addition to other changes. Those expansions, included in the Medicare Catastrophic Coverage Act, were repealed in 1989 before they took effect.

At its inception, Medicare did not cover preventive benefits. Over time, Congress incrementally expanded coverage to include benefits such as pap smears, flu shots, and mammograms. In 1997, Congress significantly expanded preventive benefits to include:

- colorectal cancer screening
- diabetes glucose monitoring
- diabetes education
- bone mass measurement, and
- prostate cancer screening.

### **Changes in Medicare Payment Policy**

Much of the major legislative activity in the 1980s and 1990s focused on making Medicare a more prudent purchaser of health care services. Hospitals and other Part A providers were moved from cost-based payment to prospective payment systems. Physicians and many other Part B suppliers were moved from charge-based payment to fee schedules. Managed care plans' risk-based payment was modified to reduce the geographic variation in payment amounts and to adjust for the relative health status of their patients. Medicare has new prospective payment systems for home health care, skilled nursing facility care, and outpatient hospital care.

### **Changes to Protect Medicare Patients**

Medicare has moved aggressively to protect the rights of its enrollees. In 1980, for example, the federal government began to oversee the sale of private supplemental, or Medigap, insurance to beneficiaries to cover costs not covered by Medicare. Regulation of Medigap insurance was significantly strengthened in 1990 to eliminate the sale of duplicate or overlapping policies. The Health Insurance Portability and Accountability Act of 1996 contained a number of tools to reduce fraud and abuse in Medicare. It established a mandatory appropriation to secure stable funding for program integrity activities and opened program integrity contracts to competitive procurement. The 1997 Balanced Budget Act included several important protections for Medicare patients enrolled in managed care plans. Those protections were expanded under an Executive Order signed by President Clinton.

### **Chronology of Legislative Activity**

**July 30, 1965** - Medicare is enacted (as Title XVIII of the Social Security Act) to provide health insurance coverage for the elderly. Medicaid (Title XIX of the Social Security Act) also is created, providing matching federal payments to states for health care services to low-income aged, blind and disabled individuals, and parents and their dependent children on welfare.

**July 1, 1966** - Medicare benefits begin for more than 19 million individuals enrolled in the program.

**1972** - Medicare eligibility is extended to individuals under age 65 with long-term disabilities after 24 months of Social Security disability benefits and to individuals with end-stage renal disease (ESRD) after a three-month course of dialysis. About 2 million individuals subsequently enrolled in Medicare.

**1980** - Medicare's home health benefit is broadened by eliminating the prior hospitalization requirement and time limits on visits. Medicare supplemental insurance, also called Medigap, is brought under federal oversight.

**1982** - A prospective risk-contracting option for health maintenance organizations is added to facilitate plan participation. Hospice benefits for the terminally ill are covered. Medicare is made secondary payer for aged workers and their spouses. Medicare utilization and quality control Peer Review Organizations are established. Limits are placed on payments for inpatient hospital services.

**1983** - An inpatient hospital prospective payment system (PPS), in which a predetermined rate is paid based on patients' diagnoses, is adopted to replace cost-based payments. Federal employees are required to participate in Medicare.

**1985** - Medicare coverage is made mandatory for newly hired state and local government employees.

**1988** - The Medicare Catastrophic Coverage Act (MCCA) is enacted. It includes an outpatient prescription drug benefit, a cap on patient liability for catastrophic medical expenses, expanded skilled nursing facility benefits, and modifications to the cost-sharing and episode-of-illness provisions of Part A. States, through Medicaid, are required to provide medical assistance for Medicare cost-sharing expenses for low-income Medicare beneficiaries.

**1989** - MCCA is repealed. A new fee schedule for physician services, called the Resource-Based Relative Value Scale, or RBRVS, is enacted and serves as a model of reform to private insurers and payers. Physicians are required to submit bills to Medicare on behalf of Medicare patients. Beneficiary liability for physician bills, above and beyond what Medicare pays, is limited.

**1990** - Additional federal standards for Medicare supplemental insurance policies are established.

**1993** - The Hospital Insurance (HI) payroll tax is applied to all wages rather than the lower Social Security capped amount with revenues placed in the HI trust fund. Under Medicaid, states are required to provide additional assistance to low-income Medicare beneficiaries.

**1996** - The Health Insurance Portability and Accountability Act contains a number of tools to reduce fraud and abuse, establishes a mandatory appropriation to secure stable funding for program integrity activities, and opens program integrity contracts to competitive procurement.

**1997** - The Balanced Budget Act of 1997 (BBA) includes the most extensive legislative changes since the program was enacted. The BBA:

- reduces payment increases to providers, thereby extending solvency of the HI trust fund;
- establishes Medicare + Choice, a new array of managed care and other health plan choices for beneficiaries, with a coordinated annual open enrollment process, a major new beneficiary education campaign about their health plan choices, and significant changes in payment rules for health plans;
- expands coverage of preventive benefits;
- creates new home health, skilled nursing facility, inpatient rehabilitation and outpatient hospital prospective payment systems for Medicare services;
- improves payment accuracy and helps further restrain the growth of health care spending;
- creates new approaches to payment and service delivery through research and demonstrations.

**1999** - The Balanced Budget Refinement Act increases payments for some providers relative to the payment reductions in the BBA of 1997.

#### **IV. Improving the U.S. Health Care System**

*"I tell my young friends that three generations of Americans were spared the awesome task of taking care of their parents so that they could concentrate on the care and education of their children. The security of the elderly and the health of the American people should be built on the experience and the foundation provided by Medicare and Social Security."*

Former Congressman Charles Vanik, a member of the Ways and Means Committee when Medicare was passed by Congress, in a letter to HCFA Administrator Bruce Vladeck at the 30th Anniversary of Medicare's implementation, 1996.

In addition to serving the health care needs of the elderly and people with disabilities, Medicare plays an important role in supporting and shaping the U.S. health care system. Medicare covers about 14 percent of the population and finances about 21 percent of the nation's health care spending [Figure 20]. As the senior population has increased both in number and as a proportion of the U.S. population, Medicare's share of health care spending has changed over time as Medicare has become a more important source of financing of health care. For example, in 1970, Medicare financed about 11 percent of all health care spending [Figure 21]. Medicare paid for 19 percent of all hospital spending in 1970; by 1998, Medicare's share rose to 32 percent.

##### **Protecting the Health Care "Safety Net"**

Medicare provides special financial support for inner-city and

rural health care facilities that serve a disproportionate share of low-income and uninsured patients. In fiscal year 2000, Medicare paid \$4.6 billion in payments to these safety net providers, allowing them to serve Medicare patients as well as many younger, uninsured Americans.

##### **Training a New Generation of Providers**

In fiscal year 2000, Medicare paid nearly \$8 billion to U.S. hospitals to support the training of new physicians and other health care providers. By playing such an important role in medical education, Medicare helps ensure that future generations of Americans will have access to high-quality care.

##### **Ensuring Safety and Quality**

Medicare's role in quality assurance in hospitals, nursing homes and other settings helps to ensure that all Americans receive high-quality health care services from those providers. Through its conditions of participation standards, Medicare establishes quality and safety requirements for these facilities that apply to all patients served.

##### **Combating Fraud and Abuse**

Since 1993, Medicare has waged an aggressive battle against fraud and abuse. The result is a record series of investigations, indictments and convictions, as well as new management tools to identify improper payments to health care providers. Last year, the federal government recovered nearly \$500 million as a result of health care prosecutions. Since 1996, aggressive enforcement has recovered nearly \$1.9 billion.

The President's budget proposes to build on these efforts and save \$38 billion over 10 years by expanding anti-fraud policies and enhancing Medicare's competitiveness, efficiency, and quality.

In 1995, Department of Health and Human Services Secretary Donna E. Shalala launched Operation Restore Trust, a groundbreaking and ongoing anti-fraud project aimed at coordinating federal, state, local and private resources in targeted areas. In his fiscal year 2001 budget proposal, President Clinton also unveiled a new investment of more than \$40 million to ensure a swift and coordinated response to waste, fraud and abuse involving the private insurance companies, which, by law, process and pay claims on behalf of Medicare.

