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Association of Community Cancer Centers

October 4, 2004

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BY ELECTRONIC DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1427-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates) – Pass-Through; Non-Pass-Throughs; HCPCS Codes; Orphans; Radiopharmaceuticals; Drug Administration; E/M Services Guidelines; and Brachytherapy

Dear Administrator McClellan:

On behalf of the Association of Community Cancer Centers (ACCC), I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS) published in the Federal Register on August 16, 2004 (the Proposed Rule).1 ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45% of all U.S. cancer patients. Combined with our physician membership, ACCC represent the facilities and providers responsible for treating over 60% of all U.S. cancer patients.

1 69 Fed. Reg. 50448 (Aug. 16, 2004).

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies. We support and appreciate CMS' continued efforts to implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in a timely and straightforward manner. The MMA's payment floors for 2005, as implemented by CMS, will help ensure appropriate reimbursement for many drugs[2] critical to the treatment of cancer. ACCC also applauds CMS' proposed improvements to the OPPS. In particular, we support CMS' proposal to provide immediate reimbursement for drugs for which Healthcare Common Procedure Coding System (HCPCS) codes have not yet been assigned, as required by the MMA.[3] We also applaud the proposal to treat all new drugs with HCPCS codes as pass-through therapies, without requiring an application for pass-through status.[4] ACCC supports CMS' proposals to continue to exclude certain orphan drugs from the OPPS[5] and the agency's recognition that radiopharmaceuticals are in fact drugs and biologicals.[6] CMS also correctly decided not to apply an equitable adjustment or functional equivalence in the Proposed Rule.[7] We also applaud CMS' proposal to set pass-through payments at zero and to apply the unused funds from the pass-through pool toward increasing the conversion factor. Each of these proposals is a significant step toward providing the adequate reimbursement essential to protect patient access to advanced cancer therapies. ACCC therefore asks CMS to implement these proposals in the final rule.

Although ACCC commends CMS for these proposals, we remain concerned that Medicare's payment policies will present obstacles to patient access to critical cancer therapies. In our comments on the proposed physician fee schedule for 2005,[8] we discussed widespread concerns among providers that payment rates based on 106% of average sales price (ASP) may not adequately reimburse providers for the costs of acquiring drugs, much less the costs of storing, handling, and administering them. These problems also are likely to appear in hospital outpatient departments, where pass-through therapies also will be paid at 106% of ASP. ACCC urges CMS to exercise caution in implementing the MMA's payment reforms to avoid disrupting patient care. It is imperative that CMS carefully monitor patient access and respond promptly to any access problems.

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2 We refer to drugs, biologicals, and radiopharmaceuticals collectively as "drugs" throughout our comments.

3 69 Fed. Reg. at 50516.

4 Id. at 50514.

5 Id. at 50518.

6 Id.

7 Id. at 50513.

8 Letter from Patti A. Jamieson-Baker, President, ACCC, to Mark McClellan, Administrator, CMS, Sept. 24, 2004.

To ensure access to quality cancer care, ACCC opposes any increase in the packaging threshold in the future. We recommend that CMS apply its future rate-setting methodology for "specified covered outpatient drugs" to all separately paid drugs, and we urge CMS to work with the General Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) to ensure that their cost surveys collect all the data necessary to set appropriate payment rates in the future. We ask CMS to increase its rates for Bexxar® and Zevalin® and their related procedures and administration services to ensure patient access to these breakthrough therapies. ACCC also recommends the use of G-codes to implement the new Current Procedural Terminology (CPT) codes for drug administration in 2005, instead of delaying the collection of more accurate cost data for another year. We urge CMS to issue much-needed guidance on billing for evaluation and management services to help hospitals seek reimbursement for important cancer therapy support services. Finally, we ask CMS to discuss its process for adding new brachytherapy devices to its list for separate cost-based payment, and we urge CMS to work with GAO to study these therapies' costs in order to set appropriate rates in the future.

These issues and others are described in depth below.

