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ACCC

Association of Community Cancer Centers

September 4, 2012

Marilyn Tavenner
Acting 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-1589-P (Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations)

Dear Administrator Tavenner:

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 July 30, 2012 (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 28 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] 77 Fed. Reg. 45061 (July 30, 2012).

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(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 of these treatments 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 drugs[2] 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. However, we are encouraged that CMS has altered its methodology and proposed a payment rate of Average Sales Price (ASP) plus six percent for the cost of drug acquisition and related pharmacy overhead services costs. We look forward to working with the agency to further refine its methodology in future years.

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. We believe this new payment methodology will provide for more appropriate and stable reimbursement levels for drugs and pharmacy related services.

It is imperative to continued patient access in this crucial setting that the OPPS rates in 2013 and beyond adequately reimburse hospitals for the costs of providing advanced cancer therapies. Toward this end, ACCC recommends that CMS:

- Implement the proposal to reimburse hospitals for separately payable drugs at ASP plus six percent;

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

- 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 proposal to calculate ambulatory payment classification (APC) rates using the geometric mean instead of the median costs;
- Continue to use the composite APC for implement the proposed payment rates for low dose rate (LDR) prostate brachytherapy and should verify that the proposed payment rate is correct;
- Continue to apply the current policy for establishing payment for new brachytherapy sources;
- Reinstate separate payment for radiation oncology guidance services and monitor access to these services;
- Not implement the significant proposed payment cuts for combined Computed Tomography (CT) of the abdomen and pelvis;
- Continue to work with hospitals to develop a policy that will encourage the use of radioisotopes derived from non-Highly Enriched Uranium (HEU) sources;
- Not implement the proposed changes to APCs for Proton Beam Therapy (0664 and 0667);
- Use external cost data to identify an appropriate APC assignment for intraoperative radiation therapy (IORT) CPT codes 77424 and 77425; and
- Implement the proposal for PPS-exempt cancer hospitals payments in the same manner as 2012.

Our comments on these issues and others are presented below.

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

A. Proposed Payment for Drugs and Biologicals

We are encouraged that CMS proposes to reimburse all separately paid drugs without pass-through status at ASP plus six percent.[3] 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. We are very pleased that CMS has taken these requests and the recommendations of the Hospital Outpatient Payment (HOP) Panel (and formerly those of the Ambulatory Payment Classification (APC) Panel) into account.

In our comments on prior years' proposed rules, we 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

[3] 77 Fed. Reg. at 45067.

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 a 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 addition, 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) and the continuing crisis due to drug shortages. These heightened regulatory requirements for REMS 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. In addition, the need to plan around limited dosages and search for limited quantities of drugs can also add to the burden of the pharmacy department. ACCC believes that because the number of drugs subject to REMS has increased in recent years, as have the number of drugs currently in shortage, that 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, and with the proposed change in methodology and payment rate, we feel CMS has taken the first step in recognizing this need.

1. CMS should implement the proposal to reimburse hospitals for the acquisition cost of separately payable drugs at ASP plus six percent.

For 2013, CMS has proposed to reimburse the acquisition and pharmacy overhead costs of drugs at ASP plus six percent. This is an increase from the current rate of ASP plus four percent, which CMS calculated based on its analysis of claims data and a reallocation of overhead costs from packaged to separately payable drugs. CMS proposes to abandon its claims-based determination of payment rates for drugs. Instead, the agency proposes to use the "statutory default," established by the Medicare Modernization Act of 2003, that sets the payment rate equal to that applied in physicians' offices: ASP plus six percent.[4] CMS asserts that this methodology will allow for greater stability in HOPD reimbursement rates, and ACCC agrees with this statement.

As CMS explains the history of its payment rates for separately payable drugs in recent years in the Proposed Rule, it is hard not to notice that the CMS's methodology, even with recent refinements, has not produced stable reimbursement amounts for these therapies. Final payment rates have varied from ASP plus four percent to ASP plus six percent, and CMS's estimates of

[4] Social Security Act (SSA) § 1833(t)(14)(A)(iii)(I).

cost for separately payable drugs have ranged from ASP plus three percent to ASP minus two percent. These variations do not reflect changes in hospitals' actual costs, and they indicate that the core methodology is flawed. In addition, the methodology had been very sensitive 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. CMS correctly recognizes that even with refinements, this methodology "still may not appropriately account for average acquisition and pharmacy overhead cost and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate as they could be."[5] Therefore, we encourage CMS to adopt the proposal to change its methodology and reimbursement separately payable drugs at ASP plus six percent in 2013.