The Health Insurance Portability and Accountability Act of 1996 provided Medicare with important new tools to fight fraud and abuse. It established a mandatory appropriation to secure stable funding for program integrity activities and opened program integrity contracts to competitive procurement.

### **Running an Efficient Program**

Medicare's overall administrative costs are less than 2 percent of total benefit payments [Figure 22]. Medicare's administrative costs are significantly lower than private insurers, which the Blue Cross/Blue Shield Association estimates at 12 percent for their plans. Medicare's administrative costs have been declining, reflecting greater efficiency through economies of scale and high levels of electronic claims processing. In fiscal year 1999, Medicare processed over 148 million claims at a unit cost per claim of \$0.84 for Part A fiscal intermediaries [Figure 23]. Over the last decade, the number of Part A claims doubled and the cost

per claim was cut in half. Medicare worked with the provider community and others to computerize claims payment; these efforts paved the way for others to use this technology. Electronic submission of claims increased from 74 percent of Part A claims in 1990 to 97 percent in 1999; Part B rates rose from 36 percent to more than 80 percent over the same period [Figure 24].

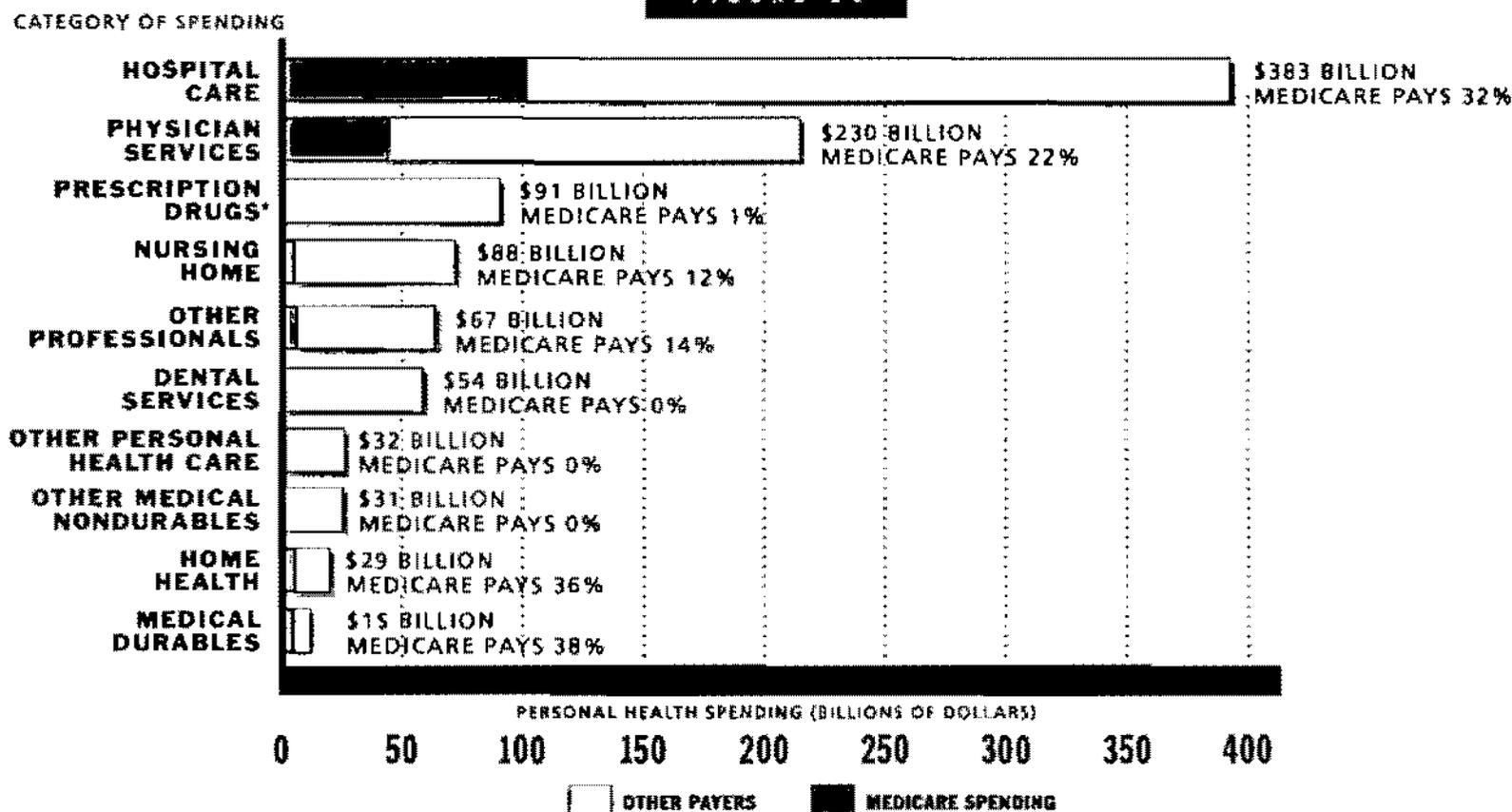
### **Serving as a Prudent Purchaser of Services**

Medicare has developed and implemented a series of reforms in the way it pays for and purchases health care services for its beneficiaries. These systems have made Medicare a more prudent purchaser, extended the fiscal solvency of the program's trust fund, and provided private purchasers with models for reforming their own payment structures.

# National Personal Health Expenditures by Type of Service and Percent Medicare Paid, 1998

Total national personal health spending in 1998 was \$1 trillion;  
Medicare accounted for 21 percent.

FIGURE 20



SOURCE: HCFA/OFFICE OF THE ACTUARY.

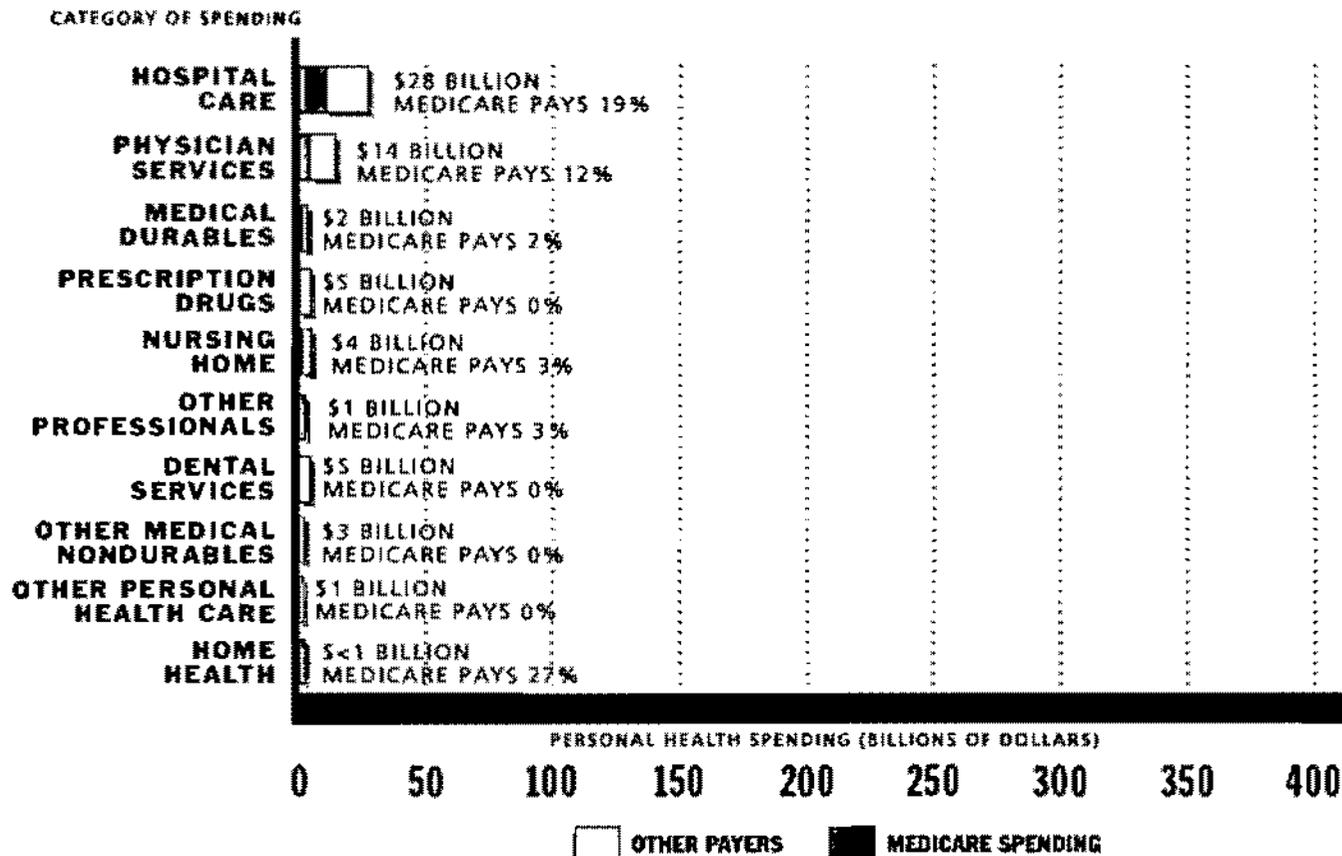
NOTE: ACCESS IS DEFINED AS AT LEAST ONE AVAILABLE PLAN IN THE COUNTY WHERE THE BENEFICIANT RESIDES.

