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AdvaMed
Advanced Medical Technology Association

December 21, 2000

Robert A. Berenson, M.D.
Acting Administrator
Health Care Financing Administration
Department of Health and Human Services
Attention: HCFA-1005-IFC
Room 443-G, Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

RE: Comments on Interim Final Rule, Prospective Payment System for Hospital Outpatient Services for Calendar Year 2001 (HCFA-1005-IFC)

Dear Dr. Berenson:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on HCFA's Interim Final Rule establishing payments and policies for the Medicare Outpatient Prospective Payment System for Calendar Year 2001 (Federal Register, Vol. 65, No. 219, November 13, 2000, pp. 67798-67830). 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.

AdvaMed recognizes that implementation of the outpatient prospective payment system (OPPS) was an extremely complex undertaking with many daunting challenges. We are especially mindful of the extensive staff resources required to implement the device and drug pass-through provision. We greatly appreciate HCFA's willingness to work cooperatively with the device industry throughout implementation and to make the many adjustments that have been necessary.

Category Basis for Designating Items on the Pass-Through List

In our September 1, 2000 comments on the August 3 interim final rule, AdvaMed emphasized the importance of moving to a category basis for designating items on the pass-through list. We believe that the legislative provisions recently enacted by Congress requiring categories will address many of the remaining issues and problems with the pass-through provision. As we have previously noted, this approach will be less burdensome for hospitals and for HCFA, and will be more equitable for device manufacturers. We stand ready to assist HCFA in the development of these categories and plan to submit specific recommendations in the near future.

AdvaMed commends HCFA for the changes made in the August 3 and November 13 rules. These adjustments will help significantly to maintain patient access to new technologies and to make implementation of the pass-through provision more consistent with congressional intent. We would like to offer these additional comments and suggestions for further refinement and adjustment of the outpatient prospective payment system.

Category B Investigational Devices

We strongly approve HCFA's decision to determine the amount of pass-through payments for Category B investigational devices exactly as they are determined for other pass-through devices. We believe that the decision not to apply the cost limitation makes the agency's implementation of the pass-through provision compliant with the statutory language.

Test for "Not Significant" Cost

The interim final rule also modifies the three criteria used to determine whether the cost of a new drug, device or biological is "not insignificant" in relation to the APC payment amount with which the item is associated. AdvaMed supports changing the first test to require that the cost of the new item be at least 10 percent of the applicable fee schedule amount rather than the 25 percent requirement that was set in the April 7 rule.

We also agree with the decision to delay the effective date of the other two "not insignificant" criteria until January 1, 2003. As HCFA notes, the delay will allow collection and analysis of data necessary to determine the current portion of the APC fee schedule amounts associated with a device, drug or biological.

Definition of an eligible pass-through device

In the August 3 rule, HCFA modified the definition of an eligible pass-through device. The eligibility criteria were changed to include devices that are surgically implanted or inserted in a patient whether or not they go home with the patient. AdvaMed strongly supports the revised policy because it will improve patient access to new technology. Also, we believe the revised criterion better reflects congressional intent concerning which devices are eligible for the pass-through payment.

In the November 13 regulation, however, HCFA further modified its interpretation of the criteria to include only devices inserted through a *surgically created incision.* The policy now provides that the definition does not include items used to cut or create a surgical opening. Based on the latest revision, HCFA deleted several devices from the pass-through list effective January 1, 2001.

Although AdvaMed understands the rationale underlying the change, we disagree with the details of the policy and of the decisions that have been made based on it. We are concerned that a misunderstanding of the nature of many surgical devices may be interfering with appropriate determinations.

For example, many surgical devices are not used to create the primary incision, but come into play after another instrument, like a steel scalpel or a trocar, has been used to create the surgical opening to provide access for the procedure. If the subsequent procedure involves excision, ablation,

removal, etc. of tissue *after the initial incision is made*, AdvaMed believes that the devices used for these procedures fully meet the requirements of §419.43(e)(4)(iv). They *"are an integral and subordinate part of the procedure performed, are used for one patient only, are single use, come into contact with human tissue, and are surgically implanted or inserted whether or not they remain with the patient when the patient is released from the hospital outpatient department."* Many of these devices involve advanced new technology that is necessary for operative procedures involving internal body tissue. For example, the technology may be specially designed to control bleeding or minimize thermal injury.

Pass-through applications process

AdvaMed is extremely pleased that the new rule states that, to the extent that resources permit, HCFA will accept applications for new devices and initiate processing before the FDA approval process is complete. We also are pleased that HCFA reiterated its commitment to a quarterly update process and trust that these efforts will extend to devices requiring the development of a new category.