Payment for the acquisition and overhead costs of drugs at ASP plus six percent will help to protect patients' access to care in the most clinically appropriate setting. It also would create parity with the physician office setting. As mentioned above, 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. To provide for stable, appropriate payment in CY 2013, CMS should reimburse drugs provided under the OPPS at ASP plus six percent, under the statutory default.

ACCC also supports CMS's plan to continue to work on developing a "method that accurately and predictably estimates acquisition and overhead costs for separately payable drugs and biologicals in order to pay for them appropriately."[6] We would be happy to assist CMS with these efforts. To ensure that CMS has accurate data to use in development such a methodology, we ask CMS to require hospitals to bill for all drugs with HCPCS codes and revenue code 636. CMS already encourages hospitals to "change their reporting practices if they are not already reporting HCPCS codes for all drugs and biologicals furnished, whether specific HCPCS codes are available for those drugs and biologicals."[7] CMS should do more than encourage hospitals to adopt this practice; it should require them to do so.

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

For 2013, CMS proposes to increase the packaging threshold to $80 and to continue to package payment for all diagnostic radiopharmaceuticals and contrast agents.[8] 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 the proposed payment rate of ASP plus six percent for the acquisition and pharmacy overhead costs of separately payable drugs, we remain concerned that packaging may discourage hospitals from providing appropriate care.

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[5] 77 Fed. Reg. at 45140.
[6] Id.
[7] Id. at 45141.
[8] Id. at 45101.

As in previous years, 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 (SCODs).[9] This interpretation disregards both the plain language of the statute and Congressional intent behind the detailed statutory payment requirements for SCODs. 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 $75.

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.[10] 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 OPPS. Contrast agents also vary in cost and may not be compensated adequately through the OPPS rates for imaging services. We urge the agency to reinstate separate payment for diagnostic radiopharmaceuticals and contrast agents.

II. The agency should implement the proposal to alter the calculation of APC rates using the geometric mean instead of the median costs.

For 2013, CMS is proposing a significant change in the methodology to calculate APC payment rates. CMS proposes to use the geometric mean costs of services within an APC to determine the relative payment weights of services, rather than the median costs that CMS has used since the inception of the OPPS.[11] The proposed change would have a limited payment impact on most providers, with a small number experiencing payment gain or loss based on their service-mix.

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[9] Id. at 45100.
[10] Id. at 45101.
[11] Id. at 45066-67.

CMS is proposing to adjust its methodology for setting OPPS payment weights because, while median costs are resistant to outlier observations, geometric means are more reflective of the average costs of services.[12] CMS believes that geometric means better capture the range of costs associated with providing services, will enable CMS to detect changes in the cost of services earlier, and will promote better stability in the payment system. CMS believes it is important to make the transition from medians to means across all APCs in order to capture the full range of costs associated with all services and to ensure that the relative payment weights of the various APCs are properly aligned.

ACCC supports this change in methodology and encourages CMS to implement it in 2013.

III. CMS should continue to use the composite APC for low dose rate (LDR) prostate brachytherapy and should verify that the proposed payment rate is correct.

For 2013, CMS proposes to continue to pay for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2012. Under this methodology, the calculated costs for the services increase slightly, but the proposed payment rate would be slightly less than the 2012 rate.[13] We ask CMS to verify that its proposed payment rate is correct and reflects increased costs for these services. Brachytherapy is an important treatment option for prostate cancer, and ACCC appreciates CMS's work to ensure that payment for this composite APC remains stable and reflects hospitals' costs. We ask CMS to implement the proposed payment increase for this composite APC.

IV. 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.[14] 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."[15] ACCC supports CMS's efforts to establish appropriate payment rates for new brachytherapy sources in a timely manner, and CMS should finalize this proposal.

