

OFFICERS:

Al B. Benson III, MD, FACP
President
(Chicago, Illinois)

Thomas L. Whittaker, MD, FACP
President-Elect
(Greenfield, Indiana)

Virginia T. Vaitones, MSW, OSW-C
Secretary
(Rockport, Maine)

George Kovach, MD
Treasurer
(Davenport, Iowa)

Luana R. Lamkin, RN, MPH
Immediate Past President
(Boise, Idaho)

TRUSTEES:

Edward B. Aribisala, RTT, MSc,
MBA
(St. Thomas, US Virgin Islands)

Frances Becker, LCSW, OSW-C
(Stamford, Connecticut)

Steven D'Amato, RPh, BCOP
(Scarborough, Maine)

Becky L. DeKay, MBA
(Shreveport, Louisiana)

Heidi Floden, PharmD
(Washington, DC)

Diane M. Otte, RN, MS, OCN
(La Crosse, Wisconsin)

W. Charles Penley, MD
(Nashville, Tennessee)

Nicholas J. Petrelli, MD
(Newark, Delaware)

Matt Sherer, MBA, MHA
(Columbus, Georgia)

Alan S. Weinstein, MD, FACP
(Mount Holly, New Jersey)

EXECUTIVE DIRECTOR:
Christian G. Downs, JD, MHA

August 31, 2010

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. SW
Washington, DC 20201

**RE: CMS-1504-P: (Medicare Program; Proposed Changes to the Hospital
Outpatient Prospective Payment System and CY 2011 Payment Rates)**

Dear Administrator Berwick:

On behalf of the Association of Community Cancer Centers (ACCC), we 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 3, 2010 (the "Proposed Rule").¹

ACCC represents more than 17,000 cancer care professionals from approximately 900 hospitals and more than 1,200 private practices nationwide. These include Cancer Program Members, Individual Members, and members from 25 state oncology societies. It is estimated that 60 percent of cancer patients nationwide are treated by a member of ACCC.

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 in the most appropriate settings. Hospital outpatient departments

¹ 75 Fed. Reg. 46169 (August 3, 2010).

(HOPDs) are a crucial part of the cancer care delivery system, providing a significant portion of this country's cancer care. Because advanced cancer treatments often are associated with considerable risk, several are available only through hospital-based oncologists, nurses, and pharmacists. Patients receiving these treatments must have substantial on-site clinical support in case of adverse reactions. ACCC members often serve patients who have numerous complications or histories of infusion reactions. In addition, some treatments, such as those involving radiopharmaceuticals, are available only in hospitals because they require specialized equipment and handling that is only available in that setting. Finally, HOPDs play an important role in the early adoption of new technologies and frequently serve patients who recently have completed participation in clinical trials.

Our members also play an important role in the health care safety net. In some cases, HOPDs are the only sites available for Medicare and uninsured patients who need cancer care. HOPDs also are becoming the only option for Medicare beneficiaries who lack supplemental insurance. As hospitals face growing numbers of patients who need care for cancer and other serious illnesses, but have nowhere else to turn, their ability to continue to provide care will depend on Medicare's payment rates.

Adequate OPPS payment rates for cancer drugs² and the services required to prepare and administer them are critical to ensuring patient access to care. Since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Medicare payments for cancer drugs have been reduced significantly. Although we are encouraged to see that CMS has proposed to reimburse separately payable drugs without pass-through status at average sales price (ASP) plus six percent in 2011,³ we remain concerned that the methodology to determine this rate remains flawed, and that the final payment rates may not be sufficient to cover the cost of drug acquisition and related pharmacy overhead services costs.

Over the past few years, ACCC and other stakeholders have presented CMS with data showing that the OPPS rates are inadequate and are based on a deeply flawed methodology. We greatly appreciate that CMS has continued to recognize the problems inherent in its rate-setting methodology, including the effects of charge compression, and that the agency has made significant adjustments to its methodology accordingly. However, we believe that CMS must make additional changes in order to achieve stable and appropriate payment rates for drugs and related pharmacy services.

It is imperative to continued patient access in this crucial setting that the OPPS rates in 2011 and beyond adequately reimburse hospitals for the costs of providing advanced cancer therapies. Toward this end, ACCC recommends that CMS:

- Reimburse the acquisition cost of separately payable drugs at no less than ASP plus six percent;
- Reallocate a larger share of costs for pharmacy overhead from packaged drugs to separately payable drugs;

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

³ 75 Fed. Reg. at 46276.

