REGULATORY CONCERNS AND ISSUES: HAVE THE BUREAUCRATS WON?
The Disconnect Between the HCFA and the FDA

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The Health Care Financing Administration (HCFA) is the federal agency in the United States that administers health care insurance for Medicare beneficiaries. Medicare is extremely important because it has an annual budget of approximately $220 billion, making it the largest health care insurer and the most influential of all third party payers. Medicare provides health care coverage for over 38 million people who fall into one of three categories: 1) all patients 65 years of age and older; 2) all end-stage renal disease patients; and 3) chronically disabled patients. Importantly, by virtue of patient demographics, Medicare pays for approximately 50% of cardiovascular services in the United States (Figure 1).

Medicare benefits are broadly categorized as Part A (payments for hospital services) and Part B (payments to physicians and for hospital outpatient services). Part A benefits are administered via fiscal intermediaries and Part B payments are administered through carriers. Thus, HCFA sets the policies (under direction from Congress) and controls the budgets, but the actual claims processing takes place through these regionally distributed, independent contractors.

The Food and Drug Administration (FDA) is the federal agency that is charged with the responsibility of ensuring that new drugs and devices are safe and effective. The FDA has undergone substantial change during the past decade as a result of the Food and Drug Modernization Act of 1997, passed by Congress in November, 1997, which has had a major impact on the responsiveness of the FDA. There has been no comparable legislation passed to address the need for modernization at the HCFA.

Differences between the HCFA and the FDA.

While the HCFA and the FDA both fall under the Department of Health and Human Services (HHS), they are driven by very different charters and incentives:

1. The FDA’s primary concern is the safety and efficacy of new products. These terms are generally well defined and/or understood. The key decision is whether or not to approve a new medical device or drug for sale. The FDA also specifies the new product labeling and whether post-market surveillance is required. In contrast, the HCFA’s primary concern is whether a new product is “reasonable and necessary”, in the case of Medicare beneficiaries. These terms have not been defined. The HCFA has to decide whether or not to cover a new technology and the appropriate reimbursement.

2. The FDA makes its decisions based on adequately controlled clinical trial data. Conversely, the HCFA considers the clinical trial data as necessary but not sufficient and requires one year of data from Medicare patients (MedPAR data) and a second year for data analysis and rulemaking once the product is approved for sale to determine the appropriate level of reimbursement.

3. The FDA’s response time for certain standard activities (e.g., IDE review, PMA review) is defined by regulation. No comparable timelines exist for the HCFA to respond to requests for reimbursement.

4. The FDA’s decisions are not influenced by concerns about the Health Care Budget; however, the HCFA has to be concerned about the potential impact of its decisions on the Health Care Budget.

5. The FDA tracks and advertises the number of new products that it approves each year. There is a positive incentive to show growth in the number of new approvals annually. In contrast, it seems that the HCFA is concerned that each new reimbursement decision will only add to their costs. Thus, it appears that there is a negative incentive to grant coverage and appropriate reimbursement to new products since all decisions must ultimately be budget neutral.
The time delay from FDA approval to appropriate reimbursement. Although the HCFA and the FDA are both part of the Department of Health and Human Services, there is not much evidence of significant interaction between the two agencies. The disconnect between the two agencies is well illustrated by the case study of the coronary stent (Figure 2). Coronary stents are now used in 70–80% of patients undergoing balloon angioplasty in this country, or approximately 600,000 patients annually. Stenting has been the major breakthrough in interventional cardiology in the past decade. The reasons for this are twofold: 1) Stenting has made angioplasty a much safer procedure, reducing the need for emergency bypass surgery from approximately 4.6% to 0.5%, and has allowed a much wider range of lesions to be treated safely; and 2) stenting has reduced the need for repeat intervention by 30–50%.

The Palmaz-Schatz™ coronary stent was approved by the FDA in August, 1994. However, it took until October 1997 — more than three years — for the HCFA to adjust payment to hospitals to the appropriate level (Figure 2). During this time, hospitals were forced to absorb the added costs of the new technology in order to make it available to Medicare beneficiaries. While this was extremely burdensome to the hospitals, and generated enormous animosity toward the manufacturers of the new technology, it was clearly technology that Medicare patients wanted and needed. The level of adoption of this technology accelerated markedly once appropriate reimbursement was available.