V. CMS should reinstate separate payment for radiation oncology guidance services and monitor access to these services.

ACCC recognizes CMS's desire to continue to expand bundling and packaging in the OPPS. We remain concerned, however, that CMS's continued expansion of packaging,

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[12] Id. at 45096.
[13] Id. at 45169.
[14] Id. at 45087.
[15] Id.

including packaging of guidance services, may negatively affect patients and hospitals. In the proposed rule for 2011, CMS presented 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.[16] 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.

VI. CMS should not implement the significant proposed payment cuts for combined CT of the abdomen and pelvis.

For 2011, new CPT codes were created for combined CT of the abdomen and pelvis. CMS made interim APC assignments for these codes for 2010, but after reviewing historic claims data for the predecessor codes, CMS created new APCs and revised composite APC assignments for these codes.[17] CMS assigned CPT code 74176 to new APC 0331 (Combined Abdominal and Pelvis CT Without Contrast) and assigned CPT codes 74177 and 74178 new APC 0334 (Combined Abdominal and Pelvis CT With Contrast).[18] CMS also assigned CPT code 74176 to imaging composite APC 8005 (CT and CTA Without Contrast) when it is reported with codes that describe CT services for other regions of the body other than the abdomen and pelvis in which contrast is not used.[19] CPT codes 74177 and 74178 were assigned to APC 8006 (CT and CTA with Contrast) when they are reported with CT codes for other regions of the body with contrast. In the Proposed Rule, CMS discusses its review of these APC assignments and concludes that it will continue to use these assignments.[20] ACCC agrees with the continued assignment of these codes and encourages CMS to implement these proposals.

We are concerned, however, about the deep payment cuts CMS proposes for these services. The proposed payment rate for APC 0331 is 24 percent less than the current rate, and the proposed payment rate for APC 0034 is 17 percent less than the current rate. These changes appear to be caused by a combination of the use of geometric mean costs and changes in hospitals' estimated costs. These dramatic cuts in reimbursement will be difficult for hospitals to accommodate and could harm access to appropriate imaging services. We urge CMS to take whatever action is necessary to mitigate these severe payment cuts.

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[16] 75 Fed. Reg. 46170, 46222 (Aug. 3, 2010).
[17] 77 Fed. Reg. at 45086.
[18] Id.
[19] Id.
[20] Id.

VII. CMS should continue to work with hospitals to develop a policy that will encourage the use of radioisotopes derived from non-HEU sources

In an effort to support the Administration's stated policy of eliminating domestic reliance on reactors outside of the United States that produce HEU, and to promote the conversion of all medical isotope production to non-HEU sources, CMS is proposing to provide a payment adjustment for CY 2013 to cover the marginal cost of hospital conversion to use of non-HEU sources to obtain radioisotopes used in medical imaging.[21] The adjustment would cover the marginal cost of radioisotopes produced from non-HEU sources over the costs of radioisotopes produced by HEU sources. For CY 2013, CMS is proposing to provide an additional payment of $10 and to establish a new HCPCS code, QXXXX to describe the Tc-99m radioisotope produced by non-HEU methods and used in a diagnostic procedure.

As discussed above, ACCC supports separate payment for all diagnostic radiopharmaceuticals using the same methodologies that apply to therapeutic radiopharmaceuticals and other drugs. We believe that separate reimbursement also would encourage the use of non-HEU sources by helping to ensure that hospitals are reimbursed for the costs of the sources they use. If CMS continues to package payment for diagnostic radiopharmaceuticals, we support the concept of a payment adjustment to cover the costs associated with non-HEU sources. We are concerned that the proposed payment may not be sufficient to cover hospitals' costs, however, and that the proposed documentation requirements may be burdensome. ACCC recommends that CMS continue to work with hospitals to identify a more appropriate method of supporting hospitals' use of non-HEU sources.

VIII. CMS should not implement the proposed changes to APCs for Proton Beam Therapy (0664 and 0667)

In 2013, CMS is proposing to change the assignment of certain codes used in Proton Beam Therapy from one APC to another. Specifically, CMS is proposing to reassign CPT code 77522 to APC 0667 and to reassign CPT code 77525 to APC 0664. Under this proposed reassignment, the estimated cost of APC 0664 would drop to $462, and the estimated cost of APC 0667 would decline to $1,138.[22] These proposed changes would cause drastic decreases in payment for proton bean therapy.