- Use an ASP file that better reflects the time period of the claims and cost report data used to calculate drug payment rates;
- Remove 340B hospital data from calculation of drug payment rates and continue to pay 340B hospitals at the same rate as non-340B hospitals;
- Make separate payment for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes, or, at a minimum, not increase the packaging threshold for drugs;
- Reinstate separate payment for diagnostic radiopharmaceuticals and contrast agents;
- Implement the new payment rates for brachytherapy sources;
- Continue to apply the current policy for establishing payment for new brachytherapy sources;
- Reinstate separate payment for radiation oncology guidance services;
- Implement the proposal to waive beneficiary cost-sharing for certain preventive services;
- Implement the adjustment to payments for PPS-exempt cancer hospitals in a truly budget neutral manner; and
- Work with providers and specialty societies to determine which new measures to add to the quality reporting requirement.

Our comments on these issues and others are presented below.

I. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status

A. Payment for Drugs and Biologicals

We are pleased that CMS proposes to reimburse all separately paid drugs at ASP plus six percent. As CMS is aware, ACCC has recommended for several years that CMS reimburse all separately paid drugs at no less than ASP plus six percent, the rate applicable in physicians' offices, to establish parity across settings and protect access to care in the most clinically appropriate setting.

We also have explained the importance of appropriate payment for pharmacy overhead and service costs to hospitals' continued ability to provide cancer drugs to patients. The advanced drugs we use to help our patients fight cancer require careful handling by specially trained personnel to ensure that each patient receives the correct dosage of each drug, in the correct sequence, and through the safest administration method. Hospitals employ complex medication use processes in which physicians, nurses, and pharmacists review drug choices at each step of their prescribing, dispensing, and administration. Pharmacists make essential contributions to these processes by using a sequence of activities commonly referred to as "safety through redundancy." Registered pharmacists consult with physicians to determine drug interactions and contraindications, toxicity management and verification of therapy appropriateness, and dosing before and during administration of chemotherapy to a patient. Pharmacists also perform critical quality assurance tasks during the preparation of drug, such as labelling, recording, and tracking mixed drugs for safety purposes, sampling drugs at random to verify quality, and developing and reviewing protocols to flag potential interactions. The costs

of these services, plus necessary supplies, equipment, and facilities used in preparing drugs, are significant.

In recent years, pharmacy service costs have increased due to the growing number of drugs subject to Risk Evaluation Mitigation Strategies (REMS) by the Food and Drug Administration (FDA). These heightened regulatory requirements increase pharmacists' work and require the drugs to be acquired only from specialty distributors, often at cost plus a handling fee that exceeds six percent of ASP. CMS's assumptions about the pharmacy overhead associated with separately payable drugs do not appear to account for these costs. In addition, because the number of drugs subject to REMS has increased in recent years, these costs are not reflected in the claims and cost report data used to calculate payment rates. It is critical that Medicare's reimbursement amounts reflect the current costs of providing care.

We also are pleased that CMS continues to recognize that it is appropriate to redistribute pharmacy overhead costs from packaged drugs to separately payable drugs to avoid underpayment for separately payable drugs to achieve more equitable payment for all drugs under the OPSS. We believe CMS has made significant steps toward establishing more appropriate payment for the acquisition and pharmacy overhead costs of drugs provided under the OPSS, and we greatly appreciate CMS's hard work on this issue.

Although we support CMS's proposed payment rate, we believe the proposed methodology continues to include flaws that produce unstable estimates of drug costs and could lead to inadequate payment. CMS calculates the proposed payment rate for 2011 using the same two-step approach it developed for the final rule in 2010. First, CMS calculates the estimated aggregate cost of separately paid and packaged drugs relative to ASP. This step produces estimated acquisition and pharmacy overhead cost for separately payable drugs of ASP plus zero and ASP plus 283 percent for packaged drugs. Second, CMS reallocates \$200 million in overhead costs from packaged drugs to separately payable drugs. As a result of CMS's proposed reallocation overhead costs from packaged drugs to separately paid drugs, CMS proposes to reimburse separately paid drugs at ASP plus six percent. The agency acknowledges that the final rate could be lower after CMS applies its methodology to updated data, however.⁴

