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AdvaMed
Advanced Medical Technology Association

June 30, 2000

Ms. Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
Department of Health and Human Services
Attention: HCFA-3432-NOI
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms. DeParle:

The Advanced Medical Technology Association (AdvaMed)—formerly the Health Industry Manufacturers Association (HIMA)—welcomes the opportunity to comment on HCFA's Notice of intent (NOI) to publish a proposed rule on criteria for making Medicare coverage decisions (*Federal Register*, Vol. 65, No. 95, May 16, 2000, pages 31124-31129, HCFA-3432-NOI). We look forward to working with you and your staff as you move forward in developing HCFA's thinking and overall approach in this area.

AdvaMed is the largest medical technology trade association in the world, representing more than 800 medical device, diagnostic products, and health information systems manufacturers of all sizes. AdvaMed member firms provide nearly 90 percent of the $68 billion of health care technology products purchased annually in the U.S. and nearly 50 percent of the $159 billion purchased annually around the world.

As you know, Medicare coverage criteria will be the standard against which every new medical technology and procedure will be judged—the standard that will determine which treatments are made available to Medicare beneficiaries. This standard will have a major effect on the practice of medicine in the United States because it will have an impact on the tools that health practitioners have available to treat their patients. In addition, this standard will directly influence the capacity of many medical device companies to undertake and develop new products because HCFA's requirements will directly affect the cost, length, and likely success of the innovation process.

Given the importance of this issue, we appreciate the agency's efforts, as expressed in the Notice, to allow the public an opportunity to provide input prior to your formal rulemaking process. We see this as an effective way to begin addressing the difficult issues associated with developing Medicare coverage criteria. All parties will benefit from an open, constructive, and thought-provoking dialogue.

AdvaMed Views on Notice of Intent to Regulate on Coverage Criteria

HCFA states that its intent is to develop criteria that "would expand access for Medicare beneficiaries." AdvaMed shares this goal, but is concerned that the criteria set forth would diminish—rather than expand—beneficiary access to appropriate medical care. It would do this by adding step-wise processes that unduly restrict the practice of medicine, that would incorporate cost as a consideration in coverage decisions, and that would establish unrealistic evidence burdens on medical technology.

We believe HCFA should rethink the fundamental principles on which the current NOI is drafted. We respectfully request that the agency withdraw this Notice and take steps to chart a new and different course in developing Medicare coverage criteria that supports timely beneficiary access to innovative medical technologies that save and improve lives. The withdrawal of the Notice will help ensure that Medicare's local and regional contractors, the Medicare Coverage Advisory Committee, and others will not mistakenly follow it in the interim.

Practice of Medicine

One of the most troubling results of the Notice, as now written, would be an intrusion into the practice of medicine. This would result in limitations on physician discretion for and patient access to appropriate medical care. This may not be the intent of the Notice; but we believe it is the effect.

We come to this conclusion because the Notice presumes a "top-down" approach toward making medical decisions, replacing physician (and local carrier) judgment on the care that is appropriate for individual beneficiaries with decisions made by Medicare coverage policy staff. As you know, physicians need a range of technologies and medical choices to treat individual patients. This is necessary, in part, because no one technology may be appropriate for all patients at all times. Nevertheless, the Notice would remove from coverage older technologies when new technologies—considered to be of greater medical benefit or lower cost—are covered. We believe it is not good policy to strictly limit the number of items or services for each disease/modality combination.

In addition, the Notice would exclude from Medicare new technologies for which clinical benefits and costs cannot yet be precisely measured. This would further narrow physician options because such data are often not available, especially during the early stages of device diffusion. Currently, beneficial technologies are covered, utilization is managed, and payment levels can reflect HCFA's views of the technology's value (both medical benefit and economic considerations).

AdvaMed is supportive of HCFA efforts to develop coverage criteria, but we believe that such efforts must permit health care providers open and continuing access to the tools they need to fully meet patient needs.

Cost as a Coverage Criterion

Another concern is that the Notice would give costs and financial considerations a clear role in coverage decisions.

AdvaMed believes that a product's *clinical effectiveness* should be the determining factor for HCFA in judging whether the product is “reasonable and necessary” and, thus, covered by Medicare. This judgment—whether or not to provide beneficiaries access to a product or service—is fundamentally a patient care decision, not a financial or cost decision. We see no support in the Medicare law for limiting beneficiary access to services due to their cost.

