

A P P E N D I X

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**Scientific and Technological
Advances for Inpatient Hospital Services**

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Medicare Payment Advisory Commission (MedPAC) believes that hospitals should not be discouraged from adopting technologies that are necessary to maintain the high quality of care available to Medicare beneficiaries, solely because they increase costs. The Commission's hospital payment update framework, therefore, includes an allowance for scientific and technological advances that accounts for emerging technologies that are quality enhancing, but cost increasing. This allowance is intended to provide additional funds for anticipated changes in resource use due to the adoption of new technologies in the upcoming fiscal year. The allowance for scientific and technological advances represents MedPAC's best estimate of the incremental increase in costs for a given fiscal year that results from hospitals adopting new technologies or new applications of existing technologies (beyond that automatically reflected in the payments hospitals receive).

In the analysis presented below, we set forth the methods used to develop the fiscal year 2000 allowance for scientific and technological advances. We review the data sources and medical literature used to identify new and emerging technologies. And we set forth a detailed explanation of the technologies the Commission believes will emerge as important treatment options that will significantly affect

hospitals' costs while enhancing quality of care.

Current framework

The analysis for fiscal year 2000 builds on work previously undertaken by Prospective Payment Assessment Commission (ProPAC). Through fiscal year 1995, ProPAC hired an independent contractor (Abt Associates Inc. 1994) to conduct a comprehensive review of hospital technologies that included the following tasks:

- identify potential technologies in an extensive literature review,
- calculate the incremental per-case costs of the included new technologies, defined as the difference between the estimated total costs of using new technological methods and the estimated total costs of using existing treatment methods, and
- calculate the total impact on Medicare costs by multiplying the incremental costs per discharge and the estimated number of beneficiaries who are helped by the new technologies.

In subsequent years, ProPAC (and then MedPAC) used a qualitative approach to estimate the allowance for scientific and technological advances by evaluating technologies identified in previous analyses, examining broad industry trends,

having informal discussions with industry representatives, and reviewing the current medical literature.

To derive the fiscal year 2000 allowance, MedPAC used a qualitative approach that was similar to the fiscal years 1996 through 1999 updates. We reviewed the technologies included in the fiscal year 1999 update and evaluated changes in their overall use and costs predicted for fiscal year 2000. We conducted an extensive review of the medical literature to identify new technological advancements for this year's update. Finally, we included only those quality-enhancing technologies that met the following criteria:

- The technology was approved by the Food and Drug Administration (FDA).
- At least 5 percent of the relevant Medicare beneficiaries would receive the technology.
- No more than 75 percent would receive the technology.
- The application of the technology would result in substantially higher treatment costs.

We began our review by evaluating the broad categories that we identified as significant contributors to costs in the fiscal year 1995 through 1999 updates:

- information systems
- cardiovascular drugs and devices
- biotechnology, and

- radiology, imaging, and nuclear medicine.

In this year's analysis, we included a new category, "other devices and technological advancements," which provides information on technologies, such as biosensors and robotics not included in any of the other categories.

As in the analyses conducted for the fiscal year 1995 to 1999 updates, the Commission did not attempt to identify all cost-increasing technologies. Rather, we focused on the most significant ones from the perspective of cost and diffusion. We used numerous data sources to identify new technological advancements, including:

- peer-reviewed published literature identified by using Medline® (National Library of Medicine's database),
- federal and private organizations, such as the FDA, the Agency for Health Care Policy and Research, the Centers for Disease Control and Prevention, the American Medical Association, the American Hospital Association, and the American Public Health Association, and
- newsletters, newspapers, periodicals, and trade journals, such as *Business Week*, *Forbes*, *Time*, *Newsweek*, *Medicine and Health*, *Modern Healthcare*, *Hospital Technology Scanner*, *Hospitals and Health Networks*, *Yahoo News*, *Wall Street Journal*, *Washington Post*.

Scientific and technological advances in fiscal year 2000

The review of new and emerging technologies suggests that technological advances are slowing in areas that made important contributions in the past, such as cardiovascular procedures, devices, and drugs. However, substantial technological advances in hospital information systems, in general, and methods to address year 2000 computer problems, in particular, will likely contribute to hospital costs.

Information Systems

Hospital health care information systems play a significant role in the trend towards coordinated care delivery and include:

- financial systems
- pharmacy systems
- radiology systems
- patient-care systems
- laboratory systems, and
- clinical data repositories and related enabling software.