We believe that CMS's methodology can be improved to produce more stable payment rates and better recognize the costs associated with providing drugs to hospital outpatients. Specifically, we offer the following recommendations to help ensure appropriate reimbursement for drugs administered in HOPDs:

- 1. CMS Should Reimburse Hospitals for Acquisition Cost of Separately Payable Drugs at No Less than ASP Plus Six Percent, as Required by the Statute.**

In the Proposed Rule, CMS explains that its proposal to reimburse drugs' acquisition and pharmacy overhead cost at ASP plus six percent is a "coincidental outcome of the proposed

⁴ Id.

methodology” and not an alternative to payment based on average acquisition costs.⁵ The agency also notes that CMS’s experience has been that the use of updated ASP, claims, and cost report data produces payment rates that are at least one percentage point lower in the final rule than in the Proposed Rule.⁶ Therefore the final payment rate under CMS’s methodology could be less than ASP plus six percent.

At its August 2010 meeting, the APC Panel recommended that CMS reimburse the acquisition and overhead costs of separately payable drugs at no less than ASP plus six percent for 2011. ACCC agrees with this recommendation and believes that appropriate payment for the acquisition and overhead costs of drugs is no less than ASP plus six percent. This will help to protect patients’ access to care in the most clinically appropriate setting. It also would create parity with the physician office setting. Moreover, this rate is consistent with the statute, which requires use of data on “average acquisition cost” or payment at the rates applicable in physicians’ offices.⁷ We disagree with CMS’s belief that its methodology based on ASP data and hospital claims data is a “suitable proxy for the acquisition cost data” required by the statute.⁸ We are particularly concerned about the methodology’s sensitivity to changes in the underlying data and assumptions used, as illustrated by the reduction by at least one percentage point between past proposed and final rules, producing results that appear to be arbitrary. To provide for stable, appropriate payment, CMS should reimburse drugs provided under the OPSS at no less than ASP plus six percent.

2. CMS Should Reallocate a Larger Portion of the Pharmacy Overhead Costs Associated with Packaged Drugs to the Separately Payable Drugs.

At its February 2010 meeting, the APC Panel recommended that CMS reallocate a larger portion of the pharmacy overhead costs from packaged drugs to separately payable drugs in 2011.⁹ We are disappointed that CMS does not propose to accept this recommendation and that CMS does not accept the analysis ACCC and other stakeholders presented at that meeting. At the February APC Panel meeting, we explained that CMS significantly underestimates the amount of overhead associated with packaged drugs. As Chris Hogan, of Direct Research, LLC, reported in February, packaged drugs billed without HCPCS codes are subject to the same markup as packaged drugs with HCPCS codes. Applying the reasonable assumption that packaged drugs not billed with HCPCS or without ASPs have the same ratio of acquisition cost to overhead cost as drugs with HCPCS codes and ASPs, produces a substantial, additional overhead pool.

When CMS studied uncoded drugs, it found “that most uncoded packaged drug costs appear with surgical services and that most coded packaged drug costs appear with medical

⁵ Id.

⁶ Id.

⁷ Social Security Act (SSA) § 1833(t)(14)(A)(iii)(I).

⁸ 75 Fed. Reg. at 46276.

⁹ Id. at 46278.

services.”¹⁰ CMS explains that it “is not confident that the drugs captured by uncoded drug cost are the same drugs captured by coded drug cost” and it believes that it cannot assume that uncoded drugs are subject to comparable overhead and handling costs as coded drugs.¹¹ This belief is unfounded. Our members report that hospital pharmacies’ overhead is spread across all drugs – including those used with surgical services – and the overhead allocated to each drug varies with cost for all drugs. Uncoded drugs used with surgical services, such as neuromuscular blocking agents, narcotic analgesics such as patient-controlled analgesia, and epidural drugs and antibiotics, require similar pharmacy services and overhead costs as coded packaged drugs and are subject to similar markups as other packaged drugs. Therefore, the same assumptions should be applied to uncoded drugs as to coded drugs.

