

August 23, 2004

The Honorable Tommy G. Thompson  
Secretary  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Docket No. 2004S-0233: Solicitation of Comments on Stimulating Innovation on Medical Technologies**

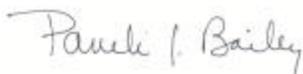
Dear Secretary Thompson:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide these comments on the Department of Health and Human Services' Solicitation of Comments on Stimulating Innovation in Medical Technologies. As an industry devoted to developing life-saving and life enhancing innovations, we look forward to working with you and your task force to encourage further advances in patient care.

AdvaMed is the largest medical technology trade association in the world, representing more than 1200 medical device, diagnostic products, and health information systems manufacturers of all sizes. AdvaMed member firms provide nearly 90 percent of the \$75 billion of health care technology products purchased annually in the U.S. and nearly 50 percent of the \$175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than \$30 million in sales annually.

We commend you for the many efforts you have already begun in the effort to both stimulate innovation and improve patient access to technology, including the Roadmap initiative and the Critical Path initiative. Enclosed please find AdvaMed's recommendations for additional ways to partner with industry to encourage investment in the development of medical technologies as well as improve patient access to these needed advances through streamline government regulatory and reimbursement processes.

Sincerely,



Pamela G. Bailey

Enclosure

## THE NATIONAL INSTITUTES FOR HEALTH (NIH)

**Basic, Applied, and Transitional Research.** Historically, NIH has engaged primarily in basic research with an occasional foray into applied work. Recently, Congress established the National Institute for Biomedical Imaging and Bioengineering (NIBIB), which is the only NIH institute whose mission includes basic research, applied research, and translational research. The NIBIB Mission includes “promoting fundamental discoveries, design and development, and translation and assessment of technological capabilities in biomedical imaging and bioengineering, enabled by relevant areas of information science, physics, chemistry, mathematics, materials science, and computer sciences.”<sup>1</sup> The NIBIB Mission also states that, “The Institute coordinates with the biomedical imaging and bioengineering programs of other agencies and NIH Institutes to support imaging and engineering research with potential medical applications and facilitates the transfer of such technologies to medical applications.”<sup>2</sup>

AdvaMed believes that NIBIB can play a key role in the success of the FDA Critical Path Initiative. In the medical devices area, much of the potential research resides in general areas of applied research that appear to fall within the NIBIB mission. For example, as software control becomes nearly ubiquitous in electronic devices, an effective, efficient user interface becomes vital. Devices use fewer keys and buttons to control more functions. There is a need for more advanced human factors research to examine these newer interfaces, and we believe that NIBIB should fund and otherwise encourage this work.

We also believe that with the formation of NIBIB, the medical devices industry has a rare opportunity to develop a research agenda within NIH that can address some of the applied research that industry would like to see. However, we note that NIH has a long and distinguished history of performing basic health care research. Its grant approval process was set up to evaluate basic clinical research proposals, and the people who participate in it are used to that paradigm. To evaluate applied research proposals properly, NIH will need to approach them differently. Proposals for applied work deserving of funding would likely be scored low if one were to rate them using the same values one would use to rate a basic research proposal. The approval process will need to be significantly revised to refocus on proposals for applied work.

## THE FOOD AND DRUG ADMINISTRATION (FDA)

**Feedback processes.** Due to the unique nature of medical technology product development, particularly medical devices, AdvaMed believes that feedback processes need more structure to encourage innovation. Feedback processes include premarket information (e.g., data obtained from the manufacturing process) and postmarket information (e.g. adverse event reports). In January 2004, JAMA published an article co-authored by Rosalie Bright of FDA that examined several methods of hospital surveillance of adverse events.<sup>3</sup> The report observed that the various surveillance methods examined yielded different and inconsistent results. It would be worthwhile to pursue a discussion of post market surveillance methods while addressing feedback loops, since manufacturers gain a great deal of useful information from postmarket sources, both formal and informal.

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<sup>1</sup> NIBIB Mission statement

<sup>2</sup> Ibid.

<sup>3</sup> Samore, Matthew H., et al., “Surveillance of Medical Device–Related Hazards and Adverse Events in Hospitalized Patients,” *JAMA*. 2004;291:325-334

A project to define the feedback paths and iterations related to medical device development is likely to result in a better understanding of a key element of the development process. We believe that this could lead to postmarket reporting that would be less burdensome and more informative than the current systems.

