



June 12, 2006

Administrator Mark McClellan, M.D. Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

The National Venture Capital Association (NVCA) appreciates this opportunity to comment on the proposed Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, as issued by the Centers for Medicare and Medicaid Services (CMS) on April 25, 2006.

NVCA applauds your continued commitment to modernizing the health care delivery system, as well as your efforts to bring innovative medical technologies to market as rapidly as possible. The venture capital community works closely with many of the companies developing these new technologies. The NVCA therefore offers a unique and important perspective on several of the issues raised in the proposed rule. NVCA proposes to work closely with CMS to develop a refined pathway for Medicare coverage and reimbursement of new technologies used in the inpatient setting, including innovative new medical devices, drugs, and biological products.

Background on the National Venture Capital Association

The National Venture Capital Association is the trade association that represents the U.S. venture capital industry. NVCA's mission is to foster greater understanding of the importance of venture capital to the U.S. economy and to support entrepreneurial activity and innovation. The NVCA advances the common interests of the venture capital community by maintaining high professional standards, providing reliable information and data regarding our industry, sponsoring professional development, and facilitating interaction among Association members.

The life sciences industry has traditionally been one of the largest sectors of investment for venture capitalists, in 2004 totaling almost \$6 billion, or approximately 30% of all venture capital dollars invested. It is estimated that more than 100 million Americans have benefited from innovations developed by life sciences companies originally financed with venture capital.

Many such innovations have revolutionized the practice of medicine by helping physicians detect diseases earlier, treat chronic diseases, and reduce mortality. For example, innovations in treating heart disease—the leading cause of death in the U.S.—such as angioplasty, minimally invasive by-pass, and implantable defibrillators, were all originally pioneered by venture-backed companies. Much of the current innovation in medical technology is focused in particular on replacing surgery with minimally invasive or noninvasive procedures that eliminate or substantially reduce the need for cost-intensive hospitalization and inpatient services. Such cost-effective technologies have dramatically improved the quality of life for millions of patients by lengthening their productive years, decreasing the incidence and duration of disability, and ultimately extending life expectancy.

Venture capital investment is especially important for the life sciences industry because of the significant time and expense associated with bringing innovative new technologies to market. Due to the high costs of clinical trials required to satisfy FDA safety standards, life sciences companies tend to require greater investment than startup companies in other industries. In most cases, these costs must be incurred before the company starts generating revenue. Further, due to the long span of time before any return on investment is typically realized, as well as the high degree of risk involved, investment by individuals is usually insufficient, and investment from banks and public capital markets is unlikely. Venture capital is thus the only viable source of funding to support the development of the majority of life sciences innovations.

DRGs: Severity of Illness

NVCA has long been concerned that the diagnosis-related group (DRG) assignment system does not always adequately capture the costs of many new technologies and that, as a result, hospitals are often not appropriately reimbursed. CMS's proposal to undertake the largest overhaul in the history of the DRG system presents an opportunity to address this problem. The proposed rule would modify the DRG classification system to better recognize the severity of illness among patients. Specifically, CMS proposes to refine the system by consolidating the 1,258 All Patient Refined Diagnosis Related Groups (APR-DRGs) into 861 severity-adjusted DRGs. NVCA supports this proposed reform.

NVCA is concerned, however, that the proposed APR-DRG system does not explicitly recognize technologies that involve increased complexity in the absence of greater severity of illness. For example, CMS currently uses separate DRGs for coronary angioplasty with and without the insertion of stents. However, the APR-DRGs do not differentiate between the two. By accounting for complexity in DRG assignment, CMS would help to ensure that hospitals provide optimal treatment to each patient notwithstanding the relative severity of his or her condition. Indeed, the proposed rule acknowledges that reform of the DRG system should incorporate “*a method of recognizing technologies that represent increased complexity*” of particular products. To that end, CMS solicits comments on the development of “*criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with existing statutory provisions for new technology add-on payments.*” 71 Fed. Reg. 24014 (April 25, 2006).