\*NOTE: MEDICARE PAYMENTS ARE FROM MANAGED CARE PLANS ONLY, SINCE FEE-FOR-SERVICE MEDICARE DOES NOT GENERALLY COVER OUTPATIENT PRESCRIPTION DRUGS.

# National Personal Health Expenditures by Type of Service and Percent Medicare Paid, 1970

Total national personal health spending in 1970 was \$64 billion;  
Medicare accounted for 11 percent.

FIGURE 21

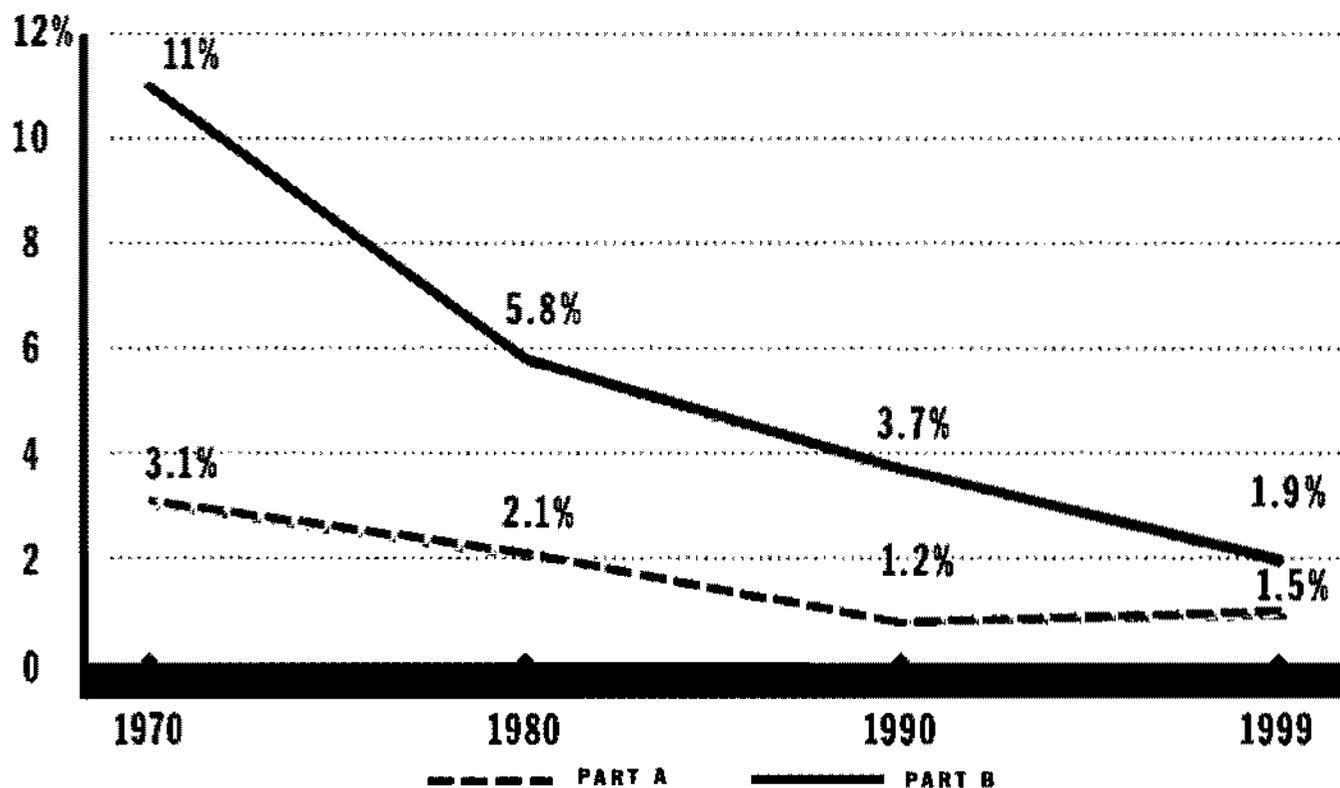


SOURCE: HCFA/OFFICE OF THE ACTUARY.

# Medicare Administrative Expenses as a Percent of Benefit Payments, Fiscal Years 1970-1999

*Medicare's administrative costs have been declining as a percentage of total program spending.*

FIGURE 22



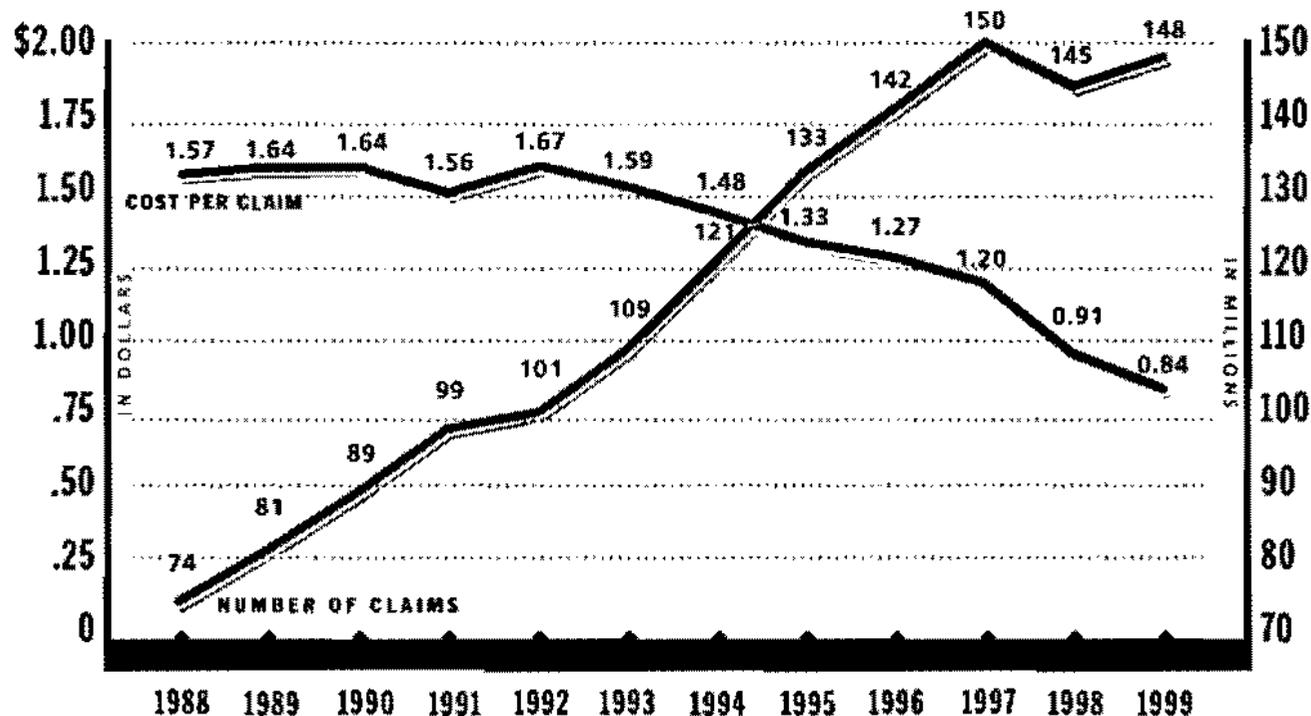
SOURCE: HCFA/OFFICE OF STRATEGIC PLANNING: DATA FROM MEDICARE CURRENT BENEFICIARY SURVEY.