We continue to be concerned, however, that a four to seven month time lag remains between FDA approval of a new device and its addition to the pass-through list should a new category be required. We would like to work with HCFA and with hospital associations to explore ways to reduce the time lag without placing an adverse burden on HCFA or hospitals.

Removing cost of predicate item (i.e., pass-through offset amounts)

Although HCFA did not publish the data used to determine offset amounts for certain medical technology eligible for pass-through payments as of January 1, 2001, we reiterate our recommendation made in our comments on the April 7 and August 3 rules. For future determinations, HCFA should make data available to the public through notice and comment rulemaking in advance of applying offset amounts.

Limitation on variation of costs within an APC

In applying the two-to-one limitation on the variation of costs of items and services included within an APC, HCFA exempted codes for unlisted services and procedures. HCFA also exempted codes that represent less than 2 percent of the claims in the APC because it considered these to be low volume, as permitted by the statute.

AdvaMed is concerned about the impact of eliminating these low-volume procedures. We urge HCFA to examine the impact of this rule on APC classifications and relative weights. We ask that HCFA determine whether basing relative weights on the mean cost rather than the median would be more appropriate, especially given the agency's treatment of low volume procedures.

Annual review and updating of OPPS and Advisory Panel

HCFA will initiate its full annual update process in calendar year 2001. As required by law, the November 13 regulation states that HCFA will establish and consult with an expert advisory panel. The rule says only that the panel will *"…review and make recommendations to us on the clinical integrity of the groups and weights and may use data other than those collected or developed by us for their review and advisory functions."*

AdvaMed is extremely interested in the Advisory Panel on APC Groups and in the annual update process.

- AdvaMed believes that there should be a representative of the medical technology sector on the Advisory Panel. We are disappointed that the panel's charter, as described in the December 5, 2000 notice in the Federal Register (FR pp. 75943-4), does not provide a seat for this crucial player in outpatient healthcare.

- We therefore request that the Advisory Panel on APC Groups include members that are familiar with the clinical applications of new technology as well as their impact on hospital costs.

- We also ask that HCFA quickly establish and publicize a process whereby external data can be made available to HCFA and to the expert panel. And, it would be helpful if HCFA could identify areas where the agency would find external data helpful to supplement Medicare program data.

Pro rata reductions to pass-through payments

The regulation does not mention the issue of pro rata reductions, but the accompanying press release does. The press release notes that the number of devices eligible for pass-through will reach almost 1,000 effective January 1, 2001, but that *"there will be no pro rata reduction in 2001."*

Although not mentioned in either the regulation or the press release, we understand that HCFA has pledged to Ways and Means Committee Chairman Bill Thomas to address the issue of the pass-through cap next year. AdvaMed would like to re-emphasize the recommendations that we made in our comments on the April 3 rule:

- HCFA should not impose a pro-rata reduction in the pass-through payment for new technologies unless it has sound and reliable data upon which to base such a pro-rata reduction. Further, the agency should make public both the methodology and the data it uses in making this calculation.

- HCFA should, through rulemaking, inform the public when it is considering making a pro-rata reduction in the pass-through payments for new technologies. The agency should explain its reasoning, provide any data that it is relying upon in making the judgment, and explain any methodology that it intends to apply.

Multiple units of a device

In responding to comments on the August 3 rule, HCFA did not respond substantively to the AdvaMed question concerning how the "not insignificant cost" test would be applied when a procedure involved multiple devices or multiple units of a device. The agency said it would address the issue when it implements all three "not insignificant" criteria in 2003. The concern raised by the question, however, is currently an issue with the 10% test. We request that HCFA clarify how the "not insignificant" test would be applied in the case of a procedure needing multiple new devices. We believe that if multiple devices are required for a single procedure, the agency should determine congruity with the criteria based on the combined cost of the needed devices. We urge HCFA to

make this clarification and to not apply the "not insignificant" criteria separately to each of the multiple devices.

Also, we do not believe that HCFA responded fully to a concern about discounting pass-through devices that are associated with multiple surgical procedures. HCFA responded that pass-through payments are not subject to the multiple surgical discount. However, HCFA did not address the corollary issue of how to protect devices from the multiple surgical discount when they are packaged into the APC after the two-to-three year pass-through period. We would like HCFA to respond further to this issue.

New Technology Covered as Inpatient Only

AdvaMed recommends that when new medical technology is assigned to a new pass-through category, but then is placed on the "inpatient-only" list, the two- to three-year pass-through "clock" should not start until the item is recognized for outpatient use.

We appreciate the opportunity to submit these comments.

Sincerely,

Carol A. Kelly
Executive Vice President
Health Care Systems and Federal Legislative Policy