We also believe that better understanding of the feedback mechanism could provide a means to create more effective postmarket studies that would benefit all parties. A good postmarket study should be a source of useful information for the manufacturer to use in its required risk management system, which is intended to assist the manufacturer in assuring the safety of current devices and guiding the development of device enhancements.

**Guidance Documents.** Guidance documents are of great value to both industry and FDA staff. When a good guidance document is in place, the industry understands what the agency expects to see in a submission. Similarly, the FDA reviewer can be comfortable that most incoming submissions will be close to the mark in terms of appropriate content. Historically, there has been a need for more guidance than FDA has staff time to produce. Thus, many existing documents have fallen out-of-date and present little value to either industry or FDA. In addition, many existing and emerging technology areas and devices suffer from a lack of written guidance. This lack of current guidance makes it much more difficult for companies to provide FDA with the data and information they expect in submissions. This slows the approval process and can act as a significant barrier to companies just entering a particular field.

Unfortunately, the promulgation of the agency's Good Guidance Practices, intended to bring greater transparency to the process, may have had the inadvertent effect of slowing the development process. In recent years, FDA staff has been much more cautious about working with industry on guidance, even at the drafting stage. We believe that we need to develop mechanisms to permit FDA and industry members to work together to develop first drafts of guidance documents. Developing the first draft is the major hurdle in developing either guidance or a standard. Once a draft that has at least a first level of agreement is completed and made available for public comment, the process can flow much more smoothly and rapidly. We believe any efforts to expedite both the development of new and the revision of existing guidance documents would have dramatic positive impact on the development and availability of significant new medical technologies.

**Data Summary Template.** We recommend that CDRH prepare a data summary template for each standard that it recognizes and publish it along with the data sheet on the recognition of that standard. This would ensure that both manufacturers submitting a Declaration of Conformity and the reviewer receiving it would have a common understanding of what is required.

**IVD Issues.** In a report dated March 2001, Deutsche Banc Alex. Brown estimated that "home brews"<sup>4</sup> accounted for 30 percent of the nearly \$5.0 billion market for "life science reagents."<sup>5</sup> Others have estimated that the market share for home brews may be even higher. Research conducted by the Task Force on Genetic Testing suggests that 55.3 percent of non-profit clinical

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<sup>4</sup> Home brews are diagnostic assays or tests created by clinical laboratories for use by that laboratory.

<sup>5</sup> See Deutsche Banc Alex. Brown, LIFE SCIENCE REAGENT COMPANIES: HELPING DECIPHER THE GENETIC CODE 9 (2001).

laboratories offering genetic testing services used tests developed in-house, as did 47.8 percent of biotechnology companies providing such services.<sup>6</sup>

Most laboratories that perform genetic testing use their own tests, which are unregulated by FDA.<sup>7</sup> In fact, according to FDA, in 2000, at least 301 clinical or research genetic tests were offered in the U.S.,<sup>8</sup> and 158 laboratories offered clinical tests.<sup>9</sup> Yet at the time, FDA had approved only six specific gene tests.<sup>10</sup> With up to 80 percent of all healthcare decisions relying on clinical laboratory tests,<sup>11</sup> and up to 10 billion lab tests performed in the U.S. each year,<sup>12</sup> the risks posed by lab-made tests that lack FDA oversight cannot be overestimated.

Tests developed and performed in labs do not require prior review by FDA, while tests developed by manufacturers and sold to labs do. Laboratorians believe that it is necessary to provide testing services for newly recognized analytes and for analytes that represent niche markets, and both laboratorians and the physicians who order tests are unwilling to wait for tests to go through the FDA review process. This suggests that FDA needs a much speedier process than is currently available for enabling tests that identify new analytes to get to market.

In many cases, particularly when home-brew tests have proliferated, there is ample evidence of the clinical significance of the analyte. When such evidence exists, FDA could grant marketing permission for new diagnostics based on characterization of analytes rather than on full clinical testing. The requirement for FDA approval would apply to both manufacturer- and lab-developed tests. This would provide a greater degree of FDA oversight than at present and could assure that tests, wherever developed, comply with FDA requirements for registration and listing, labeling and instructions for use, adverse event reporting, and good manufacturing practices. Previously, when confronting this challenge, FDA took the position that it lacked the resources to deal with the influx of applications that would result. Currently, however, FDA has the ability to collect user fees for diagnostic reviews, which could provide the needed additional resources.

