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August 31, 2009

Charlene Frizzera
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-1413-P (Medicare Program; Revisions to Payment
Policies Under the Physician Fee Schedule and Other
Revisions to Part B for CY 2010)**

Dear Acting Administrator Frizzera:

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 payment policies under the Medicare physician fee schedule (PFS), published in the Federal Register on July 13, 2009 (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 900 member institutions and organizations treat 60 percent of all U.S. cancer patients when combined with our physician membership.

Many cancer patients turn to physician offices to receive their treatment and related care, and it remains vitally important that physicians are reimbursed appropriately for these services. Accordingly, ACCC is pleased to support CMS's proposal to remove drugs from the Sustainable Growth Rate (SGR) formula as it will help avoid negative SGR updates in the future. We encourage CMS to

¹ 74 Fed. Reg. 33519 (July 13, 2009).

continue to take the steps necessary to ensure physicians are adequately reimbursed for the quality cancer care that they deliver to their patients by developing a stable update formula for the future.

The proposed change to the SGR methodology does not, however, eliminate the expected 21.5 percent reduction in payment rates for this year. In conjunction with the use of new survey data and new equipment utilization rates to update Practice Expense (PE) Relative Value Units (RVUs), both medical and radiation oncologists face substantial reimbursement cuts. We are very concerned about the effect of these cuts on physicians' ability to respond to the growing need for their services and the associated threat to patient access to care.

With these general concerns in mind, we recommend that CMS:

- Continue to use existing survey data to update PE RVUs or phase-in use of the new survey data during a refinement period of at least four years;
- Not implement the proposed increase in the equipment utilization rate for equipment priced over \$1 million;
- Eliminate its proposal to replace consultation codes with other initial visit codes;
- Exercise caution as it evaluates potentially misvalued services and include representatives of providers and specialty societies in any "group of experts" it creates;
- Implement the PQRI proposals because they will lead to improved quality of care for patients and minimize administrative burdens for providers;
- Work with ACCC and other providers and specialty societies on the report due to Congress on May 1, 2010 on the transition to value-based purchasing;
- Implement the requirement that organizations designated to accredit suppliers furnishing the technical component (TC) of advanced diagnostic imaging services disclose plans for reducing the burden and cost of accreditation to small and rural suppliers;
- Establish a threshold for reporting financial relationships of immediate family members of individuals responsible for developing recommendations for compendia recognized for the determination of medically-accepted indications for off-label uses of drugs and biologicals in anti-cancer chemotherapeutic regimens;
- Adopt a grandfathering provision that would allow beneficiaries who are being treated under off-label anti-cancer chemotherapeutic regimens included in recognized compendia before December 31, 2009 to maintain coverage through the completion of their treatment

protocols even if the relevant compendium does not meet the new requirements as of January 1, 2010;

- Implement the agency's Competitive Acquisition Program (CAP) proposals and restore the full geographic scope of CAP as soon as possible;
- Implement the proposal to eliminate drugs from SGR formula and continue to work with Congress to develop a permanent and stable update formula; and
- Revise the date of service (DOS) regulations to provide that the date of service for certain complex diagnostic laboratory tests is the *date of performance* rather than the *date of collection*.

We discuss these recommendations in depth below.

I. CMS should continue to use existing survey data to update PE RVUs or phase-in use of the new survey data during a refinement period of at least four years.

In the past, CMS has used the American Medical Association's (AMA's) Socioeconomic Monitoring Survey (SMS) and supplemental surveys to update PE RVUs. The AMA has conducted a new survey, the Physician Practice Information Survey (PPIS) that was designed to update the data used to develop PE RVUs. For calendar year (CY) 2010 CMS proposes to use PPIS data to update PE RVUs for specialties that participated in the survey.²

Use of PPIS survey data significantly contributes to the large expected decrease in payment rates for medical oncologists and radiation oncologists.³ The impact of the proposed PE RVU changes, including use of the PPIS data, is to reduce payment rates by five percent for medical oncology and 17 percent for radiation oncology. The total impact of all proposed RVU changes is to reduce payment rates by six percent for medical oncology and 19 percent for radiation oncology.⁴ Such reductions themselves will have drastic consequences for oncologists and their patients as discussed above. When considered in conjunction with the proposed -21.5 percent update based on the SGR methodology, this would result in a total payment reduction of 27 percent for medical oncologists and 40.5 percent for radiations oncologists. It is difficult to imagine how oncology practices can remain viable without significant reorganization.