The Commission believes that information systems will continue to be the primary source of increased costs in fiscal year 2000 as they were in our fiscal year 1999 assessment. This assessment is based on the operating and capital costs required to address the year 2000 computer problem and continued investment in new, quality-enhancing information systems. The FDA Center for Devices and Radiological Health has also predicted that computer-related technology will experience significant development over the next five to ten years (Herman, Marlowe, Rudolph 1998).

Year 2000 computer problem

Hospitals depend heavily on computing technology and information systems to support their administrative and clinical operations. For hospital facilities, year 2000 malfunctions and service disruptions can come from both internal and external sources such as:

- administrative and clinical information systems
- medical devices
- health care suppliers and vendors of food services, medical supplies, and pharmaceuticals, and
- third-party payers.

Year 2000 malfunctions could potentially compromise patient care, interrupt core practice continuity, and create substantial liability exposure for hospitals. Clinical departments that are particularly dependent on automation

and susceptible to year 2000 malfunctions include the laboratory, radiology and emergency departments, and operating rooms. A broad spectrum of services may be affected from electronic data interchange for patient records, medical research, and billing to medical devices with embedded computer systems, such as pacemakers and life support systems.

Medical device malfunctions due to unaddressed millennium problems include:

- confusion when device results are displayed out of order,
- service disruption if a device indicates it needs maintenance when it does not,
- significant service disruption when the device shuts down and must be restarted, and
- significant service disruption when the device shuts down and will not restart or when the device appears to operate correctly yet produces incorrect results that are difficult to detect, such as dose calculations based on patient age.

The FDA has taken numerous actions to ensure that medical device manufacturers are aware of the year 2000 issue, such as establishing a product-specific database on the FDA world wide web site and convening seminars.

Hospital accounting departments may also be vulnerable to the year 2000 problem because they use numerous date fields, including patient birth date, insured birth date, date of admission/registration, certification and recertification dates, date of illness, procedure dates, payment dates, and claim submission dates.

Because hospitals rely heavily on outside vendors for numerous medical and nonmedical goods and services, such as pharmaceutical agents, food, and linens, they are developing contingency plans to address potential disruptions from vendors and suppliers who are not year 2000 compliant.

Finally, hospitals may be affected by the preparations of its third-party payers, such as the Health Care Financing Administration (HCFA) and its contractors, for the year 2000. The General Accounting Office (GAO) reported that it is highly unlikely that all Medicare systems will be compliant to ensure the delivery of uninterrupted benefits and services into the year 2000 (GAO 1998). Hospitals are concerned that poor communication with HCFA and Medicare's fiscal intermediaries will affect their accounting and electronic data interchange systems and cause delays in receiving operating revenues.

To prepare and address potential year 2000 failures, hospitals are conducting many of the tasks set forth in Table C-1. The Commission is concerned about a differential effect on small rural and inner-city hospitals that may lack the necessary project management, technical, and financial resources for year 2000 preparation. Numerous sources have noted a significant shortage of qualified personnel, particularly biomedical engineers who can assist in developing hardware and software solutions.

Based on the findings of an informal survey conducted by the American Hospital Association (AHA), most hospitals have started addressing year 2000 problems (AHA 1998). Nearly nine percent of survey respondents projected completing their year 2000 solutions by 1998, 81

percent of respondents projected 1999, and 9 percent of respondents projected 2000. Less than one percent of respondents reported that they would not complete their year 2000 solutions by 2000.

Operating and capital expenses devoted to address health care systems' millennium problems are substantial. Organizations have budgeted an average of \$8.5 million for capital and \$7 million for operations to solve millennium problems in 1998 (Morrissey 1998). To address millennium problems during 1998 to 2000, average capital and operating budgets are forecasted to be \$17 million and \$12.5 million, respectively.

Development of other information systems

In addition to devoting resources to address the millennium problem, hospitals will continue to invest in new information systems during the next fiscal year. Hospitals are investing more resources in information systems, particularly telemedicine, clinical data repositories, and multisite integrated data networks.

The FDA has predicted that the use of telemedicine—the electronic delivery of health care information and services—will significantly increase over the next five years. Telemedicine is becoming an important technology for rural hospitals. For example, it has been used to deliver

consulting services from large teaching hospitals to rural community hospitals. Additionally, rural hospitals use telemedicine to monitor their patients in their homes, resulting in enhanced quality of life for patients. The 1996 Telecommunications Act and the rules implemented by the Federal Communications Commission should enable telemedicine to continue to diffuse, especially in rural settings. Under the Act, rural-based local health care hospitals can receive discounts on their telecommunications rate changes to equalize disparities in the rural-urban payment rates.