NVCA is pleased that CMS recognizes the importance of both making the DRG system more granular and accounting for the complexity of new technologies in DRG assignments. Many new technologies, particularly medical devices, are used in the hospital inpatient setting, and payment is bundled into the applicable DRG. Hospitals are often reluctant to use new technologies, however, when they are not accompanied by an increase in hospital payment. This in turn limits the utilization of many new technologies that benefit patients and, by reducing medical complications and readmission rates, provide potential long-term cost savings to Medicare.

An inpatient procedure that uses a new technology with increased complexity should be assigned to a DRG with a higher payment weight. Under the current inpatient system, complexity is classified by CMS according to the type and relative volume of diagnostic, therapeutic, and bed services required for the treatment of a particular illness.

Additional factors that CMS could consider when evaluating the complexity of a new technology for DRG assignment include:

- whether the technology entails clinically meaningful advantages over existing approved alternative treatments;
- whether the technology represents a breakthrough that provides a clinically meaningful advantage over existing technology; and
- the absence of an approved alternative treatment or means of diagnosis.

New Technology

NVCA expresses its strong support for the new technology add-on payment, and commends CMS for its efforts to open the process to the public. Congress has expressed its expectation that CMS will utilize the new technology add-on payment. Until recently, such payments were subject to the budget neutrality requirements of the inpatient hospital prospective payment system. However, section 503(d)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 removed this requirement, providing that “there shall be no reduction or other adjustment in payments under section 1886 of the Social Security Act because an additional payment is provided under subsection (d)(5)(ii)(III) of such section.” Congress clearly intended this affirmative exemption to encourage the approval of additional payments.

As it is currently administered, however, the new technology add-on payment is flawed and underutilized. Relatively few products have been approved for such payments, and the payments themselves are often quite limited. To qualify for a new technology add-on payment, (1) the product must be “new”; (2) the product must represent a “substantial clinical improvement” over existing products; and (3) the cost of cases in which the product is used must be substantially higher than the cost for comparable cases, thus making the typical Medicare reimbursement rate inadequate. A manufacturer that fails to meet any of these criteria may re-apply, but such

reapplications are often denied because the passage of time since the initial application renders the product no longer new.

NVCA is concerned that these criteria have been selectively applied and have not been developed through the rulemaking process, consistent with congressional intent. NVCA wishes to draw particular attention to certain difficulties in the operation of two of the three criteria.

Newness

The current CMS framework often reduces considerably the period of time for which a product would otherwise be considered “new.” CMS measures a product’s “age” from the date of FDA approval, rather than the date that the date of issuance of the ICD-9-CM code describing the administration of the product, as provided by both the Social Security Act and CMS’s own regulations.¹ The application process itself can also consume a significant portion of the two-to-three-year period during which products will qualify as “new.” For example, applications for new technology status for FY ’07 were due on October of 2005, but payments will not be effective until October 2006. Products that received FDA approval after August 1, 2005, will therefore not be eligible for a new technology add-on payment until more than one year after launch.

We encourage CMS to take advantage of the full two to three years of data collection permitted under the Medicare statute and regulation. NVCA proposes that CMS allow manufacturers to apply for a new technology add-on payment on an ongoing basis, and that the agency issue quarterly updates announcing the approval of new add-on payments. A similar process has been implemented for pass-through and new technology payments in the hospital outpatient setting.

Furthermore, a product that otherwise qualifies as new based on age nevertheless will not be considered new if it is “substantially similar” to an existing product. For example, in the proposed rule CMS requested comments on whether Cardica’s C-Port Distal Anastomosis System is new, and how to distinguish it from other predicate services. CMS notes that C-Port was found to be substantially equivalent to predicate devices under the FDA 510(k) approval process.

A determination of substantial equivalence by the FDA under 510(k) does not mean that the new and predicate devices are identical. Rather, approval simply indicates that the new device is at least as safe and effective as the predicate device. 510(k) approval should not be used by CMS as a bar to a determination of “newness.” Any clinical determination for New Technology status should instead be addressed under the “substantial clinical improvement” prong discussed below.