Indeed, ACCC members are reporting that if the cuts to Medicare payments are implemented as proposed they will have to shift more patients to hospitals and

² Id. at 33531.

³ Id. at 33661.

⁴ Id.

likely will have to cut staff. Even if Congress acts to reverse the conversion factor reduction, the significant decrease in payment rates caused by use of the new PPIS data will force oncologists to consider reducing the number of Medicare patients they treat, forgo investments in new technologies, and find other cost-saving measures that could limit beneficiaries' treatment options. ACCC is concerned that patients, as a result, may begin to encounter access issues. In addition, many members are concerned that private payers will implement similar reductions as most base their reimbursement on Medicare payment rates.

Moreover, ACCC is deeply concerned that using the PPIS data is not truly indicative of oncology practice expense. Only about 50 oncology practices participated in the survey – a very small percentage of the universe of oncology practices in the United States. ACCC therefore urges CMS to continue to use the SMS and the supplemental survey data to update PE RVUs. To the extent CMS determines that it is appropriate to proceed with using the PPIS data, ACCC urges CMS to phase in the new rates over at least four years. This will give CMS the time to work with affected specialty societies to collect additional detail and refine the data as necessary to ensure that it accurately reflects practice expenses. It also will give providers and beneficiaries the opportunity to adjust to the dramatic change in reimbursement and plan for the future.

II. CMS should not implement the proposed increase in the equipment utilization assumption for equipment priced at over \$1 million.

CMS proposes to increase the equipment usage assumption rate for calculating PE RVUs from the current 50 percent usage rate to a 90 percent usage rate for equipment priced over \$1 million.⁵ This change contributes to the significant proposed reduction in payment rates for radiation oncologists and also would reduce payment for critical imaging services.⁶ As described above, ACCC is very concerned about the impact of such a drastic reduction on patient access to necessary cancer treatments and diagnostic imaging services.

We are particularly concerned that CMS proposes to implement this change to all equipment priced over \$1 million, including radiation therapy equipment, based on limited data on two types of imaging equipment and no data on radiation therapy. CMS refers to studies one small study cited by the Medicare Payment Advisory Commission (MedPAC) on the use of CT and MRI equipment and another study of CT equipment use.⁷ The first of these surveys collected data from providers of CT and MRI services in six urban markets in 2006. MedPAC itself acknowledges

⁵ Id. at 33532.

⁶ Id. at 33660-61.

⁷ Id.

that the data are not “nationally representative,”⁸ and MedPAC’s staff have acknowledged that this survey “was not designed to determine equipment use rates.”⁹ Moreover, the data were collected before the Deficit Reduction Act (DRA) caps on imaging payment became effective. The second survey collected data on CT equipment use in 2007, and based on this data, MedPAC incorrectly concludes that the average provider uses its CT scanner 50 hours per week. MedPAC used data on the number of hours that the CT scanner is available for use, rather than data on the time the machine actually is in use, and therefore overestimated the utilization rate for these machines. Neither survey included radiation therapy equipment, but because the equipment in the surveys cited by MedPAC is priced at over \$1 million, CMS proposes to increase the utilization rate on all equipment priced over \$1 million across the board.¹⁰

In fact, recent surveys show that providers’ utilization rates for CT, MRI, and radiation therapy equipment are close to 50 percent, far less than the 90 percent proposed by CMS. A recent data survey by the Radiology Business Management Association (RBMA) found utilization rates of 56 percent for urban providers and 48 percent for rural providers.¹¹ In addition, the American Society for Radiation Oncology (ASTRO) surveyed 103 free-standing radiation oncology centers located throughout the country to determine the utilization rates of six types of radiation therapy equipment. The survey found that five types of radiation therapy equipment were used less than 51 percent of the time, and the sixth type of equipment was used 63 percent of the time.¹² CMS should rely on these recent surveys, rather than MedPAC’s older and limited surveys, and make no change to the utilization rate for equipment priced over \$1 million.