I. Pass-Through – Transitional Pass-Through Payment for Additional Costs of Drugs and Biologicals

A. Concern About Payment at 106% of ASP

ACCC is concerned that setting payment rates for new drugs with transitional pass-through status at ASP plus 6% may not be adequate to ensure hospitals' ability to provide these therapies to patients. In our comments on the Medicare physician fee schedule proposed rule, we discussed the negative consequences the new ASP-based rates may have on patient access to important cancer therapies.[9] These effects are likely to be felt in hospital outpatient departments as well because the Medicare statute requires CMS to set payment rates for pass-through drugs at the rate applicable to physician offices.[10] We believe these rates may pose a greater risk to patient access to care because they apply exclusively to new therapies regardless of the setting in which they are administered. In the past, if Medicare reimbursement for a drug was inadequate in one setting, providers could ensure continued access to care by shifting a therapy's administration to the other setting. Pass-through payments helped to ensure that patients could access new therapies in the outpatient setting. Now that rates for pass-through therapies in outpatient departments

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9 Id.
10 SSA § 1833(t)(6)(D)(i).

and in physician office reimbursement have been reduced to 106% of ASP, if rates are inadequate in both settings, patients who need new, advanced therapies may have nowhere to turn. Ironically, traditional therapies that are not recognized as pass-through drugs will not have this problem because they will be paid at different rates in the hospital outpatient and physician office settings.

ACCC urges CMS to carefully implement the MMA's payment reforms to ensure that patients continue to have access to important, advanced cancer therapies in appropriate outpatient settings. We recommend that CMS carefully monitor patient access as it implements the new ASP-based rates. If any access problems are reported, we urge CMS to respond promptly.

B. Other Pass-Through Reforms

ACCC supports CMS' proposals to set pass-through payments at zero[11] and to dedicate the unused portion of the pass-through pool to increasing the conversion factor.[12] These proposals eliminate the potential for a pro-rata reduction in payments and thus ensure that pass-through drugs receive the full payment possible under the law, helping to protect beneficiary access to new, advanced cancer therapies. ACCC commends these proposals, and we urge CMS to implement them in the final rule.

ACCC also applauds CMS' proposal to treat all new drugs with HCPCS codes as pass-through therapies, regardless of whether a pass-through application actually has been submitted.[13] We discuss this proposal below, and we recommend that it be implemented in the final rule.

II. Drugs, Biologicals, and Radiopharmaceuticals Non-Pass-Throughs

A. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

CMS proposes to implement the MMA's requirement[14] to pay separately for drugs, biologicals, and radiopharmaceuticals whose median cost per day exceeds $50.[15] ACCC supports this step, but we are concerned about CMS' desire to increase the packaging threshold in future years. CMS has expressed a preference for additional packaging after 2006, when the MMA no longer requires a certain threshold. ACCC agrees with the need to continue to study

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11 69 Fed. Reg. at 50503.
12 Id. at 50527.
13 Id. at 50514.
14 MMA § 621(a)(2).
15 69 Fed. Reg. at 50505.

this issue, and we recommend that CMS give careful consideration to the likely effect on patient access to critical therapies before proposing an increased threshold. Unless a thorough study reveals that additional packaging will not harm patient access to drugs, biologicals, and radiopharmaceuticals, ACCC opposes any increase in the packaging threshold.

ACCC applauds CMS' recognition that the $50 packing threshold could impede patient access to injectible and oral forms of anti-emetic treatments as well as its proposal to exempt all of these therapies from the packaging policy.16 The $50 threshold requires some, but not all, of these therapies to be packaged, creating incentives for hospitals to choose therapies based on their ability to obtain additional reimbursement, rather than the therapies' benefits for individual patients. We agree with CMS's assessment that this policy could "impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician."17 We urge CMS to examine whether its packaging threshold impedes access to other therapies and to implement this proposal in the final rule.