Hospitals will continue to develop clinical data repositories—also referred to as electronic medical records. Clinical data repositories capture clinical data from many sources, store the information consistently, and present the results in tabular and graphical formats.

These repositories are being developed on multisite integrated networks to permit easy transfer of data through a secure data connection across multiple providers within a health care system, including hospitals, physicians, laboratories, and insurers. These networks, also referred to as medical intranets, are sophisticated systems that use a private network to provide access to a single source of clinical and administrative data. These networks are designed to support clinical decisionmaking, provide medical reference information, and support clinical research. Hospitals are replacing information systems developed more than 10 years ago without these functional capabilities.

Other new computerization projects predicted to experience growth in the upcoming year include scheduling, point of care, and quality/risk management systems.

MedPAC will continue to monitor these and other developments in information systems, including integrating diagnostic imaging results into clinical data repository systems, voice recognition systems, and wireless information devices.

**TABLE
C-1**

Recommended year 2000 action plan

Tasks

1. Identify relevant systems, including:
 - systems used to input, store, analyze, and report dates: subsystems, operating systems and other utility software used to sort, archive, restore, report, or generate dates, and
 - active, historical, and archival files that store dates; internal and external interfaces that pass date information, including the electronic transmission of insurance data to payers.
2. Contact outside vendors and suppliers to determine their plans for year 2000 compliance.
3. Define solutions, including developing a conversion plan for active and historical files and developing contingency plans for year 2000 internal and external malfunctions.
4. Make corrections to hardware, software, and data.
5. Test software, data, and interfaces to ensure dates are consistent.
6. Monitor all output to ensure successful resolution.

Source: Romzek P J. Are your information systems ready for the year 2000? *Healthcare Financial Management*. January 1998, p. 500-555.

Cardiovascular drugs, devices, and techniques

MedPAC believes that two new anticoagulants (eptifibatide and tirofiban hydrochloride), used for the treatment of patients with acute coronary syndromes and approved by the FDA in May 1998, will result in significant hospital cost increases. These agents, also called glycoprotein IIb/IIIa inhibitors, represent a new family of anticlotting medications developed to help prevent heart attack and stroke. The estimated costs per episode of patient care associated with these anticoagulants range from \$200 to \$1,200 (Hensley 1998a).

Other recent cardiovascular device advancements that will lead to increased hospital costs include a laser treatment—transmyocardial revascularization—approved by the FDA in August 1998 to treat patients with coronary heart disease. The acquisition cost for this latest high-tech laser is reported to range from \$200,000 to \$400,000 (Hensley 1998b).

Another recent cardiovascular advancement is the approval of the first of a new class of commercially available blood-derived products—fibrin sealants—that are applied topically to help control bleeding. Fibrin sealants are used to stop oozing from small, sometimes inaccessible, blood vessels during surgery when conventional surgical techniques are not feasible. This product is effective for use in cardiopulmonary bypass and colostomy operations and also in traumatic injury to the spleen.

Additionally, new cardiovascular-related devices have been developed that assist in sealing arterial punctures following cardiovascular procedures, such as angiograms and angioplasties. These arterial wound closure devices include a collagen protein plug that expands to fill the wound and another device that fits inside the hole left by a catheter.

The Commission will monitor the use of these drugs and treatments as well as other new developments, including the escalating trend toward microprocessor-based intelligent devices, such as cardiac

implants and robotics, and minimally invasive cardiovascular surgery. Two examples of applications of these new technologies are:

- coronary bypass surgery, which was recently conducted using a minimally invasive, experimental device in which robotic arms were manipulated by the surgeon, and
- direct access minimally invasive mitral valve surgery, which was found to be efficacious and resulted in accelerated recovery and pain reduction.

Biotechnology

Advances in molecular medicine continue, including genetic diagnostics, genetic therapy, and tissue-engineered devices. Recent developments include use of biological markers to identify disease conditions, such as thrombogenesis during acute coronary syndromes, and use of prognostic antibodies to detect the spread of prostate and gastric cancers. Monoclonal antibodies are being used to manage various cancers, including non-Hodgkin's lymphoma, colorectal, breast, and small-cell lung. The Commission believes that these important biotechnological advances are used to treat relatively small patient populations and will account for modest hospital cost increases.