ACCC urges CMS not to implement the proposed increase in the utilization rate. This change, on top of the changes to the PE RVUs caused by the PPIS data, would produce devastating cuts in reimbursement to cancer care providers. If these providers no longer are reimbursed appropriately for the care they provide, beneficiaries may have to seek care in other settings, potentially requiring them to travel long distances and disrupting their course of treatment. We particularly are concerned about access to care in rural communities. Although CMS concludes that this proposal would not create access problems in rural areas because beneficiaries could access CT and MRI services in hospitals,¹³ CMS does not consider the

⁸ MedPAC, Report to the Congress: Medicare Payment Policy, March 2009, at 108.

⁹ Transcript of MedPAC Meeting, Statement of Nancy Ray, April 19, 2006, at 237.

¹⁰ 74 Fed. Reg. at 33532.

¹¹ <http://rightscanrighttime.org/wp-content/uploads/2009/06/sfc-rbma-utilization-rate-excerpt.pdf>.

¹² DMRkynetec, Equipment Utilization Survey Prepared for ASTRO, August 2009, 5, available at <http://www.astro.org/MedicareCuts/documents/EURfinal.pdf>.

¹³ 74 Fed. Reg. at 33532.

hardship imposed on patients who must change providers, particularly for fatigued and immune-compromised cancer patients.

An ASTRO survey of its membership found that payment cuts of 20 to 30 percent could cause up to 39 percent of practices to close and up to 60 percent of practices to consolidate locations.¹⁴ These closures and consolidations would cause an estimated 43 percent of patients to have to drive more than 50 miles roundtrip for care.¹⁵ If CMS decides to implement this change, we strongly recommend that it phase in the new utilization rate while collecting additional information about its appropriateness. A phase-in also would allow physicians and providers to adjust to payment reductions and prevent disruptions in beneficiaries' care.

III. CMS should eliminate its proposal to replace consultation codes with other initial visit codes.

CMS proposes no longer to recognize the billing codes for consultation services and to assign the work RVUs that were allotted to these services to the work RVUs for new and established office visit services, initial hospital visits, and initial nursing facility visits.¹⁶ This proposed change would be implemented in a budget neutral manner, meaning it would not increase or decrease total PFS expenditures. CMS would make this change budget neutral for the work RVUs by increasing the work RVUs for new and established office visits by approximately six percent to reflect the elimination of the office consultation codes and the work RVUs for initial hospital and facility visits by approximately two percent to reflect the elimination of the facility consultation codes.

Physicians would bill an initial hospital care or initial nursing facility care code for their first visit during a patient's admission to the hospital or nursing facility in lieu of the consultation codes these physicians previously may have reported. Because of an existing Current Procedural Terminology (CPT) coding rule and current Medicare payment policy regarding the admitting physician, CMS would create a modifier to identify the admitting physician of record for hospital inpatient and nursing facility admissions. For operational purposes, this modifier would distinguish the admitting physician of record who oversees the patient's care from other physicians who may be furnishing specialty care. Subsequent care visits by all physicians and qualified non-physician practitioners (NPPs) would be reported as subsequent hospital care codes and subsequent nursing facility care codes.

¹⁴ ASTRO, Proposed 20 to 30 Percent Medicare Cuts in Radiation Oncology Would Devastate Cancer Care, <http://www.astro.org/MedicareCuts/documents/CMSfactsheetsGR.pdf>.

¹⁵ Id.

¹⁶ 74 Fed. Reg. at 33553.

CMS's rationale for the proposal includes the following points:

- There are unclear and ambiguous terms and instructions in the AMA CPT related to the definition of a consultation, transfer of care, and documentation requirements.
- The payment for both inpatient consultation and office/outpatient consultation services is higher than for initial hospital care and new patient office/outpatient visits, but the associated physician work is clinically similar.¹⁷