B. Extending the Future Rate-Setting Methodology for SCODs to All Separately Paid Drugs

ACCC appreciates CMS straightforward implementation of the MMA's payment methods for "specified covered outpatient drugs" (SCODs) in 2005, and we urge CMS to begin planning now for implementation of the MMA's payment reforms in 2006 and subsequent years. The MMA requires CMS to use a GAO study of hospital acquisition cost data and a MedPAC study of pharmacy service and overhead costs to develop a payment methodology for SCODs for years 2006 and beyond. The MMA does not mandate a payment methodology for other drugs, however, allowing CMS to determine how to set rates for those therapies.

If CMS opts to implement different methodologies for SCODs and other separately-paid drugs, it risks introducing even more complexity, unfairness, and inconsistencies into the already complicated OPPS. For example, Oxaliplatin, a drug used to treat progressive or recurring colorectal cancer, that currently is a pass-through but technically is not a "specified covered outpatient drug," could be paid based on CMS' current, flawed rate-setting methodology in 2006. On the other hand, CMS appropriately would base payment for Irinotecan, another therapy commonly used to treat progressive or recurring colorectal cancer that is a "specified covered outpatient drug," on the therapy's hospital acquisition cost. It makes no sense to treat these two drugs differently based on the dates of their pass-through status. It also makes no sense to

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16 Id.
17 Id.

continue to use the current rate-setting methodology that clearly is fundamentally flawed. As the GAO recently reported, CMS' current methodology for deriving costs from hospital charges may over or underestimate hospital costs and the use of a constant cost-to-charge ratio may not accurately calculate hospital costs.18 There is no reason CMS should continue to use this fundamentally flawed rate-setting methodology for any drug.

We firmly believe that the purpose of the MMA's payment reforms – to improve the appropriateness of Medicare reimbursement for drugs – is best served by applying the acquisition cost-based payment methodology to all separately paid drugs. Nothing in the statute would bar the agency from extending the hospital acquisition cost payment methodology to other drugs. CMS itself acknowledged its authority in this area in the Proposed Rule.19

Indeed, ACCC commends CMS for recognizing the need for a fair and consistent payment methodology for drugs. In the Proposed Rule, CMS explains that only three of the thirteen expiring pass-throughs are not SCODs because they began to receive pass-through payments after December 31, 2002. Rather than "penalize those products for receiving pass-through status on or after January 1, 2003"20 by applying a different methodology to them, CMS proposes to treat them as if they are SCODs. This common sense proposal will protect patient access to these therapies by ensuring that they are reimbursed appropriately. We strongly encourage CMS to apply this example to other therapies and to use the cost-based methodology for all separately paid drugs in the future.

C. CMS Cooperation with GAO and MedPAC on Cost Studies

The payment methodology for 2006 and beyond will be based on studies by the GAO, and later CMS, of hospital acquisition costs of SCODs. MedPAC also will study pharmacy service and overhead costs for these therapies. CMS' ability to set appropriate payment rates in the future depends on the accuracy and completeness of the data collected today. Furthermore, a fair and consistent payment methodology will require data on not only the SCODs, but also on all other separately paid drugs. ACCC therefore urges CMS to work with GAO and MedPAC today to ensure that these studies examine all separately paid drugs. In particular, we recommend that the three expiring pass-through products that CMS proposes to treat as SCODs and any therapies that will roll off pass-through status in 2006 be included in these surveys. We appreciate the

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18 U.S. General Accounting Office, "Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services," No. GAO-04-772 (Sept. 2004), at 16, 18

19 69 Fed. Reg. at 50513.

20 Id.

inclusion of the designated orphan drugs in the first round of surveys, recently sent to 1000 hospitals. If these surveys cannot be amended to include the three expiring pass-through products that CMS proposes to treat as SCODs and any therapies that will roll off pass-through status in 2006, we ask CMS to work with GAO to ensure that they are included in the second round of surveys to be issued next summer. The inclusion of these drugs is essential to ensure appropriate payment rates for them in the future.