Alternatively, should FDA continue to not regulate tests developed and performed by clinical laboratories, easing submission requirements would enable manufacturers to obtain marketing clearance with the same type and quantity of data that laboratories currently collect prior to offering a new testing service. FDA would thus assure a level playing field and would enable manufacturers, for which the FDA approval process provides the added assurance of safety and effectiveness, an incentive to develop new tests rapidly.

**IRB Review and Informed Consent for Certain IVD Studies.** We recommend that FDA set guidelines for waiving IRB review and informed consent requirements for IVD studies that utilize leftover or banked samples that are either unidentified or unlinked. AdvaMed further suggests that

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<sup>6</sup> National Human Genome Research Institute, *Final Report of the Task Force on Genetic Testing, Appendix 3. State of the Art of Genetic Testing in the United States: Survey of Biotechnology Companies and Nonprofit Clinical Laboratories and Interviews of Selected Organizations* 14 (1997).

<sup>7</sup> Cystic Fibrosis FAQ, Genetics & Public Policy Center, <http://www.dnapolicy.org/cf/faq.jhtml>, (last visited April 12, 2004).

<sup>8</sup> David W. Feigal, Jr., Center for Devices and Radiological Health, "Future Trends" (July 18, 2000) (presented before the AdvaMed Submissions Workshop, Washington D.C.).

<sup>9</sup> *Ibid.*

<sup>10</sup> *Ibid.*

<sup>11</sup> See Nancy Williams, *How Reliable is Laboratory Testing?*, [www.labtestsonline.org/understanding/features/reliability.html](http://www.labtestsonline.org/understanding/features/reliability.html) (last modified May 19, 2003).

<sup>12</sup> *Ibid.*

FDA waive the informed consent requirements (but not the IRB review) for limited data or coded samples.

Historically, IVD companies have utilized leftover or banked samples to characterize the performance of their products and to control manufacturing processes. These samples have been collected by laboratories when patients were referred for specific testing and have typically been characterized by a medically accepted test or method. There are many advantages to using these samples, particularly for those diseases or conditions where positive samples appear infrequently, e.g., atypical pneumonia caused by *M. pneumoniae*. By using banked samples, a company may be able quickly to demonstrate a test's sensitivity and specificity, rather than waiting several years to enroll a large enough number of test sites to find positive patients.

Generally, studies that utilize leftover or banked samples require little to no personal health information to be transferred with the sample or the test result. These studies can typically be performed on unidentified, unlinked, limited data, or coded samples.<sup>13</sup> In its report issued in August 1999, the National Bioethics Advisory Commission (NBAC) determined that:

- ?? “Research conducted with unidentified samples is not human subjects research and is not regulated by the Common Rule” (no IRB or informed consent necessary).
- ?? “Research conducted with unlinked samples is research on human subjects and is ... eligible for exemption from IRB review” (IRB exempts study from review, no informed consent necessary).
- ?? “When a study is of minimal risk, informed consent is no longer needed.... IRBs should operate on the presumption that research on coded samples is of minimal risk to the human subject if a) the study adequately protects the confidentiality of personally identifiable information obtain in the course of research, b) the study does not involve the inappropriate release of information to third parties, and c) the study design incorporates an appropriate plan for whether and how to reveal findings to the sources or their physicians should the findings merit such disclosure.”

Although the NBAC report was referring to the Common Rule (45 CFR 46), and not to FDA's IRB and Informed Consent rules (21 CFR 50 and 21 CFR 56), the same principles should apply. The two rules should be consistent.

- ?? Notwithstanding our comments regarding the speed to market of new IVD tests, including genetic tests, there may be situations in which clinical validation of a molecular test is necessary or desirable to support a product claim. Here, it would be beneficial to identify new approaches to clinical validation of molecular diagnostics. Such approaches could include:
  - a. The use of literature to establish or bridge clinical validity when supported by analytical claims;
  - b. Obtaining a statistically adequate number of specimens by phenotype, rather than genotype;
  - c. Statistical methodologies applied to existing literature; or

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<sup>13</sup> Limited data samples are those that include certain demographic information, as defined by HIPAA, but cannot reasonably be identified from that information. An unidentified sample is one that has no accompanying demographic information or identifying information or an individual sample that has been pooled with other samples so that it is no longer individually distinguishable.