An analysis by The Moran Company supports our members’ statements that drugs used with surgical procedures and drugs used with medical procedures are subject to similar markups. In fact, many packaged drugs are used with both types of procedures. Currently, CMS cannot identify many drugs packaged with surgical procedures because they are uncoded. The Moran Company studied claims from a group of “expert coder” hospitals – hospitals for which coded packaged drugs made up 85 percent or more of packaged drug costs – that illustrate what CMS’s claims data would look like if hospitals reported codes for all drugs that have HCPCS codes. The claims data from these expert coder hospitals allow us to see exactly which drugs are used with medical or surgical procedures. The claims data from these hospitals included 174 coded packaged drugs. One hundred of those drugs, or 57 percent, were reported with both medical and surgical procedures. This significant overlap supports a conclusion that many packaged drugs are used in both medical and surgical procedures, and the same assumptions about hospitals’ markups should be applied to these drugs.

For coded drugs, CMS believes that one-third to one-half of total pharmacy overhead associated with coded packaged drugs is an appropriate amount to redistribute to separately payable drugs. Consistent with its approach in the 2010 final rule, CMS proposes to reallocate approximately 25 percent of the total cost (acquisition and overhead) of coded packaged drugs to separately payable drugs. This approach seems reasonable in light of surveys showing that pharmacy overhead should be at least 25 percent of total pharmacy costs. In contrast, CMS proposes to reallocate only 8 percent of the total cost of uncoded packaged drugs. It is clear that CMS’s \$50 million “conservative estimate of the pharmacy overhead cost of uncoded packaged drugs”¹² is far too small, and CMS should transfer a similar share of overhead from uncoded drugs and coded drugs. We urge CMS to reallocate a larger share of overhead costs from uncoded packaged drugs to separately payable drugs in the final rule.

ACCC also understands that CMS’s ability to calculate more accurate payments in future years will depend on the quality of data available. Under current billing guidance, hospitals may have used different, but permissible, approaches to reporting packaged drugs. These practices have resulted in CMS not collecting complete and detailed data on the costs of all packaged drugs. We appreciate CMS’s continued encouragement for hospitals to “bill all drugs and

¹⁰ Id.

¹¹ Id.

¹² Id. at 46274.

biologicals with HCPCS codes, regardless of whether they are separately payable or packaged.”¹³ We agree with the APC Panel’s recommendation that CMS require hospitals to report all drugs with HCPCS codes using revenue code 0636 regardless of payment status. In the Proposed Rule, CMS also states, “a practice of billing all drugs and biologicals with HCPCS codes under revenue code 0636 (Pharmacy – Extension of 025X; Drugs Requiring Detailed Coding) would be consistent with NUBC billing guidelines and would provide [CMS] with the most complete and detailed information for ratesetting.”¹⁴ ACCC has urged its members to follow this recommendation, but also believes that CMS should now require hospitals to bill all drugs with HCPCS codes under revenue code 0636. Not only will requiring this coding provide CMS with better data for future rate-setting, but it also will help the agency comply with the requirement in section 9008 of the Patient Protection and Affordable Care Act of 2010 (ACA) to separately track use of branded prescription drugs for purposes of the annual fee on branded pharmaceutical manufacturers. The statute requires the Secretary to “establish a process for determining the units and allocated price . . . for those branded prescription drugs that are not separately payable or for which National Drug Codes are not reported.”¹⁵

3. CMS Should Use an ASP Data File That Better Reflects the Time Period of the Claims And Cost Report Data Used to Calculate Payment Rates.

Consistent with its standard methodology, in the Proposed Rule, CMS compares the costs derived from claims data from 2009 and cost reports beginning in calendar year 2008 to the ASP file from April 2010.¹⁶ CMS proposes to use the ASP file from July 2010 in the final rule, and the agency acknowledges that use of updated data could produce lower estimates of aggregate cost, just as it has in recent years’ final rules compared to the proposed rules. This effect is due to use of misaligned data that fail to recognize the effects of inflation on hospitals’ costs of drugs, and, as a result, underestimate the acquisition and overhead costs of these drugs. CMS cannot accurately estimate hospitals’ costs as a percent of ASP if it compares hospital’s acquisition cost from one time period to ASPs from another period. When we compared the claims data to the July 2009 ASP file that is better aligned with the claims and cost report data, we found that CMS’s estimated costs relative to ASP for separately payable drugs increased from ASP plus zero to ASP plus 1.11. After the reallocation of \$200 million in overhead costs to separately payable drugs, the estimated cost increased from ASP plus six percent to ASP plus eight percent. To improve the accuracy and stability of CMS’s rate-setting calculations, we urge CMS to use ASP data from the same time period as the claims and cost report data to calculate the amount in addition to ASP that Medicare will reimburse separately payable drugs. In response to CMS’s concern that using a different quarter of ASP data would require an adjustment to its cost to charge ratios (CCR), we disagree that an adjustment is appropriate. Because the agency’s rate-setting methodology for separately paid drugs establishes a ratio between ASP and hospital costs, the most accurate approach is for the quarter of ASP used for this calculation to be the quarter closest in time to the cost data that is being compared.