D. Payment for Specified Covered Outpatient Drugs – Zevalin® and Bexxar®

ACCC applauds CMS for classifying separately paid radiopharmaceuticals as SCODs, as required by section 621(a)(1) of the MMA,[21] and for finally recognizing that radiopharmceuticals are indeed drugs and biologicals. We are concerned, however, that CMS' proposed rates for Zevalin® (In-111 and Y-90 ibritumomab tiuxetan, C1082 and C1083) and Bexxar® (I-131 tositumomab, C1081 and C0182) will threaten patient access these breakthrough therapies for non-Hodgkin's lymphoma (NHL).

Zevalin® and Bexxar® are complex therapies whose administration is divided into two separate doses, one of a diagnostic dose and a second of a therapeutic dose. Because these therapies must be administered in hospital outpatient departments, Medicare beneficiaries' access to these therapies is wholly dependent on appropriate OPPS reimbursement for the radiopharmaceuticals, their preparation and administration, and related procedures.

CMS proposes to pay for both Zevalin® and Bexxar® in 2005 at the SCOD floor of 83% of average wholesale price (AWP). ACCC urges CMS to consider raising these rates above the 83% floor, as the agency is permitted to do, to ensure that hospitals are compensated for the costs of acquiring these therapies. Additionally, we urge CMS to evaluate the costs of preparing and administering these therapies as well as the costs for related procedures and to adjust the OPPS rates for these services to appropriately reimburse hospitals for their costs. We remind CMS that beneficiary access to advanced life-saving therapies requires adequate reimbursement for all of the services associated with their administration as well as for related procedures.

E. Equitable Adjustments

The Proposed Rule does not apply an "equitable adjustment" to the payment rate of darbepoetin alfa (Q0137), but the agency solicits comment on

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21 Id. at 50507, 50518.

whether such an adjustment should apply again.[22] ACCC repeatedly has denounced the application of "functional equivalence" – by any name – because it denies Medicare beneficiaries access to new, innovative therapies. Without the promise of adequate payment rates, innovation will be discouraged. Manufacturers simply will not devote precious resources toward improving current therapies or in developing new therapies that could be seen as "functionally equivalent" to another product.

With respect to cancer care, these results are particularly troubling. Often, innovations with respect to less frequent dosing or a more convenient mode of administration mean greater compliance for a treatment regimen or an increased willingness of patients to undergo more aggressive, and typically, more effective therapy. This is particularly true for sick or elderly patients as well as those who live in rural areas without convenient access to hospital outpatient departments. Similarly, therapies with fewer side effects increase the probability that patients can receive the full dosage of their chemotherapeutic regimens, making cures and longer remissions more likely.

We still are learning so much about treating cancer that it is often difficult to predict who will benefit from a particular new therapy and how precisely that therapy will be used until the drug has been on the market for a few years. Moreover, a drug that is only incrementally beneficial for one patient could be significantly beneficial for another. ACCC firmly believes that physicians are the only ones who should determine that one drug is an appropriate substitute for another drug, and this decision only should be made on an individual patient basis. This position is consistent with Congress' position on the issue as well. Section 622 of the MMA prohibits the future application of functional equivalence by preventing the Secretary from publishing regulations that apply a functional equivalence or similar standard, except for purposes of determining pass-through eligibility for drugs to which the standard already was applied prior to enactment.[23] Section 622 also prohibits the Secretary from applying a functional equivalence standard for "the purpose of any other payments under this title."[24] Accordingly, ACCC commends CMS on not proposing to apply an "equitable adjustment" for any drug in the Proposed Rule, and we urge CMS to comply with the MMA and not apply "functional equivalence" – by any name – to any drug in 2005 or future years.

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22 Id. at 50513.
23 MMA § 622; SSA § 1833(t)(6)(F); H.R. Conf. Rep. No.108-391 at 683 (2003).
24 MMA § 622; SSA § 1833(t)(6)(F)(ii)(II).

F. Proposed CY 2005 Payment for New Drugs and Biologicals with HCPCS Codes and without Pass-Through Application and Reference AWP

CMS proposes to treat new drugs with established HCPCS codes as pass-throughs, regardless of whether a pass-through application has been made.[25] ACCC supports this proposal because it will help ensure appropriate and timely separate payment for new therapies. Rather than packing payment for these therapies, potentially restricting beneficiary access to them, this proposal will allow immediate payment at the physician office rate. ACCC recommends that CMS implement this proposal in the final rule.