NOTE: DATA ARE REPORTED FOR COMMUNITY-DWELLING BENEFICIARIES ONLY.

# Medicare Part A Cost Per Claim and Number of Claims, FY 1988 - 1999

*Over the last decade, the number of Part A claims has doubled while the cost of processing each claim has been cut in half.*

FIGURE 23



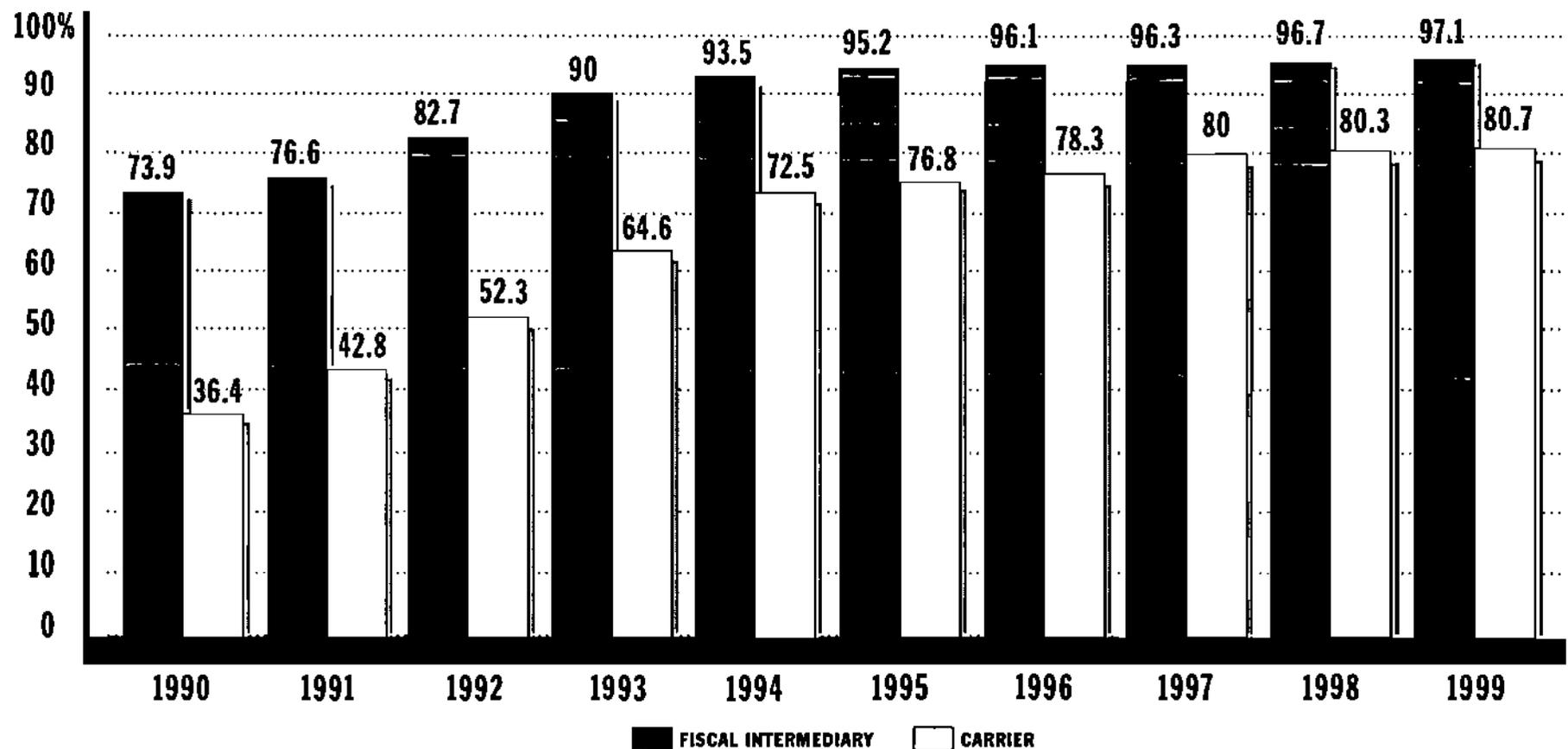
SOURCE: HCFA/CENTER FOR BENEFICIARY SERVICES.

NOTE: 1999 DATA ARE PRELIMINARY ESTIMATES. COST PER CLAIM IS IN NOMINAL DOLLARS.

# Electronic Claims, CY 1990-1999

*The rate of electronic submission of Medicare claims has grown considerably over the last decade.*

FIGURE 24



SOURCE: HCFA/CENTER FOR BENEFICIARY SERVICES.

## V. Improving Medicare for the Future

*"I just hope it lasts, because I could not manage without it."*

Medicare beneficiary, Medicare Current  
Beneficiary Survey, 1999

In many ways, we can only imagine what the world will look like in 2030. What we do know, however, is that there will be a major demographic shift. The aging of the population will test our ingenuity to continue to ensure that programs like Social Security and Medicare will be available to meet income and health care needs in 2030 and beyond. The elderly in 2030 will be a more diverse group than today. About one in three will be members of racial or ethnic minority groups. They will also be better educated; about one in four seniors will be college graduates.

While the sheer number of elderly, and their share of the population, will present challenges to the nation's ability to finance health care services, there are encouraging data about declines in the proportion of the elderly with functional limitations. The incidence of functional limitations among the elderly has declined since the early 1980s. According to a 1997 survey, there was less than half the growth in the actual number of functionally disabled people than might otherwise have been expected (Manton, et. al., 1997). Moreover, between 1985 and 1997, the percentage of the population aged 85 and older residing in nursing homes has declined by 13 percent (Forum, 2000) as home health services, assisted living facilities, and other alternatives have enabled more elders to live in the community.

At the same time, the elderly are projected to have a longer life expectancy and the proportion of Medicare beneficiaries who are over 85 will continue to increase. Over the next 30 years, improved

access to health care and continuing scientific breakthroughs are expected to result in more than 300,000 Americans living until age 100 or longer (Census Bureau, 1999).

### Financing Challenges

In its most recent report, the Medicare Board of Trustees estimated that Medicare's Hospital Insurance (HI) trust fund would remain solvent until 2025. This represents a remarkable improvement over the 1993 estimate that the HI trust fund would be insolvent by 1999. Changes made in the Omnibus Budget Reconciliation Act of 1993 and the Balanced Budget Act of 1997, along with government-wide fraud and abuse detection and prevention efforts, prudent management of the program, and the strong economy, have all helped to significantly delay that date, while also contributing to paying down the national debt.

Despite this significant achievement, concern remains about the financing of Medicare once the baby boom generation retires, starting in 2010. In 2030, 22 percent of Americans will depend upon Medicare — up from 14 percent today. The aging of the population also means that the number of workers paying Medicare taxes to support the benefits of a retired or disabled beneficiary will drop. In 1970, 3.7 workers paid for every retiree. In 2000, that figure is 3.4 workers. In 2030, it is projected to be 2.2 workers.