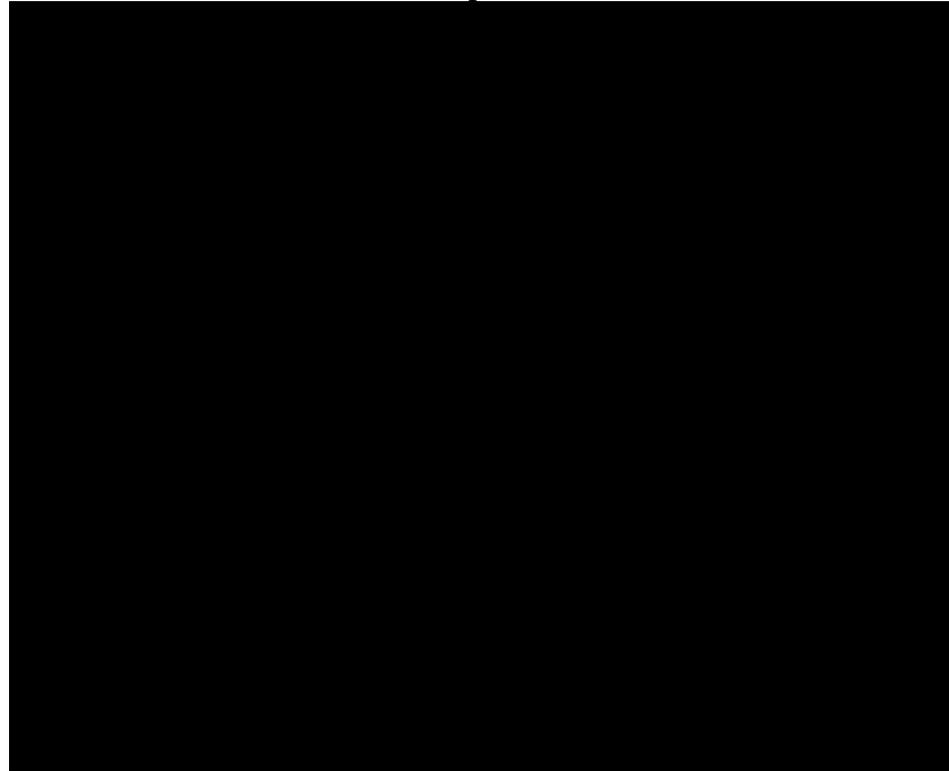
The impact of this proposal is a reduction in payment to those specialties that typically provide consultative services and an increase in payments to those specialties that provide primary care services. We recognize the importance of primary care and generally support the efforts of CMS and the Congress to assure adequate payment for the primary care specialties. However, we cannot support this proposal which we view as unjustified and contrary to the principles of Medicare's resource-based fee schedule.

First, it is our understanding that changes in CPT that would address CMS's concerns already have been approved and will be published in CPT 2010. Second, the Medicare statute requires the development of relative values for physicians' services with three components: work, practice expense and malpractice expense. The term "work component" is defined in the statute as the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service. The original Harvard RBRVS study clearly demonstrated that the work and time of consultations differs from the work and time of office and hospital visits, and those findings have been affirmed many times by CMS since the fee schedule was implemented in 1992, most recently with the completion of the third five-year review of work in 2007.

In order to maintain budget neutrality, CMS had to make assumptions as to how the consultation services likely were to be coded if they were eliminated. The financial impact of the CMS assumptions on specialists is clear when the 2009 payments for consultations are compared to the proposed 2010 payments for the codes that would be used in 2010 under the CMS assumptions. The CMS crosswalk of the office consultation codes is presented below to illustrate the impact. For each of the five office consultation codes, CMS assumes 50 percent would be reported using the corresponding level of new patient office visit code, and 50 percent would be reported using the corresponding level of established patient office visit code. The table below includes the 2009 work RVUs (RVW), typical times, and 2009 payments for the office consultation codes (99241-99245) and the 2009 RVW, typical

¹⁷ Id. at 33552-53.

times, and proposed 2010 (increased) payments for the new patient office visit codes (99201-99205) and established patient office visit codes (99211-99215).



Note that for every level of consultation code, payments will be decreased in 2010 relative to 2009, regardless of whether a new patient or established patient visit code is used. Thus, while the proposal may be “budget neutral” overall, it clearly is not budget neutral for physicians who provide consultations. Note also that the 2009 work RVUs and typical times of an office consultation code always exceed the 2009 work RVUs and typical times of the codes that CMS assumes would be used if the consultation codes were eliminated. It is clear that the work and time of office consultations and office visits are not “clinically similar” as CMS contends.

We also oppose this proposal because the elimination of the consultation codes will be confusing for physicians and be an administrative burden on physicians and CMS contractors. In addition, other payers will continue to recognize the consultation codes, further increasing the confusion and administrative burden on physicians and payers. We urge CMS to withdraw this proposal in the final rule.