Several biotechnologies were approved by the FDA in 1998 for chronic disease conditions. A new genetically engineered protein (etanercept) reduces the symptoms of moderate to severe, active rheumatoid arthritis. A monoclonal antibody (infliximab), manufactured using cells containing human and mouse antibody genes, is the first approved treatment for Crohn's disease. Rituximab is the first biotechnology product to treat patients who have low-grade B-cell non-Hodgkin's lymphoma and who have not responded to chemotherapy or other standard treatments. Daclizumab is the first monoclonal antibody to help prevent acute kidney transplant rejection and is used with a standard course of immunosuppressive therapy to help prevent kidney rejection.

The Commission will monitor these and other advancements in genetic diagnosis and tissue-engineered devices during the next several years.

Radiology, imaging, and nuclear medicine

The past three decades have seen an enormous growth in the field of radiology, imaging, and nuclear medicine. During the upcoming fiscal year, we anticipate continued advances in this area, especially improvements and further applications for magnetic resonance imaging, positron emission tomography, ultrasound, and computed tomography. MedPAC believes that the diffusion of these advances will have a modest impact on hospital costs in fiscal year 2000.

Recent advances in the area of imaging include solid-state systems that combine ultrasound with balloon and stent placement; combined imaging atherectomy devices; high frequency imaging; improved methods for characterizing tissue; and three-dimensional reconstruction techniques.

A new generation of computed tomography scanners will soon be available that are faster than previous devices and provide improved clarity. This newer technology may result in expanding the use of computed tomography scanners in trauma, vascular, and cardiac scanning.

Technical developments have increased the speed and versatility of magnetic resonance imaging, including imaging for many cardiac conditions. High-speed magnetic resonance methods are capable of imaging the entire brain with a temporal resolution of a few seconds. Additionally, new contrast agents are being developed to better image the liver during magnetic resonance imaging.

Recent advances have occurred in ultrasound devices and ultrasound imaging drugs. A new ultrasound device has been developed to diagnose osteoporosis and assess the risk of bone fracture. In January 1998, the FDA approved a contrast agent-injectable solution of microscopic gas bubbles that

brighten ultrasound images when sonar-like waves hit them.

Recent developments and advances in contrast echocardiography have improved the diagnosis and evaluation of cardiac structures and function. The new developments in acoustic instrumentation with new contrast agents have improved studies previously obtained by standard two-dimensional echocardiography.

Nuclear medicine advances include improving imaging resolution and increasing sensitivity and quantitative accuracy. Positron emission tomography and single photon emission computed tomography are being used for new applications, such as determining the presence and severity of segmental and diffuse coronary artery disease. The range of biology studied with positron emission tomography radiopharmaceuticals has greatly expanded, involving more sophisticated tracers and more sophisticated data analysis. Improvements in nuclear scanning have improved visualization of various neuropsychiatric disorders, for example.

In the future, the Commission expects functional and multimodality imaging to continue developing and improving. We will monitor advances being made with augmented reality systems—a display technique that combines supplemental information with

the real-world environment. These diagnostic imaging systems are expected to be used in pre-operative planning and pre-operative and intra-operative data visualization. Additionally, we will monitor advances in existing technology, including improvements in imaging resolution and increased sensitivity.

Other devices and technologies

A variety of other devices and technologies have recently been developed, and MedPAC anticipates that these devices will have a small impact on hospital costs in the coming fiscal year. These technologies include microprocessor-based intelligent devices, drug delivery devices, robotic aides, and laser treatment systems.

Based on a review of the literature and the findings of the FDA expert panel, we anticipate an escalating trend toward microprocessor-based intelligent devices used in hospitals. These technologies include cardiac and drug-delivery implants and robotics used during minimally invasive cardiovascular and neurosurgery surgery. For example, during 1998, the FDA approved the use of a monitor that measures the brain's response to anesthesia to ensure patients are completely unconscious during surgery. The Commission anticipates

continued advances in both minimally invasive cardiovascular surgery and invasive neurosurgery. Additionally, we expect continuing advances in endoscopic procedures including fiber optic laser surgery, miniaturized robotic and other devices. For example, in January 1998, the FDA approved a new laser treatment for men with benign prostatic hyperplasia. Substantial developments are anticipated for microminiaturized devices in the next ten years.

We also anticipate continued advances in the development of combination device and drug products, such as:

- devices designed for implanted delivery of drugs, including intelligent devices with biosensors to monitor concentrations in body fluids and make adjustments in delivery rates, and
- drug-impregnated devices, in which drug delivery is an adjunct to the device function, such as cardiac implants with antithrombogenic drugs.

Finally, the Commission anticipates advances in the development of robotic aides over the next 10 years. These advances may lead to diffusion of telesurgery and the use of nontraditional settings as surgical sites. ■

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