The imperative to address the future needs of the Medicare program and its beneficiaries is reflected in President Clinton's proposals for Medicare reform. These proposals include:

## Coverage for Prescription Drugs

*"There are medications that I have been told to take that I don't take because they are so expensive. I need an allergy medicine daily, 365 days a year. One month of it costs \$78. So, I don't take it all the time. Then there is medicine my doctor tells me to take for my joint problems. Again, I don't buy it because it is so expensive."*

Female Medicare beneficiary in Richmond, VA

As noted earlier, Medicare's benefit package was modeled on the private insurance plans prevalent in 1965 when outpatient prescription drugs were not covered. Today, outpatient drug coverage is a common feature of private insurance. Yet research has shown that nearly half of Medicare beneficiaries do not have drug coverage at some time during the year and about one in three are without drug coverage for the entire year. In addition, existing coverage is unstable and declining. Seniors without drug coverage purchase one-third fewer drugs but pay nearly twice as much out of pocket for the drugs that they do buy, compared with those with coverage. One in 10 beneficiaries without drug coverage reports being unable to purchase needed prescriptions—a level five times higher than those with coverage.

The President's Medicare reform proposal will provide all beneficiaries access to a voluntary prescription drug benefit through a program administered by private sector organizations. When fully phased in, the plan would cover half of all drug costs up to \$5,000 and provide additional protection against catastrophic prescription drug costs. Under the President's plan, Medicare will contribute at least 50 percent of the premium for such coverage and provide special protection to low-income beneficiaries.

## Improving Access to Preventive Services

*"I am happy that they are finally paying for exams like pap smears and bone density for my wife. They were not paying for them before."*

Medicare beneficiary, Medicare Current  
Beneficiary Survey, 1999

Medicare coverage of preventive services has expanded significantly but still covers only a limited set of preventive services including: pap smears; screening mammography; pelvic and clinical breast exams; pneumonia, hepatitis B, and influenza vaccines; colorectal cancer screening; diabetes glucose monitoring; diabetes education; bone mass measurement; and prostate cancer screening. Medicare has nationwide quality improvement activities and public and provider awareness campaigns, particularly regarding flu, pneumonia, pap smears and mammograms to increase the utilization of these important services [Figures 25 and 26].

Since 1991, Medicare has made considerable progress in raising the rates for both flu and pneumonia shots but needs to make more progress to reach the Healthy People 2010 goal of 90 percent coverage for each vaccination. The Healthy People 2010 goals for mammograms are 70 percent of women 40 and over receiving a mammogram within the past two years and 90 percent of women 18 and older receiving a pap test within the previous three years. Medicare also is working to reach those goals.

### **Mammograms**

Mammography is the most effective method of diagnosing breast cancer. Women whose cancer is detected at earlier stages have

better outcomes. Although early detection reduces mortality resulting from the disease, Medicare mammography screening rates are still too low. In response to the lower utilization rates for minorities, Medicare undertook special efforts to increase utilization in these communities, including partnering with minority organizations, the Centers for Disease Control and Prevention and state health departments to expand outreach in minority communities [Figure 27]. Medicare also has directed its contractors for quality improvement, known as Peer Review Organizations, to increase the percentage of Medicare beneficiaries who have had a mammogram. Activities aimed at improving these rates are ongoing in all 50 states.

### ***Pneumonia and Influenza Vaccines***

Pneumonia and influenza are the sixth leading causes of death in the United States. More than 90 percent of the nation's 20,000 annual deaths from flu, and the 40,000 annual deaths from pneumonia, occur among the elderly. Proper vaccinations, especially among those living in nursing homes and at high risk for flu and pneumonia, could prevent many of these deaths. Medicare has launched an initiative known as standing orders in nursing homes for flu and pneumonia vaccinations so that all residents are personally reminded each fall that it is time for their shot, which they can receive on the spot from an appropriate health care professional. The evidence shows that such practices are the most effective method for getting people vaccinated—an especially important service for vulnerable nursing home residents.

Medicare has directed Peer Review Organizations to include increasing statewide immunization rates for pneumococcal and influenza vaccines as one of their quality indicators. The main

objective of this Medicare Peer Review Organization initiative is to decrease the morbidity and mortality associated with pneumonia in Medicare beneficiaries. Projects underway in all 50 states will help beneficiaries in the future.

To increase use of flu and pneumonia shots, Medicare started the Good Neighbor Project in Baltimore, which established links with local organizations to work with physicians and minority beneficiaries to improve utilization of flu and pneumonia shots [Figure 28].

### ***Eliminating Cost-Sharing on Preventive Services***

President Clinton's Medicare reform plan would eliminate all cost-sharing for preventive benefits in Medicare, including colorectal cancer screening, bone mass measurements, pelvic exams, prostate cancer screening, diabetes self-management, and mammographies. The plan also includes a three-year demonstration project to provide cost-effective smoking cessation services to beneficiaries and a national health promotion campaign for all Americans over 50.

### ***Providing Additional Revenue***

It is not possible to adequately address the cost of doubling Medicare's enrollment by simply reducing what Medicare spends and increasing premiums and other charges to beneficiaries. President Clinton has proposed dedicating \$115 billion of the non-Social Security surplus to Medicare, thereby extending the solvency of the HI Trust Fund and eliminating the need for future excessive cuts and radical restructuring of the Medicare program.

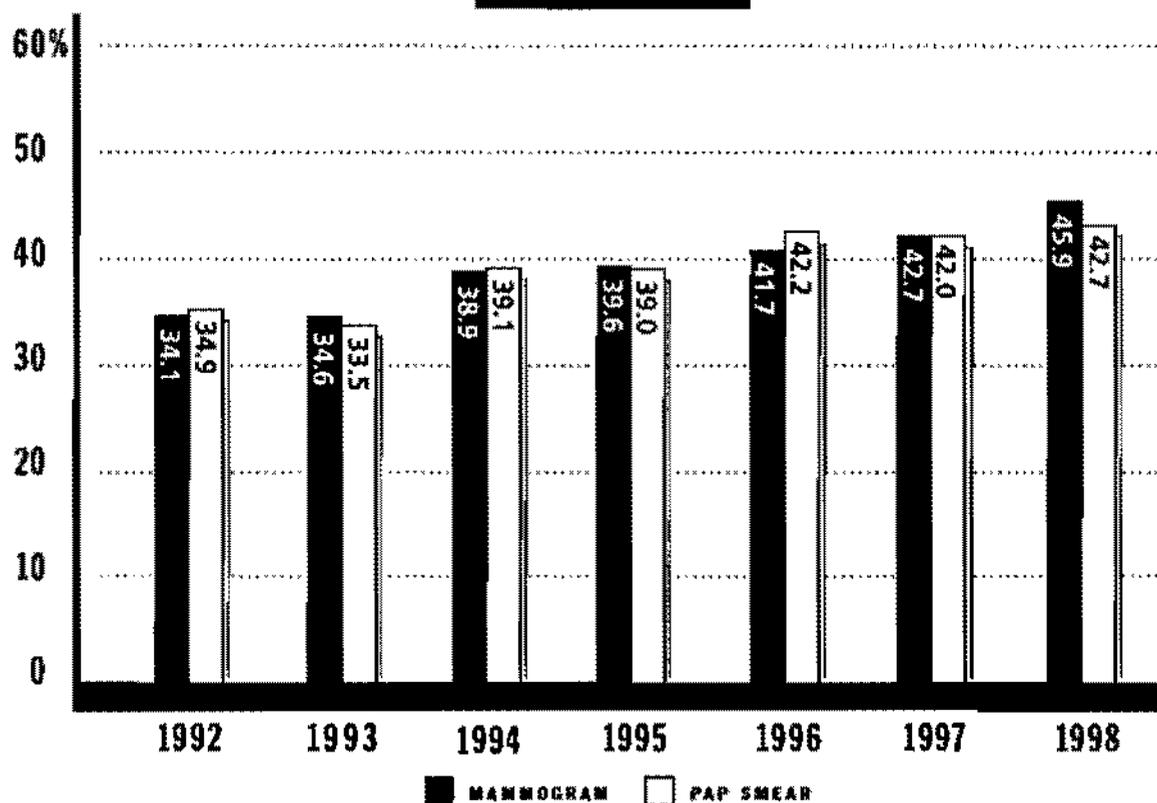
### **Creating Insurance Options for Early Retirees**

The President's plan would allow Americans between the ages of 62 and 65 to buy into Medicare for approximately \$300 a month. Workers between the ages of 55 and 62 who lose their jobs could buy in at a slightly higher premium (about \$400 a month). The President's fiscal year 2001 budget includes a new tax credit to offset part of the cost of this buy-in to encourage more uninsured early retirees to enroll.