The problem of a major time delay from FDA approval until appropriate reimbursement is provided for new technology has not been solved and unfortunately continues to persist. A current example is cited to illustrate this point. The next major breakthrough technology in interventional cardiology is likely to be intravascular radiation therapy for in-stent restenosis. This highly effective therapy, which targets a very difficult problem, is likely to be approved by the FDA very soon (Autumn, 2000). However, as shown in Figure 3, based on the present HCFA system which necessitates collection of one year’s worth of MedPAR data and essentially another full year to gather and review the data, appropriate reimbursement to hospitals will not occur until at least the Autumn of 2002 — a two-year delay. This means that hospitals will have to choose either to adopt this technology and absorb the incremental costs themselves for every Medicare patient that is treated, or alternatively choose not to adopt this technology. This will clearly be a major dilemma for physicians and hospital administrators, given the current financial state of hospitals.

Figure 1. Percentage of payments for cardiovascular care according to third party payers.

Coronary Stents: A Case Study of Reduced Medicare Patient Access

- 85% to 95% of eligible patients received the technology 1994-1997
- 70% to 80% of eligible patients now receive the technology

Figure 2. Timeline for appropriate reimbursement of the coronary stent by Medicare.

Intravascular Radiation Therapy: Medicare Two-Year + Delay Puts Patients at Risk

- $8,500 Medicare Payment
- $19,000 Procedure Cost

Figure 3. Anticipated timeline for appropriate reimbursement for intravascular radiation therapy (brachytherapy).
Why HCFA reform is urgently needed. Reform of the HCFA is urgently needed for the following reasons:

1. There is currently at least a two-year delay between FDA approval and appropriate reimbursement for new technologies.
2. Private third party payers frequently take their lead from the HCFA.
3. In 1999, a large percentage of hospitals in the United States lost money as a result of the Balanced Budget Reform Act.
4. Hospitals can no longer afford to absorb the unreimbursed costs of new technologies.
5. There will be increasing pressure on physicians not to use new, inadequately reimbursed technology, and on industry not to introduce new technology into the marketplace until it is appropriately reimbursed.
6. It seems difficult to imagine that Medicare beneficiaries will not be denied the best care under these circumstances.

Congressional action. Over the past two years, there has been a growing awareness in Congress of the problem of major delays in the appropriate reimbursement for new technologies after they have been approved by the FDA. Bills have been sponsored and introduced in both the House and the Senate. Some key elements of these bills include:

1. The HCFA should update its process annually to reflect changes in medical practice and technology.
2. The HCFA should allow the use of external (i.e., non-MedPAR) data as well as sample (i.e., less than one full year) of MedPAR data.
3. The HCFA should assign new codes on a quarterly basis during the IDE review process. This will enable pre-FDA approval data to be collected by the HCFA that can be used in lieu of post-approval MedPAR data for reimbursement decisions.
4. The HCFA should report progress annually to Congress to ensure timely access to innovative technologies. This would introduce an element of accountability into the process that is currently not evident.
5. The HCFA should continue to use local procedure codes to ensure the availability of the most current medical technology. Local coverage decisions play a very important role in the diffusion of new technology that would be severely hampered by any greater emphasis on centralized, national coverage decisions.

Conclusion. While there is a growing awareness of this issue in Congress, it is not currently a legislative high priority. The medical industry supports the need for improvement at the HCFA, but much more can and should be done by physicians and the medical specialty societies. Ultimately, a more effective coverage, coding and reimbursement process is in the best interest of patients; the central reason for the existence of physicians and hospitals is to provide better clinical outcomes and quality of life for their patients. Both Congress and the HCFA are much more responsive to the wishes and desires of their physician constituents than to industry. Therefore, it is imperative that the medical societies focus not only on the issue of appropriate reimbursement for physicians but also on appropriate reimbursement for hospitals, since these are two sides of the same coin. If Medicare patients are to receive the same level of care, including access to new technology as patients covered by private insurance carriers, the appropriate, timely reimbursement for both hospitals and physicians for the use of new technology is essential. Therefore, physicians and medical societies need to become more actively engaged in the pursuit of reform of the HCFA Reimbursement Process (Coverage, Coding and Payment Systems). If this is not done soon, the introduction of new health care technologies will be stifled.

REFERENCES