III. HCPCS Codes – Proposed Payment for New Drugs, Biologicals, and Radiopharmaceuticals Before HCPCS Codes Are Assigned

ACCC is pleased that CMS finally implemented the MMA's provision requiring immediate reimbursement for drugs for which HCPCS codes have not yet been assigned.[26] CMS has assigned a single miscellaneous code for new drugs and requires claims using this code to be processed manually. It is too soon to tell whether this procedure will improve patient access to new therapies. We urge CMS to monitor access closely and to respond quickly to providers' concerns. If hospitals find that this procedure does not allow claims to be processed quickly and efficiently, we urge CMS to reconsider the Ambulatory Payment Classification (APC) Panel's recommendation, endorsed and favored by ACCC, to add several new HCPCS codes to the system and then assign new drugs to these codes upon their approval by the Food and Drug Administration (FDA).[27]

IV. Orphan Drugs – Proposed Changes in Payment for Single Indication Orphan Drugs

ACCC commends CMS for proposing to make separate payments for designated orphan drugs.[28] Although these therapies also could meet the statutory definition of SCODs, CMS recognized that reimbursing for these therapies at the SCOD rates would result in "lower payments which could impede beneficiary access to these unique drugs dedicated to the treatment of rare diseases."[29] Instead, CMS proposes to pay for the 12 designated orphan drugs at the higher of 88 percent of AWP or 106 percent of ASP capped at 95

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25 69 Fed. Reg. at 50514.
26 Id. at 50516.
27 See id.
28 Id. at 50517.
29 Id. at 50518.

percent of AWP.[30] ACCC thanks CMS for exercising its authority to set payment rates that will protect patient access to these critical therapies. We urge CMS to implement this proposal in the final rule.

V. Radiopharmaceuticals – Proposal to Change Payment Policy for Radiopharmaceuticals

ACCC also appreciates the agency's recognition that radiopharmaceuticals are, in fact, drugs and biologicals.[31] As CMS observes in the Proposed Rule, Congress included radiopharmaceuticals in the definition of SCODs, thereby extending the MMA's payment requirements and other protections to radiopharmaceuticals. ACCC urges CMS to implement this proposal.

VI. Drug Administration – Proposed Coding and Payment for Drug Administration

ACCC thanks CMS for recognizing the need to improve the accuracy of coding and payment for drug administration services. ACCC has advocated that reductions in reimbursement for drugs should be offset by adequate increases for drug administration and other services in order to ensure that Medicare patients may access the care they need. Patient access to life-extending cancer therapies will suffer unless physicians are appropriately compensated for both the drugs they provide to their patients and the labor and resources associated with administering those drugs.

The OPPS currently uses three Q-codes (Q0081, Q0083, and Q0084) to pay for chemotherapy administration and infusion of other drugs. Because these four codes' descriptions are too broad to distinguish among therapies or the resources need to administer them, CMS has not been able to collect sufficiently detailed cost data that would allow the agency to set more appropriate reimbursement rates. In the Proposed Rule, CMS recognizes the need to adopt more precise coding that will help create more appropriate payments in 2007. We commend CMS for recognizing this need, but we believe that its proposal to use the 2005 CPT codes for drug administration instead of the current Q-codes[32] is not the best way to achieve the agency's goals. We recommend instead that CMS use the new 2006 CPT codes for drug administration services as adopted by the American Medical Association's (AMA) CPT Editorial Panel and implement them in 2005 via G-codes as the agency has proposed in the physician office setting.

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30 69 Fed. Reg. at 50518.
31 Id.
32 Id. at 50519.