# Female Medicare Beneficiaries Who Report Receiving Mammograms and Pap Smears, 1992-1998

*Utilization of mammography and pap smears has been growing over the decade, but has not yet reached Healthy People 2010 goals.\**

FIGURE 26



SOURCE: HCFA/OFFICE OF STRATEGIC PLANNING: DATA FROM MEDICARE CURRENT BENEFICIARY SURVEY.

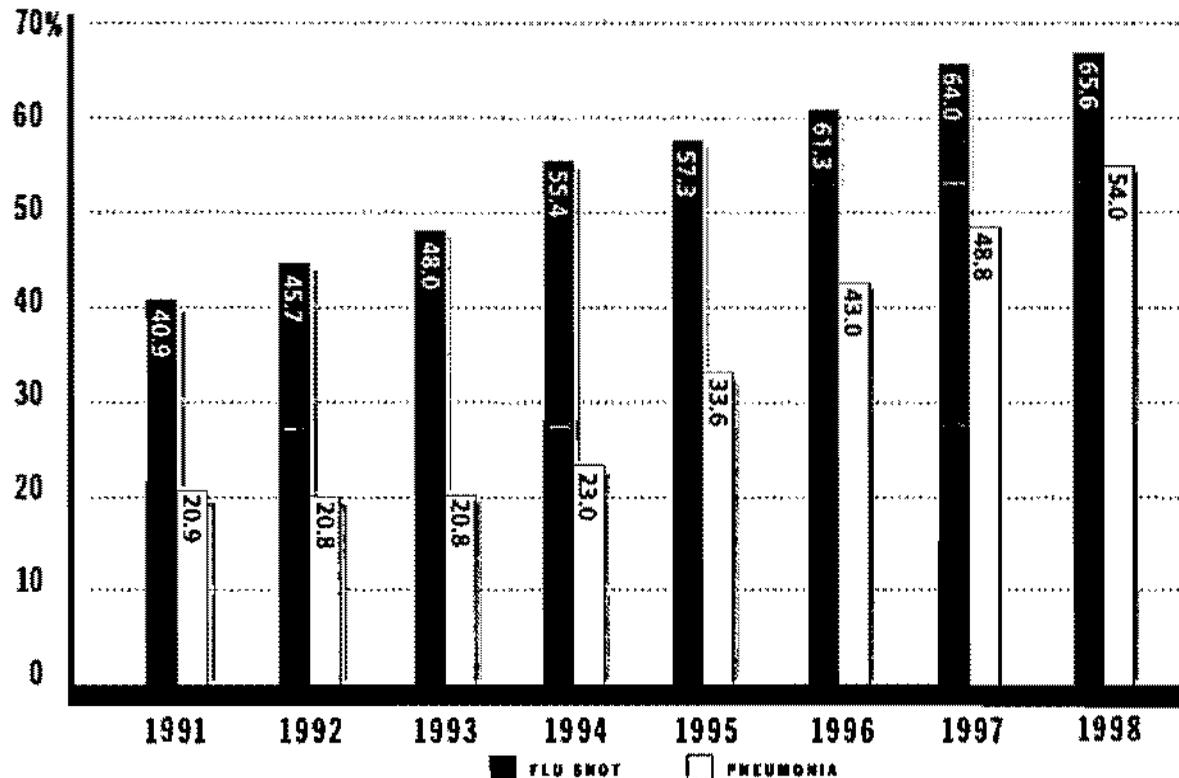
NOTE: DATA ARE REPORTED FOR FEMALE BENEFICIARIES WHO REPORT RECEIVING MAMMOGRAMS AND PAP SMEARS IN THE PAST YEAR AND INCLUDE BOTH PREVENTIVE AND DIAGNOSTIC SERVICES. MCBS SURVEY INCLUDES FEE-FOR-SERVICE AND MANAGED CARE ENROLLEES AS WELL AS AGED AND DISABLED BENEFICIARIES. DATA ARE REPORTED FOR COMMUNITY-DWELLING BENEFICIARIES ONLY.

\*NOTE: HEALTHY PEOPLE 2010 GOALS: 74% OF WOMEN RECEIVING A MAMMOGRAM WITHIN LAST 2 YEARS AND 80% OF WOMEN RECEIVING A PAP SMEAR TEST WITHIN THE PAST 3 YEARS.

# Medicare Beneficiaries Who Report Receiving a Preventive Service: Flu and Pneumonia\* Vaccinations, 1991-1998

*Utilization of flu and pneumonia shots has been growing over the decade, but has not yet reached Healthy People 2010 goals.\*\**

FIGURE 26



SOURCE: HCFR/OFFICE OF STRATEGIC PLANNING: DATA FROM MEDICARE CURRENT BENEFICIARY SURVEY.

NOTE: DATA ARE SELF-REPORTED BY BENEFICIARIES AND INCLUDE THE AGED, DISABLED, FEE-FOR-SERVICE AND MANAGED CARE ENROLLEES. DATA FOR OHA-COVERED PREVENTIVE SERVICES (E.G., PROSTATE CANCER SCREENING, BONE MASS MEASUREMENTS, COLONRECTAL CANCER SCREENING, AND DIABETES SELF-MANAGEMENT) WILL BE COLLECTED IN THE FALL 2000 WERS. DATA ARE REPORTED FOR COMMUNITY-DWELLING BENEFICIARIES ONLY.

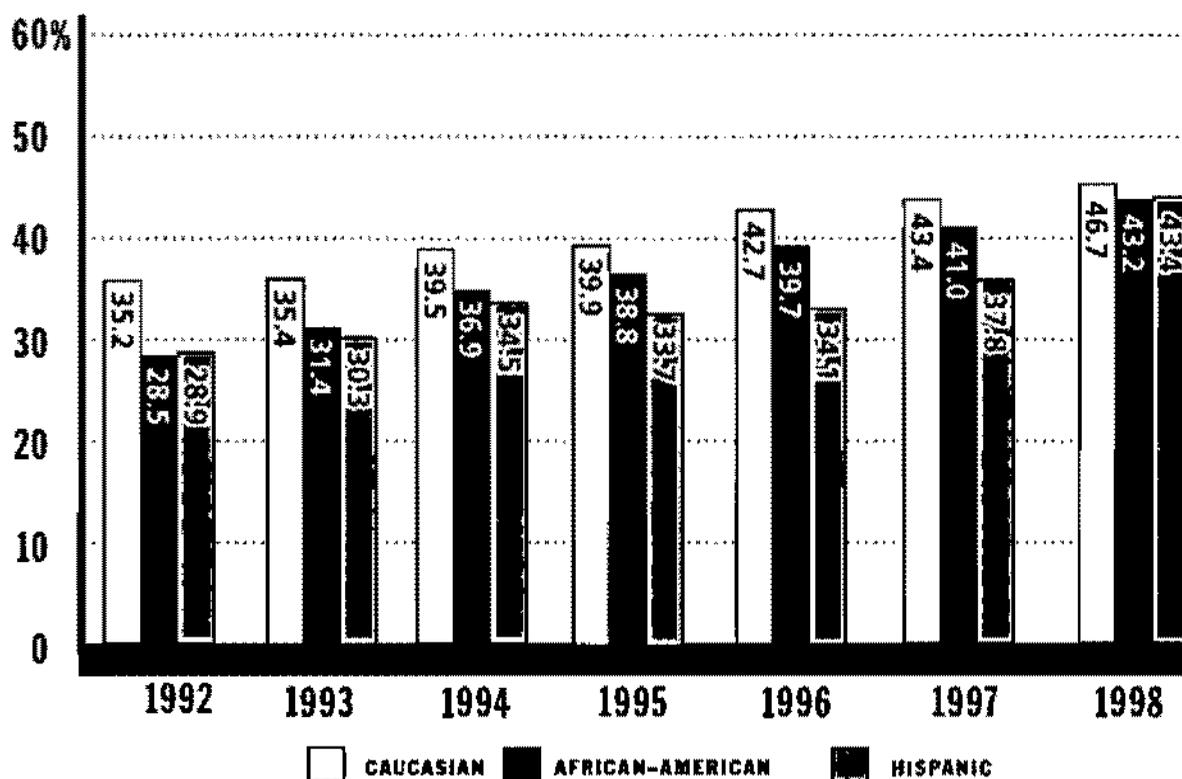
\*NOTE: PNEUMONIA VACCINATIONS ARE GENERALLY RECOMMENDED ONCE IN A LIFETIME—THUS, THE NUMBERS HERE ARE A CUMULATIVE PERCENTAGE OF PERSONS REPORTING THAT THEY HAVE EVER RECEIVED THE SHOT. THE FLU SHOT IS RECOMMENDED ANNUALLY—THE NUMBERS REFLECT ANNUAL RECEIPT OF THE SHOT.