- d. The use of DNA specimens collected from previously completed clinical trials for prospective clinical validation by blinding those genotyping the specimens from the clinical data under a pre-specified analysis plan.

**Risk-Based Approaches for IVD Product Development.** Risk-based approaches applied to areas of the IVD product development cycle, such as process validation, can expedite the availability of IVDs to address emergent diseases. Risk-based models for IVD process validation need to be developed based on concepts such as: (1) the use of components from other validated assays, (2) process point inspection (i.e., process points that through FMEA are traceable to critical product quality attributes) and test verification, in lieu of validation, or (3) validation plans designed for post-approval validation.

**CDRH Reviewer Education Programs.** Technology is changing extremely rapidly, and it is difficult for FDA reviewers to remain current, not only with the technology itself, but also with the medical procedures for which the technology is employed. There needs to be a well understood, carefully designed system for providing the needed educational opportunities to the CDRH reviewers. This seems to be an ideal vehicle for collaboration among FDA, industry, and academia.

As part of the overall education/training effort, it would be worthwhile to investigate the possibility of setting up more forums like the National Cancer Institute's (NCI) National Forum on Biomedical Imaging in Oncology, which NCI, FDA, and NEMA sponsor jointly. According to the NCI website, "The National Cancer Institute (NCI) is committed to facilitating the translation of promising new discoveries into the clinic."<sup>14</sup> The site also explains that "The National Forum on Biomedical Imaging in Oncology (NFBIO) was created in 1999 to facilitate partnerships with the imaging industry and government agencies to address new biomedical opportunities and challenges in oncology, and to focus on the regulatory, coverage, and reimbursement issues for more developed and established technologies."<sup>15</sup> We believe that it would be fruitful to examine the possibilities of establishing similar entities in additional specialty areas.

**Data Collection for New Uses of Devices.** In general (mammography being an exception) FDA does not regulate the practice of medicine. This is a long-standing principle that the FDA, the medical device industry, and the medical profession would like to maintain. Because of this fundamental principle, clinicians are free to apply medical products (drugs, biologics and devices) in ways and for purposes that neither the manufacturer nor the FDA considered during the application and approval process (provided the physician has determined the therapy to appropriate and necessary). In effect, this "off-label" use of medical products often serves as a proving ground for novel device applications (i.e., unfunded research and development).

In the spirit of the "least burdensome" principle, we recommend FDA be open to the use of data collected from independent, formal clinical trials to facilitate approval of new uses of existing medical devices. This becomes particularly important when an 'off-label' use has become so commonplace within the medical community that it has become the standard of care? thus making it impossible to enroll patients in a randomized clinical study that seeks to enroll one-half of the patients into a control group using an approved (yet obsolete) therapy or device.

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**Note:** <sup>?</sup> indicates a topic that will also be relevant to Secretary Thompson's Innovation Initiative.

<sup>14</sup> National Cancer Institute Web site: <http://otir.nci.nih.gov/ir/forum.html>

<sup>15</sup> *Ibid.*

There are circumstances in which it would be appropriate for FDA to accept data from an independent, formal clinical trial (or multiple such trials) to validate an off-label use, and there are circumstances where this would not be so. We believe that FDA could improve the flow of approvals for additional indications for already approved devices by defining reasonable guidelines for the use of independent rather than company-sponsored clinical trials.

**Model Development Criteria.** We propose an effort to develop criteria to determine when models are appropriate as a substitute(s) for clinical testing. We believe that several areas have high potential and should be the first addressed: software, materials, toxicology, sterilization, and statistics. As the power of computers has grown, it has driven the complexity and sophistication of computer modeling has increased substantially. In the appropriate circumstances, computer models could replace clinical data collection. The challenge here is to define those circumstances and to determine whether the cost of and the time required for model development make it worthwhile. In some instances, a good model could reduce both the cost of and time for an FDA approval. In other cases, the cost of the model itself could outstrip the savings, or, when technology is moving very rapidly, the time to develop the model could exceed the market life of the products.

## **THE CENTERS FOR MEDICARE AND MEDICAID SERVICES**

**Standards of Evidence.** AdvaMed believes that the standards of evidence used by Medicare to make coverage determinations should be sensitive to the unique nature of advanced medical technology innovation and ensure patients access to quality medical care. Evidence-based medicine is defined as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine integrates individual clinical expertise with the best available external clinical evidence from systematic research.