¹³ Id. at 46279.

¹⁴ Id.

¹⁵ ACA § 9008(g)(2).

¹⁶ Id.

4. CMS Should Remove Data for Drugs Purchased under the 340B Program from the Calculation of Drug Payment Rates, While Continuing to Reimburse All Hospitals at the Same Rate.

ACCC also requests that CMS remove data from hospitals that participate in the 340B program from its rate-setting methodology for drugs. The APC Panel has recommended in the past that these data should not be included in the calculation of drug reimbursement rates under the OPDS because sales under the 340B program are excluded from the calculation of ASP. To include data from 340B hospitals, as CMS currently does, unfairly penalizes non-340B hospitals by artificially lowering drug reimbursement rates. This effect could be even greater in future years because recent legislation allows more hospitals to participate in the 340B program. Given this result, along with the other flaws in CMS's methodology for setting payment rates for drugs, ACCC believes that CMS's calculations do not accurately reflect hospitals' drug acquisition and pharmacy overhead costs. CMS can take a significant step toward more accurate reimbursement rates by removing data from 340B hospitals from its drug payment calculations.

ACCC does not believe that there should be two separate reimbursement rates – one for 340B hospitals and one for non-340B hospitals. We believe that all hospitals should be paid the same. Reducing reimbursement to 340B hospitals would be inconsistent with the clear intent of Congress and the Health Resources and Services Administration (HRSA) for participating hospitals to use savings on drug costs to expand care for their patients. It also would be unfair to those patients, who might see reductions in services available from these safety net hospitals if reimbursement is reduced. Therefore, we urge CMS to remove the 340B drug data from the calculation of drug payment rates, while continuing to reimburse both types of hospitals at the same rate.

5. CMS Should Make Separate Payment for All Drugs with HCPCS Codes, and, at a Minimum, Not Increase the Packaging Threshold for Drugs.

For 2011, CMS proposes to increase the packaging threshold to \$70 and to continue to package payment for all diagnostic radiopharmaceuticals and contrast agents.¹⁷ We are concerned that continued use of any threshold and the implementation of expanded packaging could harm hospitals' ability to provide essential cancer care. Even if CMS implements our other recommendations to establish appropriate payment for acquisition and pharmacy overhead costs, we remain concerned that packaging may discourage hospitals from providing appropriate care.

We continue to be troubled by CMS's policy of packaging payment for contrast agents and diagnostic radiopharmaceuticals. CMS explains that it believes these drugs function as supplies and are not subject to the statutory payment requirements for specified covered outpatient drugs. This interpretation disregards both the plain language of the statute and

¹⁷ Id. at 46265, 46271.

Congressional intent behind the detailed statutory payment requirements for specified covered outpatient drugs. Congress enacted these provisions after CMS set a high packaging threshold in 2003, and we believe that Congress intended for CMS to continue to protect access to care by keeping the packaging threshold low. For these reasons, we recommend that CMS make separate payment for all 5-HT3 anti-emetics, contrast agents, diagnostic radiopharmaceuticals, and all other drugs with HCPCS codes. At a minimum, CMS should maintain the packaging threshold at no more than the current level of \$65.

B. CMS should reinstate separate payment for diagnostic radiopharmaceuticals and contrast agents.

CMS proposes to continue to package payment for diagnostic radiopharmaceuticals and contrast agents, regardless of their cost per day.¹⁸ Although we understand that CMS has increased payments for many diagnostic and imaging services as a result of its expanded packaging policies, we are concerned that the increase might not be sufficient to protect beneficiary access to important cancer therapies and diagnostic services. Radiopharmaceuticals are extremely complex therapies to prepare and administer. Preparation and administration of each drug requires a unique bundle of services, such as compounding, infusions, and scanning of the patient to assess bio-distribution of the therapy. The costs of these services vary for each therapy, and many of these costs are not reimbursed adequately under the OPSS. Contrast agents also vary in cost and may not be compensated adequately through the OPSS rates for imaging services. We urge the agency to reinstate separate payment for diagnostic radiopharmaceuticals and contrast agents.