IV. CMS should exercise caution as it evaluates potentially misvalued services and include representatives of providers and specialty societies in any “group of experts” it creates.

In the Proposed Rule, CMS describes various approaches to identify misvalued services under the PFS.¹⁸ One is to rely on the recommendations of the AMA’s Relative Value System Update Committee (RUC).¹⁹ ACCC believes it is appropriate for CMS to consider such recommendations. We continue to be concerned, however, with CMS’s recommendation that the RUC review the fastest growing procedures codes to identify potentially misvalued codes. ACCC believes that such an approach may target services based on growth and spending, not inappropriate use.

ACCC urges CMS to exercise care in evaluating the RVUs for services identified as potentially misvalued based on rapid growth when addressing the RUC’s recommendation in the CY 2010 PFS final rule with comment period. Many of the fastest growing codes represent newer, more innovative therapies in the field of oncology care, and increasing utilization rates may indicate improved quality of care. A reduction in reimbursement may lead to a decrease in patient access for these therapies. If CMS is concerned that a fast growing code potentially is misvalued, ACCC recommends that CMS work closely with specialty societies in determining the proper value of these procedures.

CMS is considering creating a group of experts separate from the RUC to help the agency improve the review of relative values.²⁰ We believe this group also should be used to examine utilization and access to care data between settings to determine whether reimbursement may be impeding beneficiary access to medically necessary items and services. If CMS does establish such a group, ACCC requests that CMS open the process to include representatives from organizations such as ACCC.

V. CMS should implement its PQRI proposals because they will lead to improved quality of care for patients with minimal administrative burdens on providers.

ACCC supported the creation of the Physician Quality Reporting Initiative (PQRI) by Congress in 2006. We believe that the implementation of pertinent quality reporting measures will lead to improved quality of care for patients. ACCC also supports the extension and expansion of the PQRI program for 2010.²¹ To

¹⁸ Id. at 33554-57.

¹⁹ Id.

²⁰ Id. at 33556-57.

²¹ Id. at 33559-89.

ensure that the program encourages quality improvement, we recommend that the agency use data from the previous PQRI reporting periods to determine if the current measures are appropriate and effective. We also recommend that CMS continually evaluate and revise the standards, if necessary, to ensure that they align with clinical practice and can be reported by physicians with minimal administrative burden.

ACCC supports the proposal to retire the following codes because they were too analytically challenging: Oncology: Medical and Radiation – Pain Intensity Quantified and Oncology: Medical and Radiation – Plan of Care for Pain.²² ACCC also supports the addition of a new quality measure for Cancer Stage Documented.²³

Furthermore, ACCC supports efforts by CMS to make the reporting process easier for providers, by, among other things, providing for electronic health record (EHR) reporting and implementing the group practice reporting option.²⁴ These changes should not only allow for more providers to participate in the program and thus earn bonus payments, but they also will provide CMS with better quality reporting, leading to better care for patients in the future. ACCC recommends that CMS continue to work with providers and specialty societies both to develop new quality measures and to ensure the best and most administratively simple reporting methods are being used.

VI. CMS should work with ACCC and other providers and specialty societies on the report due to Congress on May 1, 2010 on the transition to value-based purchasing.

CMS is required to develop a plan to transition to a value-based purchasing (VBP) program for Medicare payment for covered professional services made under, or based on, the PFS.²⁵ A report containing the plan, and any recommendations for legislation or administrative action that the Secretary determines are appropriate must be submitted to Congress by May 1, 2010.²⁶ ACCC is very interested in being a part of any discussions regarding a transition to a VBP program, and we believe that our input would be vital to the overall discussion. As we have seen from debates surrounding other changes to the PFS, as well as health care reform generally, the input of individual providers and specialties, including those based in community settings, meaningfully contributes to the development of new proposals.

²² Id. at 33574.

²³ Id. at 33581.

²⁴ Id. at 33561, 33569-71.

²⁵ Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. No. 110-275, § 131(d) (2008).

²⁶ Id.

ACCC appreciates CMS's efforts to solicit and respond to stakeholder input,²⁷ and ACCC looks forward to working with CMS in developing the VBP plan.

VII. CMS should implement the requirement that organizations designated to accredit suppliers furnishing the technical component (TC) of advanced diagnostic imaging services disclose plans for reducing the burden and cost of accreditation to small and rural suppliers.

