

The “Substantial Clinical Improvement” Requirement for New Technology Add-On Payments:

Statement of the National Venture Capital Association

The National Venture Capital Association (NVCA) appreciates the opportunity to participate in this Town Hall Meeting, and specifically to comment on the “substantial clinical improvement” requirement for new technology add-on payments. The NVCA would like to work closely with CMS to develop a reimbursement critical path for novel, high-value medical products. Refining CMS’s process of reviewing applications for add-on payments to ensure greater consistency and predictability is a critical component of this effort.

The National Venture Capital Association is the trade association that represents the U.S. venture capital industry. The 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. Because the venture capital community works closely with the companies developing innovative new technologies, the NVCA offers a unique perspective on Medicare coverage and payment with respect to emerging medical products.

The NVCA applauds CMS’s continued commitment to modernizing the health care delivery system, and to making innovative medical technologies available as rapidly as possible. The new technology add-on payment is critical to the efforts of technology innovators to bring novel, high-value products to the medical marketplace. Indeed, Congress’ purpose in providing for add-on payments was to enhance the Medicare population’s access to such products.

As it is currently administered, however, the application and review process for new technology add-on payments—and particularly the administration of the substantial clinical

improvement requirement—is inconsistent and unnecessarily opaque. From FY 2003 through 2006, CMS approved six of eleven unique applications where the agency had to apply judgment about whether the applicant had satisfied the criteria (i.e. excluding applications that were denied on the basis of “objective” newness or cost criteria). CMS notes that this represents an approval rate of over 50 per cent. However, this figure obscures the extent to which many more would-be applicants have likely been deterred by the unpredictability of the process. The absence of a precise and transparent standard for the agency’s substantial clinical improvement determination has created considerable confusion among manufacturers, with the result that add-on payments are seriously underutilized.

At present, in order to qualify for an add-on payment, an applicant must demonstrate, in addition to the newness and cost requirements, that the product in question “represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.” CMS has suggested that applicants can satisfy this requirement by showing, for example, that their product “reduces mortality, decreases the number of hospitalizations or physician visits or reduces recovery time.” However, CMS has not provided clear guidance with respect to the type of data that applicants must submit to make such a showing.

The NVCA finds CMS’s inconsistent use of external data to be particularly problematic. In the Final Rule for FY 2007, for example, CMS rejected Cardica Inc.’s application for an add-on payment for its C-Port Distal Anastomosis System (C-Port), notwithstanding abundant evidence of C-Port’s superiority to conventional hand-sewn anastomosis, on the grounds that Cardica had not proved that superiority through a prospective clinical study. In marked contrast, in its review of St. Francis Medical

Technologies' application for its X STOP Interspinous Process Decompression System (X STOP), CMS wisely took into account all of the available data, and approved the X STOP for an add-on payment on the basis of its demonstrated effectiveness on the spines of cadavers. As these brief examples suggest, applicants for new technology add-on payments are aiming at a moving target, creating uncertainty for early stage companies and investors.

The NVCA proposes that CMS convene a panel of stakeholders, including researchers, clinicians, industry representatives and patient groups to develop specific, generally applicable criteria for the determination of whether a new product represents a substantial clinical improvement, including the creation of objective standards for the use of external data. The panel should consider, in particular, whether the Council on Technology and Innovation (CTI) might be an appropriate body to ensure consistency in the review of applications for new technology add-on payments. As a cross-component entity, CTI is well positioned to weigh the relative value and efficacy of novel technologies. Such an innovation could go a long way toward improving the transparency and predictability of the new technology add-on payment applications process, and better align Medicare reimbursement with the goal of enhancing beneficiary access to novel, clinically effective technologies.

The NVCA looks forward to working collaboratively with CMS to develop a reimbursement critical path for novel, high-value medical products, and to make the next generation of medical breakthroughs available to Medicare beneficiaries. As we have suggested today, we believe that clarifying the standards for and improving the predictability of the agency's substantial clinical improvement determination is vital to the efforts of technology innovators to bring such products to the medical marketplace. Equally important,

however, is the application of the newness and cost criteria. For this reason, the NVCA urges CMS to open up future Town Hall Meetings to those issues as well.

Thank you, again, for this opportunity to comment on the substantial clinical improvement requirement. The twenty-first century will be the life sciences century, and the Medicare program, in collaboration with the venture capital community and other stakeholders, will play a critical role in fueling technological progress.