II. CMS should implement the proposed payment rates for low dose rate (LDR) prostate brachytherapy.

For 2011, CMS proposes to increase the proposed payment for composite APC 8001 for LDR prostate brachytherapy due to increased median costs for the procedure.¹⁹ Brachytherapy is an important treatment option for prostate cancer, and ACCC appreciates CMS's work to ensure that payment for this composite APC reflects hospitals' costs.

III. CMS should continue to apply its current policy for establishing payment for new brachytherapy sources.

CMS proposes to continue the policy it implemented for 2010 regarding payment for new brachytherapy sources for which the agency has no claims data.²⁰ Under this policy, CMS assigns new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on CMS's consideration of "external data and other relevant information regarding the expected costs of the sources to hospitals."²¹ ACCC supports CMS's efforts to

¹⁸ Id. at 46271.

¹⁹ Id. at 46210.

²⁰ Id. at 46287.

²¹ Id.

establish appropriate payment rates for new brachytherapy sources in a timely manner, and CMS should finalize this proposal.

IV. CMS should reinstate separate payment for radiation oncology guidance services.

ACCC recognizes CMS's desire to continue to expand bundling and packaging in the OPPS. We remain concerned, however, that CMS's recent expansion of packaging, including packaging of guidance services, may negatively affect patients and hospitals. In the Proposed Rule, CMS presents the results of its analysis of billing for radiation oncology guidance services in 2007, before expanded packaging, and in 2009, after expanded packaging. CMS reported increases in the number of intensity modulated radiation therapy (IMRT), stereotactic radiosurgery (SRS), and brachytherapy services billed and total payments for those procedures, but found a 20 percent reduction in the frequency of billing for conventional radiation therapy services and a 10 percent reduction in total payment for those services.²² We urge CMS to continue to monitor use of and payment for these services and share these reports with stakeholders, so we can verify that Medicare's payment policies do not harm access to care. ACCC urges CMS to reinstate separate payment for radiation oncology guidance procedures. These services are vital to the safe provision of radiation therapy, and unconditionally packaging payment for them may discourage hospitals from providing them.

V. CMS should implement the proposals to waive beneficiary cost-sharing for certain preventive services, as required by the ACA.

ACCC commends CMS's proposals to waive beneficiary cost-sharing for certain preventive services, as required by the ACA. In particular, section 4104 of the ACA requires Medicare to eliminate beneficiary cost-sharing for preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population that are appropriate for the individual. Included in this list are several screening tests for cancer that are reimbursed under the OPPS, including screening pap tests, screening pelvic examinations, colorectal cancer screening, and prostate cancer screening.²³ Appropriate use of screening services is essential to identifying potential cancers early, when they are most treatable. Because beneficiaries currently must pay part of the cost of these services, some beneficiaries might postpone screening because they cannot afford the test. The ACA provisions waiving cost-sharing, combined with the new coverage of an annual wellness visit that includes a personalized prevention plan, should help beneficiaries to receive appropriate screening by identifying the preventive services appropriate for the beneficiary and allowing the beneficiary to receive those services with no out-of-pocket cost. ACCC urges CMS to finalize its proposed changes to the regulations to allow beneficiaries to receive these preventive services without cost-sharing.

²² Id. at 46222.

²³ Id. at 46312-46316.

VI. CMS should implement the adjustment to payments to PPS-exempt cancer hospitals in a truly budget neutral manner.

Section 3138 of the ACA requires the Secretary of Health and Human Services to study whether the 11 PPS-exempt cancer hospitals incur greater outpatient costs than other hospitals. If the cancer hospitals' costs are determined to be greater than the costs of other hospitals paid under the OPSS, the Secretary shall provide an appropriate adjustment to reflect these higher costs. Section 3138 also requires that this adjustment be budget neutral, and it would be effective for outpatient services provided at cancer hospitals on or after January 1, 2011.