\*\*NOTE: HEALTHY PEOPLE 2010 GOALS: 90% RECEIVING AN ANNUAL FLU SHOT AND 90% RECEIVING A ONE-TIME PNEUMONIA SHOT.

# Female Medicare Beneficiaries Who Report Receiving Mammograms, by Race, 1992-1998

*Utilization of mammograms is slightly higher for Caucasians than other racial groups, but rates for all groups are increasing over the decade.*

FIGURE 27



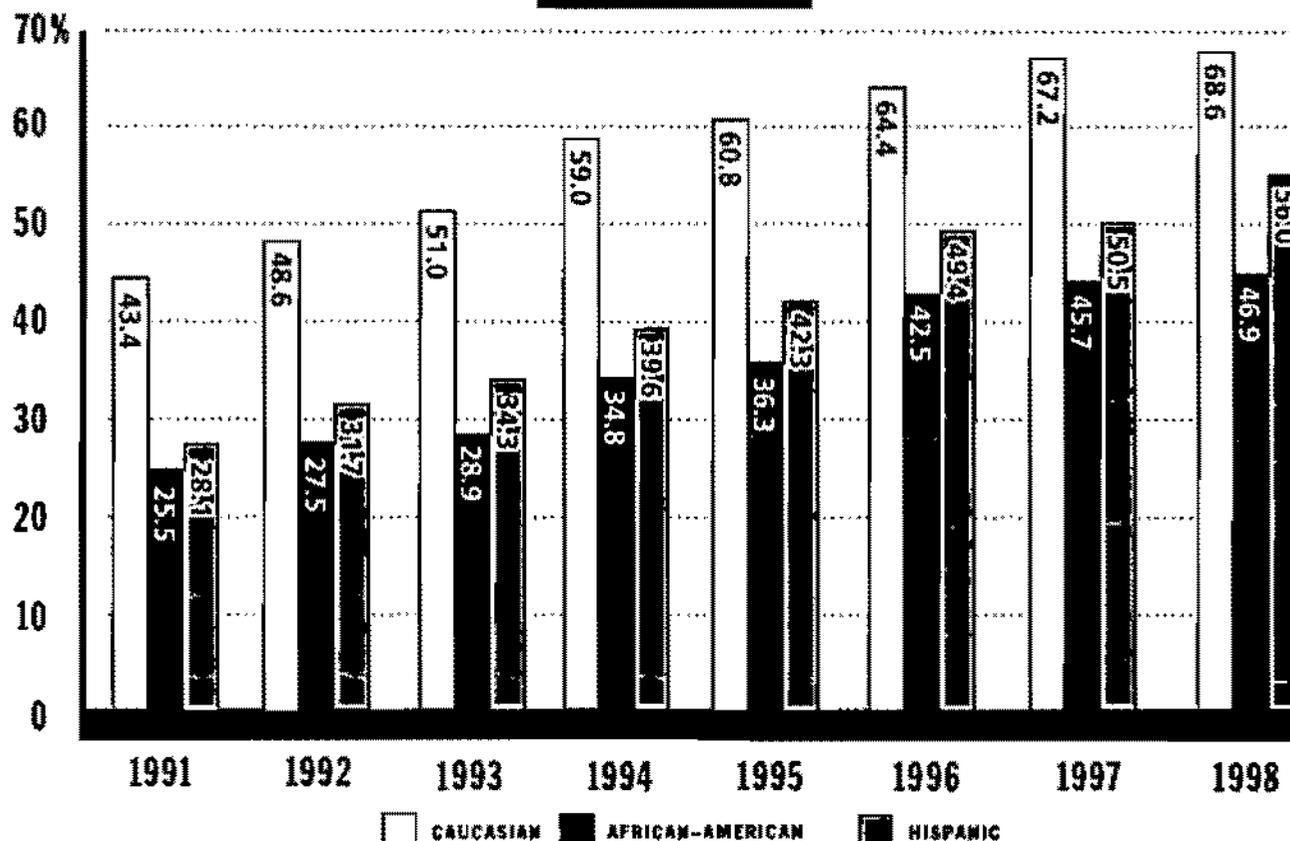
SOURCE: NCFR/OFFICE OF STRATEGIC PLANNING: DATA FROM MEDICARE CURRENT BENEFICIARY SURVEY.

NOTE: DATA REFLECTS FEMALE BENEFICIARIES WHO REPORT RECEIVING MAMMOGRAMS, IN THE PAST YEAR, AND INCLUDE BOTH PREVENTIVE AND DIAGNOSTIC SERVICES. MCBS SURVEY INCLUDES FEE-FOR-SERVICE AND MANAGED CARE ENROLLEES AS WELL AS AGED AND DISABLED BENEFICIARIES. DATA ARE REPORTED FOR COMMUNITY-DWELLING BENEFICIARIES ONLY.

# Medicare Beneficiaries Who Report Receiving Flu Shots, by Race, 1991-1998

*Utilization of flu shots is higher for Caucasians than other racial groups, but rates for all groups are increasing over the decade.*

FIGURE 28



SOURCE: HCFA/OFFICE OF STRATEGIC PLANNING; DATA FROM MEDICARE CURRENT BENEFICIARY SURVEY.

NOTE: DATA REFLECTS BENEFICIARIES WHO REPORT RECEIVING FLU SHOTS. MCBS SURVEY INCLUDES FEE-FOR-SERVICE AND MANAGED CARE ENROLLEES AS WELL AS AGED AND DISABLED BENEFICIARIES. DATA ARE REPORTED FOR COMMUNITY-DWELLING BENEFICIARIES ONLY.

## Appendix: Overview of Medicare Benefits, Cost-Sharing, and Program Structure

### Program Structure: Benefits

Medicare consists of two parts, Hospital Insurance (HI) and Supplementary Medical Insurance (SMI), also known as Parts A and B, respectively.

- Part A covers inpatient hospital services, short-term care in skilled nursing facilities, post-institutional home health care, and hospice care.
- Part B covers physician and other practitioner services, outpatient hospital and other outpatient facility services, home health care not covered by Part A, and a variety of other medical services such as diagnostic tests, durable medical equipment, and ambulance service.
- Part C (Medicare + Choice) allows beneficiaries to choose to receive their Part A and Part B benefits through private health plans such as health maintenance organizations, preferred provider organizations, and private fee-for-service plans. A demonstration project is supposed to test the use of medical savings accounts (MSAs), but no MSAs have yet joined Medicare to offer such coverage.

### Program Structure: Eligibility

#### *Hospital Insurance (Part A)*

- Individuals eligible for Social Security are automatically entitled when they reach age 65. Individuals age 65 or older who are not automatically entitled may enroll in Part A, if they pay a monthly premium.

- Individuals under age 65 are eligible if they have been disabled (qualifying for Social Security Disability Insurance) for at least two years. Most people with end-stage renal disease are eligible for coverage.

#### *Supplementary Medical Insurance (Part B)*

- Voluntary enrollment is open to individuals age 65 or older, or those under age 65 who are entitled to Part A benefits. Individuals enrolling in Part B pay a monthly premium.

### Program Structure: Financing

#### *Hospital Insurance (Part A)*

- Part A costs are met primarily through a payroll tax. The Medicare Hospital Insurance Trust Fund receives a payroll tax of 1.45 percent, from both employees and employers, with the self-employed paying the combined total of 2.9 percent. HI taxes are paid on total earnings in covered employment, without regard to the limit on the Social Security payroll tax. The HI trust fund also receives a portion of the income taxes levied on Social Security benefits, interest income on invested assets, and other minor sources.