¹ See Social Security Act § 1886(d)(5)(K)(ii)(III); 42 C.F.R. 412.87(b)(2).

Substantial Clinical Improvement

A manufacturer applying for a new technology add-on payment must also prove, through the submission of clinical evidence, that a product represents a “substantial clinical improvement” over existing products. Under 42 C.F.R. § 412.87(b)(1), “[a] new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.” A high percentage of applicants for new technology payments fail to satisfy this requirement.

CMS should broaden the definition of “substantial clinical improvement.” In the hospital outpatient context, for example, CMS views as a “separate factor” “*improvements in the medical technology itself that are so significant that we may wish to recognize them for separate payment even though they do not directly result in substantial clinical improvements.*” Such technological improvements might include advances that enhance a product’s “*convenience, durability, [or] ease of operation,*” such as “*the strength of the materials, increased battery life, [and] miniaturization.*” 66 Fed. Reg. 55853 (Nov. 2, 2001). CMS could similarly recognize additional indices of clinical advancement when evaluating whether an improvement is “substantial” in the inpatient context. In addition to the factors just noted, these might include, for example, patient comfort and convenience, ease of administration, and the like.

Pathway for Emerging Technologies

NVCA’s expertise in emerging companies and their technologies provides a unique and important perspective on several of the issues raised in the proposed rule. NVCA would like to work closely with CMS to help the agency refine the regulatory framework under which it evaluates new innovative treatments for Medicare beneficiaries.

NVCA has worked with the FDA on various small-company issues in the past, and would like to engage in similar collaboration with CMS. There has already been considerable discussion about coordination between CMS and FDA. CMS could create a clear pathway for small companies engaged in the FDA review process to elect to meet concurrently with CMS to discuss coverage, payment and coding of emerging technologies.

For example, the Center for Devices and Radiological Health operates a Division of Small Manufacturers, International and Consumer Assistance that provides substantial outreach to small and startup manufacturers. The Center for Drug Evaluation and Research (CDER)’s Office of Training and Communication (OTC) provides similar services to small business owners, and participates in programs on emerging topics of interest to small business. In collaboration with the U.S. Small Business Administration (SBA), CDER held a public workshop on April 25th of this year to provide information to small pharmaceutical businesses about FDA’s premarket requirements; good manufacturing practices; OTC and generic drug issues; and the SBA’s training, counseling, and contracting programs.

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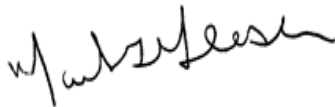
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We suggest holding a meeting of the Council for Technology and Innovation (CTI) that focuses on emerging technologies and small companies. At present there is an annual New Technology Town Hall where companies can present on the “substantial clinical improvement” requirement. The Town Hall meeting has made the process more transparent and allowed early-stage companies an opportunity to present directly to CMS. The CTI should hold a forum with early-stage companies to discuss a wide range of issues relating to coding, coverage and payment for new technologies.

Finally, CMS should harmonize its approach to clinical data with that of the FDA. As the agencies increasingly collaborate, as they did on the Oncology Biomarker Qualification Initiative, for example, it will become even more important for CMS to align its interest in clinical evidence with the clinical study requirements associated with FDA review. Stakeholders would benefit, in particular, from discussions of both the formal criteria with which CMS evaluates data produced for FDA premarket review, as well as the informal and professional perspective that the agency brings to that data. Such discussions would enable stakeholders to better understand the value and significance of FDA premarket review data to the Medicare program.

The twenty-first century will be the life sciences century, and the venture capital community will play critical roles in shaping and fueling that growth. We look forward to working collaboratively with CMS to help make the next generation of medical breakthroughs available to Medicare beneficiaries.

Very truly yours,



Mark G. Heesen
President, NVCA

cc: Marc Hartstein, M.D.
Deputy Director, Division of Acute Care