However, sound evidence consists of many different things. It includes evidence from large-scale clinical trials, but it also encompasses a broad spectrum of information available to the medical community, including the experience of individual practitioners who provide treatment in everyday practice. Outcomes research should be viewed by policy decision makers as one tool among many that are available for use by physicians and patients in making optimal practice guidelines developed by professional medical societies or other respected organizations. Guidelines by these professionals should be considered by CMS in the coverage decision making process. The independent exercise of professional medical judgment is crucial to the practice of evidence based medicine because it enables physicians and patients to use the best available evidence in making optimal treatment decisions for individual patients.

When clinical evidence is generated through the most rigorous of clinical trials, CMS should rely on that evidence and issue a Medicare coverage determination consistent with that evidence in a timely fashion. A single, well-designed randomized controlled trial showing positive benefit to the Medicare population should generate sufficient evidence in most cases to determine initial Medicare coverage for the technology or procedure at issue. Coverage policies may be revised as additional evidence becomes available.

Federal agencies, such as the FDA, CMS, NIH, and AHRQ, have extensive authority with regard to the consideration, collection, and review of evidence related to medical interventions. These agencies each have separate and distinct mandates, but communicate regularly and routinely, to the extent permissible by federal law. AdvaMed does not support any activities that would disrupt or

lengthen either the FDA regulatory clearance and approval process, or the CMS national coverage process.

It is also important to stress that, as FDA and CMS communicate with one another as part of their efforts to understand the full scope of clinical evidence, that they also carefully preserve the confidentiality of all company trade secrets and other proprietary data that are provided by manufacturers. The transfer of confidential company data from FDA to CMS should occur only at the request of the submitting manufacturer.

**Humanitarian Use Device Designations and Humanitarian Device Exemptions.** Technologies that have received humanitarian use device (HUD) designations and humanitarian device exemptions (HDEs) from the FDA involve treatments for small populations with no other viable treatment modality. Through the HDE approval process, Congress and the FDA explicitly have promoted the development of technologies that treat orphan diseases. Similarly, CMS should foster innovation in the treatment of orphan diseases through the national coverage process. By providing prompt national coverage for HDE technologies, CMS can provide access to care for Medicare patients who would otherwise go without treatment.

**Coverage Issues.** Prompt coverage permits the maximum contribution of medical therapies to society. It enables the improvement of patient health outcomes, by generating the kind of practical clinical knowledge and experience that is useful to gain a clear understanding of long-term effectiveness and clinical value. Further, it provides prompt access to medical therapies for patients and providers. The local Medicare coverage process is an excellent example of a means to provide prompt coverage, access, and knowledge that can better inform Medicare's long-term judgments on effectiveness and value.

We support Medicare coverage in Category B device clinical trials for both the costs of routine patient care and the medical devices under investigation at contractor discretion. We also endorse coverage for routine patient care costs in Category A device clinical trials consistent with the Medicare Prescription Drug, Improvement and Modernization Act (MMA). If CMS issues a national non-coverage decision, CMS should permit coverage of related Category B clinical trials in order to promote the continued development of evidence, which will inform future agency decisions about new uses of medical technology.

Knowledge of the ultimate clinical effectiveness of many medical treatments emerges slowly, over time, as practitioners gain experience, understanding grows, and therapies evolve-often through gradual, incremental adjustments and innovations in real-world practice settings. Unless Medicare recognizes this reality of incremental innovation, it runs the risk of forcing premature assessments that will yield premature judgments on the value of technology that could deny patient access to important and often cost-saving treatments. In light of this, policymakers should be wary of Medicare coverage processes that force early assessment and should bear in mind that the absence of conclusive evidence does not equate to the absence of clinical value. CMS should not make National Non-Coverage Decisions unless it has definitive clinical information that a product or service is not effective or that it causes patient harm.

Evidence is important in coverage decisions, but sound judgment is just as critical especially when evidence is incomplete or evidence cannot answer every question that may arise. Sound judgment based upon a variety of factors-from the experiences of individual practitioners and the perspectives of professional associations, to the needs of Medicare beneficiaries-is essential. In light of this, AdvaMed supports CMS flexibility in the coverage process, which allows the government to make decisions that adapt to the dynamic, evolving nature of medical care and

patient needs. Case-by-case treatment determinations at the local level allow physicians to meet the needs of individual patients.