#### *Supplementary Medical Insurance (Part B)*

- Part B enrollees pay monthly premiums (currently \$45.50) that cover about 25 percent of program costs. The balance of Part B costs are paid by general revenue of the federal government and a small amount of interest income. SMI premiums and general revenue payments are re-established each year to match estimated costs for the following year.

## Glossary

### **Aged**

As used here, those 65 years of age and older.

### **ADL**

Activities of daily living. These are basic tasks associated with daily life such as bathing, dressing, going to the bathroom, and eating.

### **Ambulatory care sensitive condition**

Medical condition that should not require hospitalization with appropriate ambulatory treatment (e.g., asthma or diabetes).

### **Ambulatory surgical center (ASC)**

A facility that provides surgical services that do not require a hospital stay. Medicare pays for use of an ambulatory surgical center for certain approved surgical procedures. Medicare also will pay for physician and anesthesia services that are provided for the procedure.

### **Assigned claim**

A claim for which the physician or supplier agrees to accept the amount approved by Medicare as the total payment, after the annual Part B deductible has been met. Medicare pays the physician or supplier 80 percent of the Medicare-approved amount. The doctor or supplier can charge the beneficiary only for the coinsurance, which is the remaining 20 percent of the approved amount. A participating physician or supplier agrees to accept assignment on all claims.

### **Center for Health Plans and Providers (CHPP)**

This HCFA component is responsible for developing policies and procedures related to health maintenance organizations,

competitive medical plans and other health care delivery systems and purchasing arrangements. CHPP is also responsible for developing purchasing strategies to improve the quality of health care choice for beneficiaries, and defining the scope of Medicare benefits and payment policies.

### **Coinsurance**

That portion of covered hospital and medical expenses, after subtraction of any deductible, for which the beneficiary is responsible.

### **Deductible**

The deductible is the amount payable by the beneficiary for covered services before Medicare reimburses the provider.

### **Disabled**

As used here, persons with disabilities under 65 years of age. Persons with disabilities become eligible for Medicare when they have been receiving Social Security Disability Insurance benefits for 24 months. Most individuals under 65 years of age diagnosed with end-stage renal disease are also eligible to receive Medicare benefits (in the data used in this report, they are included with the disabled for analytical purposes).

### **DHHS**

U.S. Department of Health and Human Services.

### **Dual Eligibles**

Dual eligibles are individuals who are entitled to Medicare Part A and/or Part B and are eligible for some form of Medicaid benefit.

**Durable Medical Equipment (DME)**

Under Medicare, DME includes certain medical supplies and items such as hospital beds and wheelchairs used in a patient's home.

**Elderly**

As used here, those 65 years and older.

**End-stage renal disease (ESRD)**

Irreversible kidney failure. The patient must either receive a kidney transplant or periodic kidney dialysis. Most individuals with ESRD are eligible for benefits.

**HCFA**

Health Care Financing Administration, an agency within the U.S. Department of Health and Human Services that administers Medicare, State Children's Health Insurance Program, and other programs.

**Health professional shortage area**

A geographic area determined by the U.S. Public Health Service to have a shortage of physicians or other health professionals.

**HMO**

Health Maintenance Organization. HMOs provide or arrange for a comprehensive package of health care services for a fixed monthly premium with nominal copayments permitted.

**HMO penetration**

The percentage of insured lives in a market area enrolled in HMOs.

**Home health agency (HHA)**

An agency that specializes in giving skilled nursing services and

other therapeutic services, such as physical therapy, in patients' homes.

**Home health benefit**

The portion of the Medicare program that pays for care to homebound beneficiaries. Care must be provided by a home health agency that participates in the Medicare program. Covered services include part-time or intermittent skilled nursing care, physical and speech therapy, occupational therapy, and part-time or intermittent services of a home health aide.

**Hospice**

A public agency or private organization that is primarily engaged in providing pain relief, symptom management, and supportive services to terminally ill people. Medicare beneficiaries may elect to receive hospice care instead of standard Medicare benefits.

**Managed care plan**

A general term applied to a wide range of insurance plans, including HMOs, where choice of providers is limited and administrative measures control utilization of services. The types of Medicare managed care plans include health maintenance organizations (HMOs), competitive medical plans (CMPs), and health care prepayment plans (HCPPs). The Balanced Budget Act of 1997 expands the types of managed care plans that can participate in Medicare.

**MCBS**

Medicare Current Beneficiary Survey. A survey of approximately 12,000 Medicare beneficiaries that collects information on demographic characteristics, health status and functioning, insurance coverage, financial resources, and family supports. Beneficiaries are reinterviewed periodically to form a continuous profile.

**Medicaid**

A joint federal-state program that provides medical assistance for those with low income. Medicaid is administered by the states and jointly funded by the states and the federal government. It was enacted in 1965 by Title XIX of the Social Security Act.

**Medicare supplemental insurance (Medigap)**

Private insurance that supplements Medicare by paying Medicare deductibles and coinsurance. There are 10 nationally standardized Medigap policies (plans A - J). Some policies offer coverage not provided by Medicare, such as coverage for outpatient prescription drugs and care outside the United States. Also called Medigap Insurance.

**NCHS**

National Center for Health Statistics. The component of the U.S. Public Health Service that collects and maintains statistics on various aspects of public health.

**Non-institutionalized**

Individuals not living in facilities such as nursing homes.

**Office of the Actuary (OACT)**

This HCFA component provides estimates of expenditures for the Medicare and Medicaid programs and of health expenditures in the United States.

**Office of Information Services (OIS)**

This HCFA component is responsible for managing HCFA's information technology assets, enterprise databases, and access paths to data and operational systems.

**Office of Strategic Planning (OSP)**

This HCFA component is responsible for HCFA's research and evaluation program, coordinating demonstration activities, developing and managing the long-term policy and strategic planning process, and for developing HCFA statistical publications including the Statistical Supplement to the Health Care Financing Review, and the preparation of this chart book.

**Participating physician/supplier**

A physician or supplier who has agreed to accept assignment on all Medicare claims (see assignment).

**Preferred Provider Organization (PPO)**

A managed care plan that contracts with networks or panels of providers to furnish services and be paid on a negotiated fee schedule. Enrollees are offered a financial incentive to use providers on the preferred list, but may use non-network providers as well (see managed care plan).

**Prospective Payment System (PPS)**

Medicare's reasonable cost payments for inpatient hospitals was replaced in the mid-1980s by PPS and has since been phased in for inpatient hospital capital costs as well. Prospective payment systems are required by the BBA for outpatient hospital services, home health, skilled nursing facility, and inpatient rehabilitation services. Prospective payment systems pay providers a fixed amount, determined in advance, for the costs of each patient based on the severity of the patient's health condition and may adjust for other factors such as geographic location, wages, service to low-income patients, and teaching activity.

**Qualified Medicare Beneficiary (QMB)**

A Medicare beneficiary with limited income and resources, eligible for Medicaid coverage for the payment of Medicare premiums and cost-sharing expenses (deductibles and coinsurance).

**Risk HMO**

An HMO that is paid a predetermined per-member payment from Medicare to provide all necessary covered services to its Medicare enrollees.

**Skilled care**

Skilled nursing care or skilled rehabilitation services, such as physical therapy. Medicare pays for nursing home stays requiring daily skilled care for a condition related to a prior hospitalization. Medicare also pays for part-time or intermittent skilled care provided by a home health agency to those who are homebound.

**Skilled Nursing Facility (SNF)**

A facility that is certified by Medicare to provide skilled nursing or rehabilitation services.

**Specified Low Income Medicare Beneficiary (SLMB)**

A Medicare beneficiary with limited income and resources, but income greater than a QMB, eligible for Medicaid coverage for the payment of Medicare Part B premiums.

**Supplier**

A provider of health care services, other than a practitioner, that is permitted to bill under Medicare Part B. Suppliers include independent laboratories, durable medical equipment providers, ambulance services, orthotists, prosthetists, and portable X-ray providers.

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