[21] Id. at 45121.
[22] Id. at 45123.

Code	Description	Proposed Payment Reduction
77520	Proton treatment, simple without compensator	-61.95%
77522	Proton treatment, simple with compensator	-6.21%
77523	Proton treatment, intermediate	-28.30%
77525	Proton treatment, complex	-70.91%

ACCC believes that hospitals will not be able to continue to provide proton therapy if these dramatic cuts are implemented, especially given the high cost of equipment in proton beam therapy. We are concerned that these proposed rates do not reflect hospitals' costs of providing this advanced therapy. Due to the extremely small number of hospitals that provide these services and the relatively small number of claims for some of these services, CMS's rate setting methodology can produce severe fluctuations in payment rates based on small changes in data. We also understand that the data from one of the three hospitals that bill Medicare for these services were flawed. We urge CMS not to implement these APC reassignments or payment rate reductions. As recommended by the HOP Panel, CMS should maintain the current APC assignments and payment rates for the proton beam codes. CMS also should work with these hospitals to verify that the data used to calculate future payment rates are accurate and ensure that reimbursement for these services remains stable and predictable.

IX. CMS should use external cost data to identify an appropriate APC assignment for CPT codes 77424 and 77425.

For CY 2013, CMS proposes to provide separate payment for new CPT codes 77424 (Intraoperative radiation treatment delivery, x-ray, single treatment session) and 77425 (Intraoperative radiation treatment delivery, electrons, single treatment session) by assigning the codes to APC 0412, currently entitled "IMRT Treatment Delivery."[23] CMS also proposes to change the title of APC 0412 to "Level III Radiation Therapy" to encompass a greater number of clinically similar radiation treatment modalities. The proposed cost of APC 0412 based on CY 2011 claims data is approximately $496. CMS plans to monitor hospitals' costs for furnishing the services described by CPT codes 77424 and 77425.

ACCC supports CMS's proposal to unpackage payment for IORT. IORT is an important treatment option for cancer patients, particularly for lower income and rural patients who are not able to return to the hospital for subsequent treatments due to lack of medical leave from work, transportation shortages, or long distances to travel. We believe that separate payment will help to protect access to it.

We are concerned that the proposed APC assignment is not appropriate, however, because it would not provide adequate payment for these services and would assign IORT to the

[23] Id. at 45124.

same APC as dissimilar services. IORT is different from the other forms of radiation therapy that share that APC because it involves delivery of a single fraction of radiation in the operating room immediately following tumor resection, instead of multiple fractions over days or weeks. IORT also uses different resources than the other forms of radiation therapy because it is provided in the operating room. Because the new CPT codes were effective January 1, 2012, CMS does not yet have claims data to use in making an APC assignment. We recommend that CMS use external cost data to identify an appropriate APC assignment for CPT codes 77424 and 77425.

X. CMS should implement the proposal for PPS-exempt cancer hospitals payments in the same manner as 2012.

Section 3138 of the Patient Protection and Affordable Care Act (ACA) required 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 were determined to be greater than the costs of other hospitals paid under the OPPS, as CMS found in 2010, then the Secretary shall provide an appropriate adjustment to reflect these higher costs. Section 3138 also requires that this adjustment be budget neutral, and it was to have been effective for outpatient services provided at cancer hospitals on or after January 1, 2011. After the proposal received numerous comments last year, CMS tabled the change in payment, and then brought up a revised proposal in the 2012 rule. The proposal was further refined after the comment period and finalized by providing additional payments to cancer hospitals so that the hospital's payment-to-cost ratio (PCR) with the payment adjustment is equal to the weighted average PCR for the other OPPS hospitals using the most recent submitted or settled cost report data.

For 2013, CMS is proposing to continue the adjustment to these hospitals in a manner similar to that in 2012.[24] ACCC agrees with this proposal and requests CMS to implement it. ACCC supports increasing the payments to these hospitals, but at the same time, we believe that the impact to all other hospitals should be as minimal as possible.

XI. 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 OPPS. Toward this end, we urge CMS to reimburse all separately payable drugs at ASP plus six percent in CY 2013 as the agency has proposed. 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.

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[24] Id. at 45109.

Respectfully submitted,

George Kovach, MD
President
Association of Community Cancer Centers (ACCC)