**Good Guidance Practices.** The MMA requires CMS to develop guidance documents in a manner similar to the way in which the FDA develops guidance documents using Good Guidance Practices ("GGPs"). A central purpose of the FDA GGPs is to describe how the public and the agency will work together to develop guidance documents. For example, they set forth (1) how and when the public may participate in guidance development, (2) the effect of guidance on stakeholders and the agency, and (3) an appeals process for guidance documents. To be effective, guidance documents need to be practical for the agency and for Medicare stakeholders. AdvaMed recommends that CMS use a public process to develop a guidance document that lays out the agency's own version of the GGPs. CMS should publicly vet a guidance document that describes how it will develop future guidance documents.

Under the GGPs, FDA may seek input from the public prior to developing a guidance document. AdvaMed believes that CMS's willingness to solicit and listen to stakeholders' input before publishing draft guidance (and before the agency becomes too invested in a particular proposal) is essential. CMS should provide stakeholders with opportunities to engage in real-time dialogues with CMS personnel to discuss issues in need of resolution before the agency even puts pen to paper.

These pre-proposal discussions are important because they can make the guidance development process more efficient and effective. By seeking public input prior to developing a draft, CMS can anticipate and address some of the comments that might otherwise come after the development of a draft. Public participation, including pre-proposal discussions, invariably leads to more sensible guidance due to the insights and experiences offered by academics, clinicians and other stakeholders.

Several avenues exist for pre-proposal collaboration, for example:

- ?? Public meetings, including CMS workshops, and conferences;
- ?? Private meetings with specific industry groups on CMS's premises;
- ?? Industry-hosted meetings that CMS attends;
- ?? Continuing meetings without uniform composition;
- ?? Meetings convened by a neutral third party; and
- ?? Written pre-proposal dialogue, either by e-mail or other correspondence.

**Temporary National Coding.** CMS should implement several key process adjustments to HCPCS temporary coding processes:

- A. Process adjustments for requests from Medicare contractors:
  - 1) Create a policy of prompt issuance – within 90 days – of G, K and Q codes for Medicare contractors that request them.
  - 2) Allow contractors to work directly through the national office, without sign-off from the Regional Office.
  - 3) If needed, temporary codes requested by Medicare contractors should be automatically assigned within 90 days, if a local policy is issued under the local medical review policy (LMRP) process; however, a LMRP should not be necessary in order to assign temporary codes.
- B. Process adjustments for requests from parties other than CMS or its contractors:

- 1) Allow for consideration of requests for temporary codes from interested parties other than CMS and its contractors, including Medicaid state agencies, patient advocacy groups, providers and manufacturers.
  - 2) Establish a process for public posting of all coding requests and issuance of temporary codes for approved requests from interested parties other than CMS and its contractors, within 120 days of receipt of the request.
- C. Process adjustments for requests from CMS and other members of the HCPCS Alpha-Numeric Panel:
- 1) Increase transparency in the development and issuance of temporary codes initiated by CMS or other members of the HCPCS Alpha-Numeric Panel, including public posting of such proposed codes and descriptors.

**Device Reimbursement in the Hospital Outpatient PPS.** AdvaMed is committed to a system that ensures that relative weights and payment rates under the hospital outpatient prospective payment system (OPPS) include sufficient resources to account for the costs of the medical technologies associated with the Ambulatory Payment Classification (APC) groups, to assure Medicare beneficiaries have access to these technologies in the outpatient setting.

The notice of proposed rulemaking, published on August 16, 2004, for the 2005 update to the OPPS, raised some issues of continuing concern. One key issue is the coding for implantable devices, or "c-codes," for items that had, at one time, been eligible for temporary pass-through payments. CMS had found that inconsistencies in device coding had resulted in underpayment for certain device-related APCs, and in past years, had screened claims out of the rate calculations that were not correctly coded with c-codes. However, once the temporary pass-through payment status expired, CMS prohibited hospitals from using those c-codes, even for tracking purposes, and so lost the ability to screen device-related claims in setting the 2005 APC rates.

AdvaMed, and the CMS Advisory Panel on APCs had recommended that CMS address this issue by: (1) stabilizing rates to the 2004 levels with a cost of living update, (2) utilizing external data provided by manufacturers and other stakeholders in addition to the claims data to adjust the actual APC rates for 2005, and (3) mandating the use of c-codes for tracking purposes in the future. AdvaMed also recommended stabilizing rates for other APCs to prevent deep cuts from year-to-year.