At CMS' request, the CPT Editorial Panel recently reviewed the coding for drug administration services. The Panel approved 12 new and 14 revised codes that will better reflect the varying levels of complexity and resource consumption associated with each drug administration service.[33] Because these codes were not approved in time to be included in the 2005 CPT book, CMS proposes to adopt these codes in the physician office setting in 2005 by using G-codes.[34] In the physician office setting, CMS concluded that the benefits of paying more appropriately for drug administration services in 2005 outweighed the costs of using temporary G-codes. We believe the same reasoning applies in the outpatient setting as well. We strongly support CMS' proposal to use G-codes in the physician fee schedule,[35] and we recommend that CMS use the same codes in the OPPS.

We also understand that one of CMS' original goals was to have Medicare use the same coding system as private payors for drug administration services, namely the CPT codes. Our members assure us, however, that the minimal burden of adopting new codes this year, as they do every year, is worth bearing to help CMS set more accurate payment rates in 2007. We therefore urge CMS to adopt the new codes' definitions through the use of G-codes in 2005 in both the physician office setting and hospital outpatient departments.

VII. E/M Services Guidelines – Hospital Coding for Evaluation and Management Services

In the Proposed Rule, CMS explains that it currently is considering recommendations from an expert panel convened by the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) for a national set of coding guidelines for hospital clinic visits.[36] These recommendations, made in June 2003, call for the creation of clear, consistent, and appropriate guidelines for billing evaluation and management (E/M) services provided by hospitals. ACCC urges CMS to complete its review of these recommendations promptly and to release proposed guidelines as soon as possible.

ACCC is concerned about the current lack of clear guidance on hospitals' use of E/M codes because these codes could include important cancer therapy support services for which hospitals traditionally have been under-reimbursed. These services help patients achieve the full benefits of their drug regimens by

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33 AMA, CPT Editorial Panel, August 2004 Meeting, Changes to Drug Administration Codes, available at http://www.ama-assn.org/ama1/pub/upload/mm/362/panelactionsdruginf2.doc.

34 69 Fed. Reg. at 47522.

35 [INSERT CITE TO PHYSICIAN FEE SCHEDULE COMMENTS]

36 69 Fed. Reg. at 50539.

managing their course of treatment, maintaining their nutritional status, providing psychological and emotional counseling, and educating patients and their families about their illness, treatment options, and possible side effects. Cancer therapy support services include:

- Social services: planning for home care, hospice and long-term care, community agency referrals, and referrals for transportation assistance;
- Nutrition services: evaluation of the patient's nutritional status, the provision of information about diet and cancer, and the development of nutrition plans to meet the individual patient's needs;
- Patient and family education: educating newly diagnosed patients and their families about their cancer, treatment options, support resources, self-care techniques, new prescribed treatments, and coping with and managing treatment side effects; and
- Psychosocial support: services to address the psychological and emotional aspects of cancer and cancer treatment.

Cancer therapy support services are indispensable components of quality cancer care, yet many hospitals are not being reimbursed for them because they do not know how to code and bill for them. Instructions in the Medicare Benefit Policy Manual state that therapeutic services provided by hospitals on an outpatient basis can be covered as "incident to" physicians' services if they are an "integral, although incidental, part of the physician's service in the course of diagnosis or treatment of an illness or injury."37 We believe these services are covered under the OPPS, but hospitals often do not know when or how to bill for them. Except for psychosocial support services (CPT codes 90804-90857), paid under APCs 322-325, these services are most likely represented by E/M codes.

The AHA/AHIMA recommendations, if adopted by CMS, would provide much needed guidance on how to code and bill for these services. Appropriate billing is especially important in light of the MMA's sweeping reforms for drug reimbursement. In the past, some hospitals may have been able to fund these services out of their drug reimbursement revenues. Now, they must be able to seek adequate reimbursement for these critical services if they are to continue to provide them to Medicare beneficiaries.