Beginning January 1, 2012, Medicare payment only may be made for the TC of advanced diagnostic imaging services to a supplier who is accredited by an accreditation organization designated by the Secretary.²⁸ CMS proposes criteria for designating organizations to accredit suppliers furnishing the TC of advanced imaging services and sets forth the required procedures to ensure that the criteria used by an accreditation organization meet minimum standards for each imaging modality.²⁹

As CMS recognizes, accreditation can be especially burdensome for small and rural providers. ACCC therefore is pleased to support CMS's proposal to require accreditation organizations to disclose fees and any plans for reducing the burden and cost of accreditation to small and rural suppliers.³⁰ This proposal will protect patient safety while at the same time preserving patient access by ensuring that small and rural suppliers will be able to afford to become accredited. ACCC therefore encourages CMS to finalize its proposal.

VIII. CMS should establish a threshold for reporting financial relationships of immediate family members of individuals responsible for developing recommendations for compendia and adopt a grandfathering provision that would allow beneficiaries who are being treated under off-label anti-cancer chemotherapeutic regimens to maintain coverage through the completion of their treatment protocols.

By statute, “[o]n and after January 1, 2010, no compendia may be included on the list of compendia [used to determine medically-accepted indications of drugs and biologicals used off-label in anticancer chemotherapeutic regimens] unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.”³¹ CMS proposes to implement this

²⁷ 74 Fed. Reg. at 33592-93.

²⁸ Social Security Act (SSA) § 1834(e).

²⁹ 74 Fed. Reg. at 33600-03.

³⁰ *Id.* at 33601.

³¹ SSA § 1861(t)(2)(B).

statutory requirement by amending the current definition of compendia in 42 C.F.R. § 414.930(a).³² CMS further proposes that a compendium could comply with the requirement to have a “publicly transparent process” by placing materials used to develop compendia recommendations and information regarding potential conflict of interests on its website.³³

ACCC supports CMS’s proposed implementation of the statutory requirement. The currently-approved compendia already have adopted and posted conflict of interest policies, so compliance should not be burdensome. ACCC agrees with CMS that in some cases it may be useful to include financial disclosures of immediate family members. We note, however, that this requirement imposes additional burdens and may become difficult to track. Therefore, ACCC recommends that CMS add a threshold for reporting financial relationships of immediate family members to minimize the burden. The threshold could be set initially at \$10,000.

Currently-recognized compendia that do not comply with the new requirements as of January 1, 2010 automatically will be removed from the list of recognized compendia.³⁴ The Proposed Rule does not provide for any contingency for patients being treated with an off-label anticancer chemotherapeutic regimen that has been determined to be medically-accepted by a currently-recognized compendium prior to January 1, 2010 in the event that the compendium fails to meet the new provisions and is removed from the list of recognized compendia as of January 1, 2010. Forcing a patient to discontinue a treatment protocol can have disastrous effects on the patient’s prognosis and well-being. ACCC therefore urges CMS to adopt a grandfathering provision that would allow patients that begin prior to December 31, 2009 an off-label anticancer chemotherapeutic regimen that has been deemed medically-accepted by a recognized compendia to continue to have the course of treatment covered even if the compendia is removed from the list of recognized compendia after that date for non-compliance with the new requirements.

IX. CMS should implement its CAP proposals and restore the full geographic scope of the program as soon as possible.

The proposed rule includes a number of CAP-related proposals including increasing the frequency of drug payment amount updates, making changes to the CAP drug list, allowing approved CAP vendors to use electronic transactions to furnish CAP drugs from vendor-owned stock located at the physician’s office, expanding the definition of physician to include nonphysician practitioners that are

³² 74 Fed. Reg. at 33621-23.

³³ Id.

³⁴ Id. at 33621.

able to legally prescribe medications, and easing the restriction on physicians transporting CAP drugs.³⁵ These proposals will make it easier for physicians and vendors to participate in the CAP program. ACCC long has supported efforts by CMS that allow physicians greater flexibility and make CAP a viable option for physicians. Therefore we support these proposals and encourage CMS to finalize them. With regard to the proposal to temporarily narrow the geographic area served by the CAP during the program's re-implementation,³⁶ ACCC encourages CMS to restore the full scope of the program as soon as possible so that the physicians in the effected states can resume participation.