In the August 16 NPRM, CMS proposed mandating the use of only a third of the device c-codes. Again, AdvaMed recommends that CMS mandate the use of all c-codes to improve OPPS data on the costs and resources involved in providing device-related services in the outpatient department. CMS addressed the deep reductions in certain device-related APCs by adjusting the median cost calculations to 90% of the medians used in the 2004 rates.

Many of the APCs that were subject to the adjustment to 90% of the medians used to calculate the 2004 payments had experienced decreases in rates from prior years, and even in 2004, had not received a reimbursement level that recognized the full costs of the devices and other resources required to perform these procedures. Also, a number of device-related APCs have been underpaid from the start of the OPPS. We are concerned that the additional proposed reductions in 2005 could prevent many hospitals from covering their costs, translate into significant losses for those hospitals that perform more of these procedures, and lead to access problems for beneficiaries.

When the medians used to calculate the 2005 payments fall below the 2004 adjusted medians used to calculate the 2004 payments, or when stakeholders present external data in response to this year's proposed rule that demonstrate the insufficiency of the data used to calculate the proposed payments or the insufficiency of the proposed payment rate, we believe that CMS should make adjustments that more accurately represent the cost of performing the device and technology-related services. Such adjustments should include incorporating external data into the median cost calculations, and continuing the rates at the levels paid in the current year.

The August 16 NPRM moved 25 device-related procedures from current New Technology APCs into clinical APCs. AdvaMed is concerned that the majority (18 out of 25) of these procedures will be moved to lower-paying APCs. Half will be reduced by at least 20% --and in some cases, by nearly 50% --from current payment levels. These reductions will not only affect access to these new services, but could have a negative effect on other new technology in the pipeline.

We are also concerned that the approval of new device pass-through categories has decreased significantly, with only three going forward into 2005. This program is an important avenue for Medicare beneficiaries to have access to new technologies, and we recommend that the agency work with AdvaMed to improve this program.

**New Technology Add-on Payments.** Congress established new technology add-on payments under the Medicare inpatient prospective payment system to ensure patient access to breakthrough technologies. The add-on payment was designed to provide adequate payment for a new technology during the two- to three-year period when the technology's cost data is first being accurately collected, and CMS has not yet adjusted the DRG relative weights to account for the new technology. Unfortunately, CMS's conservative approach to implementing the add-on payment improvements that Congress included in the MMA has the potential to frustrate congressional intent. To avoid that possibility, CMS should:

- ?? Increase the add-on payment percentage from 50 to 80 percent of the difference between the standard DRG payment and the cost of the procedure with the new technology, as Congress suggested in MMA report language;
- ?? Start the two- to three-year add-on payment eligibility time clock after the issuance of an ICD-9 code, not immediately after the date of FDA approval;
- ?? Continue to allow add-on payments for a new use of an existing technology, so long as the technology is assigned to a different DRG than that to which it was originally assigned and meets the cost threshold and "substantial improvement" criteria;
- ?? Apply the following test of payment adequacy to assure that a DRG assignment results in an appropriate payment: The difference between the base payment for DRGs to which the new technology would otherwise be assigned and payment under the proposed new DRG assignment should equal or exceed the maximum add-on payment amount if an add-on payment were made;
- ?? Amend the definition of "substantial improvement" as it appeared in the 2001 inpatient final rule to conform to the 2001 outpatient rule, most notably to account for improvements in the technology itself and in patient quality of life;
- ?? Ensure that its evidence requirements for new technology add-on payment applications do not place special burdens on smaller companies, which often are responsible for developing unique technologies and therapies;
- ?? Move forward with the implementation of ICD-10 as quickly as possible.

**Competitive Bidding.** To address strong concerns AdvaMed members have about competitive bidding for durable medical equipment and diagnostic laboratory tests, AdvaMed recommends the following during the implementation of the MMA provision:

- ?? Establish an independent, non-CMS advisory and oversight committee with significant representation from the manufacturing industry, patients, and practitioner advocates, to review products to be subject to bidding, and to identify quality standards for those products. In a June 2, 2004, notice published in the Federal Register requesting nominees to such a committee, CMS noted that it was seeking appoint 12 to 15 members. However, AdvaMed believes that limiting the committee membership to 12 to 15 individuals will restrict the scope of expertise and representation. Expanding the committee to 25 to 30 members would increase its ability to provide thoughtful and well-informed recommendations to CMS regarding the design and operation of the program, in addition to having enough representatives to handle what is expected to be an extremely demanding workload. Also, this committee should have more than one manufacturers' representative. The agency should present its implementation plan, including an identification of product codes and related quality measures, to this Committee, allowing sufficient time for committee consideration and response by the agency to the committee's comments. This committee will also participate in program review and evaluation.
- ?? Provisions should be made to assure that beneficiaries have access to new technologies in areas where alternatives to the fee schedule are implemented. Where a new technology is already covered by an existing HCPCS code, there should not be disincentives to access.
- ?? Phase-in the application of the program by starting with items that have been tested under the Medicare demonstration projects.
- ?? The bidding process between CMS and suppliers should be an open process, following the Federal Acquisition Rules. Requests for bids must include detailed specifications, with product category identified by HCPCS code (codes are not collapsed into broader categories), and standards for these products. CMS must understand the environment of the particular markets, and must evaluate bids on feasibility to provide multiple sourced, quality products and related services at the prices quoted. Multiple products are available in each product category subject to bidding to allow a range of products to meet patients' needs. The methodology to select the winning bid and amounts to be paid by Medicare will be made public.
- ?? Suppliers whose bids are equal to, or within a specified range, of the winning bid will be permitted to participate in the program. Multiple winners must be awarded to maintain a viable competitive market. The number of contractors in an area needs to meet specified capacity for growth, and expansion in the case of supplier contract cancellations, or contractors leaving the program.
- ?? Current provisions for beneficiary choice should be preserved. Mechanisms will be established to assure continuity of care for beneficiaries.
- ?? The current fee schedule and DME carrier processes should be improved to incorporate new technology and new HCPCS codes and reimbursement levels based on a timely, open, transparent process. Since DMERCs engage in a de facto national coverage decision making process, the protections associated with that process should be put into place.

**DME Prescription Requirements.** Provisions in the August 5, 2004, proposed rules governing the Medicare Physician Fee Schedule and sections of the Medicare Modernization Act (MMA), establish an overly burdensome process requiring a face-to-face visit with a physician for prescribing, determining medical necessity, renewing prescriptions, repairing, and replacing all durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

We note that MMA requires a face-to-face visit with the prescribing physician for power wheelchairs only, based on hearings and evidence provided by CMS regarding specific fraudulent activities. Congress directed CMS to establish other clinical criteria for the prescription of other DME products, as appropriate. We interpreted this to mean that CMS should examine the evidence relating to specific types of products and carefully establish appropriate clinical criteria and procedures for those particular products.

Currently, criteria have been established for selected items through local coverage determinations (LCDs) and national coverage determinations (NCDs). While we support the concept that patients who require DMEPOS items should see their physicians regularly, we believe that the all-encompassing approach required in the NPRM goes far beyond Congressional intent. We believe that requiring a face-to-face visit to prescribe all DMEPOS items is overly burdensome to the physician and the patient, and may result in reduced access and diminished treatment. The rules also contemplate the need for a face-to-face visit for renewing prescriptions for the DMEPOS items, repair and replacement. Again, we believe that, while these patients should have regular visits with their physicians, they should not be required to have a face-to-face visit for every facet in their access to DMEPOS items.

We strongly recommend that CMS rewrite the regulations by removing the face-to-face visit requirement for all DMEPOS items, and work with stakeholders on more appropriate alternatives.

#### **THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)**

In several recent instances, most notably during the anthrax scare, CDC has developed “home brew” diagnostic tests, distributed them to public health laboratories, and required the laboratories to use only those tests. CDC did not distribute these tests to privately owned laboratories, nor did the Agency ask for or receive FDA clearance for these new diagnostic tests. In all cases, there were members of the IVD industry willing to and interested in developing similar tests. However, the CDC actions preempted such efforts.

While we respect the need to move quickly in times of public health emergencies, we have concerns with federal agency(s) competing with private industry while circumventing controls that would have affected similar products that industry developed. We recommend that HHS develop internal interagency policies that would either require CDC to satisfy the same requirements that apply to industry for the same activities or preclude test development by CDC or other agencies, except in those circumstances where industry does not or cannot develop the needed tests.

Improvements are also urgently needed in the systems CDC uses for sharing samples with IVD manufacturers. Easier access to samples will improve the diagnostic testing capacity of the United States, especially for the development of tests for emerging diseases.