In the Proposed Rule, CMS discusses its study and its findings that the PPS-exempt cancer hospitals have higher costs than other hospitals. CMS estimates that on average, the OPSS payments to the 11 cancer hospitals, not including transitional outpatient payments (TOPs, or hold harmless payments), are approximately 62 percent of reasonable cost (a payment-to-cost ratio (PCR) of 0.615) compared to average OPSS payments to other hospitals of approximately 87 percent of reasonable cost (PCR of 0.868).²⁴ Individual cancer hospitals' OPSS PCRs range from approximately 48 percent to approximately 82 percent.²⁵ When TOPs are included in the calculation of the PCR, cancer hospitals, as a group, receive payments that are approximately 83 percent of reasonable cost, which is still lower than the average PCR of other OPSS hospitals of approximately 87 percent of reasonable cost.²⁶ CMS concludes that the cancer hospitals are more costly than other hospitals paid under the OPSS and that an adjustment is merited. CMS proposes to make hospital-specific adjustments ranging from 5.9 percent to 82.6 percent, with an aggregate adjustment of 41.2 percent, before application of the TOPs.²⁷ This adjustment would be offset by a 0.7 percent reduction in payments to all other hospitals.²⁸

ACCC appreciates CMS's efforts to compare the costs of the 11 PPS-exempt cancer hospitals to other hospitals and make the adjustment required by the ACA. We are concerned, however, that the proposed adjustment is not budget neutral, as required by the ACA. Currently, the TOPs for PPS-exempt cancer hospitals are approximately \$164 million.²⁹ CMS estimates that only one of the 11 cancer hospitals would continue to receive TOPs if the agency finalizes its proposal to calculate the cancer hospital adjustment without considering the current effect of the TOPs.³⁰ When Congress required the cancer hospital adjustment to be budget neutral, it did not intend for CMS to reduce spending by nearly \$164 million. This interpretation is supported by the Congressional Budget Office (CBO) analysis of section 3138 of the ACA has having no effect on spending.³¹ To be consistent with Congressional intent and to ensure appropriate payment to PPS-exempt cancer hospitals with minimal effect on other hospitals, we recommend

²⁴ Id. at 46235.

²⁵ Id.

²⁶ Id.

²⁷ Id. at 46236.

²⁸ Id. at 46447.

²⁹ 2001 OPSS NPRM Cancer Adjustment File,

http://www.cms.gov/HospitalOutpatientPPS/Downloads/CMS_1504_P_2011_cancer_adjustment_files.zip.

³⁰ 75 Fed. Reg. at 46237.

³¹ CBO, Cost estimate for H.R. 3590, the Patient Protection and Affordable Care Act, as passed by the Senate on December 24, 2009, March 11, 2009, at 19, http://cbo.gov/ftpdocs/113xx/doc11307/Reid_Letter_HR3590.pdf.

that CMS calculate the adjustment by including the TOPs for PPS-exempt cancer hospitals. This would require a smaller additional payment to PPS-exempt cancer hospitals and a significantly smaller offset for other hospitals and would be budget neutral.

Hospitals across the country are facing difficult financial circumstances in these trying economic times. Decreasing the 0.7 percent payment reduction will help us maintain the high quality care that our patients deserve.

VII. CMS should work with providers and specialty societies to determine which new measures to add to the quality reporting requirement.

ACCC supports the proposal to retain the existing 11 Hospital Outpatient Quality Data Reporting Program (HOP QDRP) measures, including a measurement for mammography follow-up rates.³² ACCC suggests that CMS continue to work with the oncology specialty societies, providers, and other quality societies in determining the best measures to add to the program. Oncology measures can be vital in determining the true quality of care, and ACCC supports their inclusion in this initiative.

VIII. Conclusion

ACCC encourages CMS to protect cancer patients' access to quality care in the most appropriate setting by providing appropriate reimbursement for cancer treatments under the OPDS. Toward this end, we urge the agency to implement the adjustment to payments to PPS-exempt cancer hospitals in a truly budget neutral manner that will reduce the payment reduction to other hospitals as much as possible. In addition, we urge CMS to implement the proposal to pay ASP plus six percent for the acquisition cost of separately payable drugs and to make an appropriate adjustment for pharmacy overhead. 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 Matthew Farber at (301) 984-9496, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to these very important matters.

Respectfully submitted,



Al B. Benson, MD, FACP
President

Association of Community Cancer Centers (ACCC)

³² 75 Fed. Reg. at 46363.