VIII. Brachytherapy – Payment for Brachytherapy Sources

Sections 621(b)(1) and (b)(2) of the MMA established separate payment for brachytherapy devices consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004 and January 1, 2007 based on a hospital's

37 Medicare Benefit Policy Manual (CMS Pub. 100-02), ch.6, § 20.4.1.

charges for the service, adjusted to cost. The MMA also provided for the creation of additional groups that classify such devices separately "in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices."[38] CMS implemented these changes in its January 6, 2004 Interim Final Rule.[39]

In February, the APC Panel met and made two recommendations with respect to brachytherapy. First, the APC Panel recommended that CMS establish new HCPCS codes and new APCs, on a per source basis, for high activity Iodine-125 and high activity Palladium-103. Second, the APC Panel recommended that CMS recommended that CMS add "per source" to each of the brachytherapy device HCPCS code descriptors for which units of payment already were not designated. CMS proposes to implement both of these recommendations in the Proposed Rule.[40] ACCC supports this action.

Also in the Proposed Rule, CMS determines that a new linear source Palladium-103 also is eligible for separate cost-based payment as a brachytherapy source. The agency proposes to implement a new C-code and separate payment for linear source Palladium-103.[41] Again, we support this proposal and ask it to be finalized. We also request that CMS discuss in the final rule the process for other new brachytherapy devices to be added to the list for separate cost-based payment. We urge the agency to add new technologies quarterly rather than wait for the next annual rulemaking.

With respect to brachytherapy device payment issues in the future, ACCC urges CMS to work with GAO today to ensure that the study GAO is conducting to determine appropriate payment amounts for devices of brachytherapy in the future[42] indeed will ensure patients have access to these vital, life-saving devices in 2007 and beyond.

IX. Conclusion

ACCC urges CMS to protect cancer patients' access to quality care in the most appropriate setting by carefully implementing the MMA's payment reforms for outpatient cancer care. We applaud CMS for the significant improvements it proposes to make to the OPPS, and we hope that our recommendations will help the agency address the remaining obstacles to care.

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38 MMA § 621(b)(2)(H); SSA § 1833(t)(2)(H).
39 69 Fed. Reg. 819 (Jan. 6, 2004).
40 69 Fed. Reg. at 50539-40.
41 Id. at 50540.
42 MMA § 621(b)(3).

To summarize our comments, we urge CMS to:

- monitor patient access carefully during the transition to ASP-based payment and to react quickly to any access problems;
- implement the proposal to zero-out pass-through payments and dedicate unused pass-through funds to increasing the conversion factor;
- continue the $50 packaging threshold for drugs in the future and finalize the agency's proposal to exclude anti-emetic therapies from this policy;
- apply the future rate-setting methodology for SCODs to all separately-paid drugs;
- work with GAO and MedPAC now to ensure that their studies of the acquisition costs and pharmacy service and overhead costs include all separately paid drugs;
- examine its payment rates for Bexxar® and Zevalin® to ensure that reimbursement for these breakthrough radiopharmaceutical therapies and their related preparation and administration costs and associated procedures is adequate to ensure patient access;
- not apply functional equivalence to any drug in 2005 or future year;
- implement the proposal to treat all new drugs with HCPCS codes as pass-throughs, without requiring a pass-through application to be filed;
- monitor hospitals' ability to receive timely and appropriate reimbursement for drugs for which HCPCS codes have not been assigned and modify the proposed procedures if necessary to ensure patients have access to new, advanced drugs;
- continue to pay separately for designated orphan drugs and implement the proposal to reimburse these unique therapies at the higher of 88 percent of AWP or 106 percent of ASP, capped at 95 percent of AWP;
- treat radiopharmaceuticals as the drugs and biologicals that they are;
- adopt G-codes for drug administration services to reflect the new CPT codes that will be effective in 2006 and begin collecting the data necessary to set more appropriate rates for these important services in the future;
- provide guidance as soon as possible regarding hospitals' use of E/M codes to assist hospitals in billing and receiving reimbursement for cancer therapy support services; and
- implement the proposals to establish new HCPCS codes and APCs for brachytherapy on a per source basis, explain how new brachytherapy devices will be deemed eligible for this payment, and work with GAO to collect data on the costs of brachytherapy devices.

ACCC appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact our staff person, Deborah Walter, at (301) 984-9496, ext. 221, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

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