X. CMS should implement its proposal to eliminate drugs from the SGR methodology and should continue to work with Congress to develop a permanent and stable update formula.

Under the existing formula for calculating the PFS updates, physicians have been threatened with severe payment reductions in each of the past several years. This is the case again this year, where physicians once again face a 21.5 percent decrease for CY 2010. In the Medicare Improvement and Patient Protection Act (MIPPA) of 2008, Congress prevented cuts and implemented a slight increase for 2009. Even if Congress acts again to freeze reimbursement, the unpredictable reimbursement environment that fails to keep pace with the costs of labor and supplies makes it difficult for physicians to plan for the future. ACCC is deeply concerned about this situation because unstable reimbursement may force physicians to reduce the number of Medicare beneficiaries they treat, delay investments in new technologies, or encourage patients to seek care in other settings.

CMS proposes to remove prescription drugs from the SGR methodology.³⁷ ACCC supports this proposal because it will reduce future negative updates to the SGR and bring increased stability to the system. The proposal also is consistent with the intended purpose of the SGR, which is to encourage physicians to regulate their collective behavior to avoid decreases in future updates. Because physicians do not have control over drug prices, there is no "collective behavior" to regulate and therefore no basis for keeping drugs in the SGR formula. ACCC encourages CMS to finalize this proposal.

As CMS notes, there is a recognized need to reform the existing physician payment formula. Removing drugs from the SGR is a good start. ACCC believes additional reforms should be implemented to make the system even more

³⁵ Id. at 33623-33.

³⁶ Id. at 33628.

³⁷ Id. at 33650-51.

appropriate and stable. ACCC encourages CMS to continue to work with Congress and other stakeholders to explore additional reforms that should be implemented.

XI. CMS should revise the DOS regulations to provide that the date of service for certain complex diagnostic laboratory tests is the *date of performance* rather than the *date of collection*.

Finally, we ask CMS to revise its regulations on the DOS for certain complex diagnostic laboratory tests. Under Medicare regulations, the date of service for laboratory tests is the date on which the specimen was collected (*e.g.*, when the biopsy was performed that harvested the tissue specimen), unless the test is performed on a specimen stored for at least 14 days following the date the patient was discharged from the hospital.³⁸ If a test is performed on a specimen obtained during a hospital procedure within 14 days of discharge, it is deemed to have been provided on the date the specimen was collected, *i.e.*, the date on which the patient was a hospital patient. As a result, under Medicare regulations, such a test is treated as if it was furnished by the hospital, even though the hospital may not have ordered, performed, or used the test.³⁹ These regulations create disincentives for hospitals to provide access to a narrow class of advanced diagnostics.

To protect access to these complex laboratory tests, ACCC asks CMS to revise the regulation at 42 C.F.R. § 414.510 to establish that the date of service for certain advanced diagnostics would be the *date of performance* rather than the *date of collection*. This revised treatment should apply only to advanced diagnostic tests that meet the following criteria:

- The test is an analysis of DNA, RNA, chromosomes, proteins, or metabolites that detects, identifies or quantitates genotypes, mutations, chromosomal changes, biochemical changes, cell response, protein expression, or gene expression or similar method, or is a cancer chemotherapy sensitivity assay or similar method, but not including methods principally consisting of routine chemistry or routine immunology;
- The specimen was collected while the patient was undergoing a hospital procedure;
- The test was performed after the period during which the individual was a patient of the hospital and the specimen was collected;
- The results of the test do not guide the treatment provided during the hospital stay or encounter when the specimen was collected;

³⁸ 42 C.F.R. § 414.510.

³⁹ 42 C.F.R. §§ 411.15(m) and 410.42.

- The test was reasonable and medically necessary for the treatment of an illness;
- The test is developed and performed by a laboratory that is independent of the hospital in which the specimen was collected; and
- The test is not furnished by the hospital where the specimen was collected to a patient of such hospital, directly or under an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients.

XII. Conclusion

ACCC appreciates the opportunity to offer these comments, and we look forward to continuing to work with CMS to address these vital issues. Please contact Matthew Farber 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 these very important matters.

Respectfully submitted,



Luana R. Lamkin, RN, MPH
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Association of Community Cancer Centers