Economic factors are more appropriately considered in the context of payment. HCFA has many tools to deal with these issues in the payment arena, with differing sets of tools for each discrete payment system (e.g., DRGs, APCs, RUGs, RBRVS, product-specific fee schedules). We also point to the Congressional testimony of past HCFA Administrators who have stated that coverage does not involve cost considerations and that, when costs are considered in comparing a new technology to an item or service that is already covered by the Medicare program, this comparison is made in the context of payment, not coverage.

Finally, there is the question of practicality. To include cost as a Medicare coverage criterion would require resources and expertise that are beyond the capacity and capability of the Agency.

Increased Evidence Burden

AdvaMed's final concern relates to the increased evidence burdens that the Notice contemplates for technologies seeking Medicare coverage. We believe that the Notice raises the evidence required for coverage to impractical levels. The result would be diminished beneficiary access to appropriate medical technology.

We are concerned that HCFA believes coverage should be delayed until conclusive evidence is available to determine how a new technology compares, in both clinical benefit and cost, to alternative covered benefits for all population groups and subgroups. As you know, such conclusive data are often not available. When they are, it is often difficult to reach consensus on what they mean—and equally challenging to arrive at a general agreement on what actions should be taken as a result. Medicare beneficiaries may lose access to FDA-approved, potentially lifesaving technology if they must wait for such consensus or conclusive data.

In contrast to this approach, AdvaMed believes that coverage assessment efforts are most likely to be successful if they take into account the unique nature of device innovation, are reasonable in their demands for clinical data, permit coverage decision-makers to approve new technologies despite the absence of absolute certainty, and—most importantly—permit timely patient access to appropriate therapies.

Specifically, AdvaMed believes that the nature of the evidence that coverage decision-makers use in assessing technology must follow the nature of the technology that is under consideration. This is a critical point, and we applaud the agency for asking for comments specifically on it. For some types of technologies, randomized controlled clinical trials may be appropriate. For others, a different level (or type) of evidence may be more appropriate. It is important, in our view, for Medicare coverage decision-makers to recognize that the effectiveness of particular technologies can be successfully demonstrated by varying levels (or types) of evidence.

We also believe that it is important for coverage decision-makers to take into account the nature of how technologies develop and come about, and how these processes differ for different types of interventions, such as medical technologies versus pharmaceuticals. As you know, medical technologies evolve over time—as they are used in everyday clinical practice. Thus, early in the life of a new technology, the quantity and quality of information that is available regarding the product may not be extensive and not sufficient to support a national coverage decision. In such cases, innovative approaches that avoid premature decision-making are critical. Where inadequate evidence exists to support a national coverage decision, a judgment on coverage should be made by Medicare contractors at the local level.

Further, we believe that the system for assessing medical innovations must be as dynamic as the innovations themselves, and it should be grounded in evidence derived from real-world health care delivery settings. Evidentiary requirements should depend on: the type of technology under review; the population to be treated; the incidence of the disease; the impact of the medical condition being treated; the level of existing knowledge of the therapy under review; the availability of alternative therapies; the time and cost of gathering new evidence; the relative degree of diffusion of the technology or procedure; and the demands of the medical community and public for access.

AdvaMed believes that, given the diversity of medical devices and the incremental and continuous nature of the device innovation process, no one evidence type should be required for a coverage decision. It is inappropriate for HCFA to try to standardize the types and levels of evidence that can be used to demonstrate the benefits of medical devices. It is critical that Medicare coverage criteria themselves do not become hurdles to continued innovation.

We also wish to underscore that even the best, most comprehensive systems of evaluation do not guarantee that information about a medical intervention will be complete; nor can they ensure consensus. Thus, coverage decision-makers must sometimes make judgments with less than conclusive evidence and in the face of differences of opinion. Willingness to offer judgments in such circumstances is critical because patients cannot wait for final consensus or certainty. To aid in dealing with such uncertainty, coverage decision-makers should actively seek the advice of medical specialty groups and those familiar with the technology as a supplement to other available evidence. In addition, they should expect to make changes in coverage policy as more information becomes available.

Conclusion

As we noted earlier, we commend HCFA for raising important questions in the Notice, and we look forward to working closely with the agency to establish criteria that:

- provide physicians with access to the tools they need in treating beneficiaries;
- are based on medical, not financial, considerations; and
- recognize the incremental, continuous nature of the device innovation process.

We believe that significant adjustments need to be made in HCFA's approach and that it would be best to incorporate our suggestions and issue a new Notice that would help create a Medicare program that is in step with patient needs for prompt access and continued innovation.

The attachment to this letter also provides additional detail and thoughts on the Notice. We would be happy to provide any further elaboration or detail.

Sincerely,

Carol A. Kelly