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August 24, 2010

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

Re: CMS-1503-P (Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011)

Dear Administrator Berwick:

On behalf of the Association of Community Cancer Centers (ACCC), we appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding payment policies under the Medicare physician fee schedule (PFS), published in the Federal Register on July 13, 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.

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 remains concerned over the proposed cut to the conversion factor due to the Sustainable Growth Rate (SGR) formula. We are aware that Congress has yet to pass a permanent fix to the formula; however, we encourage CMS to continue to work with Congress to develop a stable update formula for the future to ensure that physicians are adequately reimbursed for the quality cancer care that they deliver to their patients.

¹ 75 Fed. Reg. 40040 (July 13, 2010).

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

- Implement the proposed rebasing and revision of the Medicare Economic Index (MEI);
- Halt the cuts to chemotherapy administration;
- Continue to only apply the increase in the assumed utilization rate to certain diagnostic equipment priced at more than \$1 million;
- Exercise caution as it evaluates potentially misvalued services and include representatives of providers and specialty societies in conducting this review;
- Not expand the Multiple Procedure Payment Reduction (MPPR) policy any more than is required by the Patient Protection and Affordable Care Act (ACA);
- Not implement its proposal to use the General Services Administration (GSA) medical supply schedule to update price inputs for high cost supplies;
- Implement the proposal to waive beneficiary cost-sharing for certain preventive services;
- Implement the Physician Quality Reporting Initiative (PQRI) changes enacted in ACA because they will lead to increased participation in the program and improved quality of care for patients with minimal administrative burdens on providers;
- Continue to allow providers to bill for overfill and not include overfill in the calculation of average sales price (ASP)-based payment limits;
- Implement reimbursement for patient education about cancer therapy by physicians and nurses; and
- Work with ACCC and other providers and specialty societies on the creation of the Center for Medicare and Medicaid Innovation (CMI) and its goal of transitioning to value-based purchasing.

We discuss these recommendations in depth below.

I. CMS should implement the proposed rebasing and revision of the MEI.

In the Proposed Rule, CMS proposes to rebase and revise the MEI, the input price index used in determining annual updates to the physician fee schedule and in creating relative value units (RVUs). The MEI reflects the weighted-average annual price change for the inputs needed to provide physicians' services. The MEI was last rebased in 2003, at which time CMS updated the cost structure of the index from 1996 data to 2000 data. The Proposed Rule would rebase the MEI to reflect appropriate physicians' expenses in 2006, the most recent year for which data are available.²

ACCC believes that CMS should use the most recent data available to determine practice expense costs and other related cost factors. We understand that updating the MEI on a yearly basis would be very difficult, and therefore support updating the formula periodically with the most current information available, such as this proposed update to the 2006 data. Having up-to-

² Id. at 40088.

date information on practice expenses, physician salaries, costs of equipment, and other inputs is vitally important to establishing appropriate payment for physicians, particularly for specialists such as oncologists. Oncologists are often at the forefront of new technological advances, and it is important that Medicare reimbursement reflect the costs associated with new treatments and technologies.

ACCC also agrees with the CMS proposal to remove all costs related to drug³ expenses from the MEI since drugs are not paid under the PFS and they not are included in the definition of "physicians' services" for purposes of the SGR.⁴ This change will result in reimbursement rates that more accurately reflect costs associated with physicians' services.

ACCC supports the proposal to convene a technical advisory panel later in the year to "review all aspects of the MEI, including the inputs, input weights, price-measurement proxies, and productivity adjustment."⁵ ACCC recommends that CMS reach out to specialty societies to ensure that the review is accurate and complete. CMS should update the MEI as proposed, however, and not wait until the technical advisory panel is convened first.

Finally, ACCC supports CMS's proposal to increase the practice expense RVUs by an adjustment factor of 1.168 and the malpractice RVUs by an adjustment factor of 1.413 to ensure that the estimate of aggregate payments for practice expense and malpractice costs are in proportion to the weights for those categories in the rebased MEI.⁶

II. CMS should halt cuts to chemotherapy administration.

CMS proposes to continue to phase-in revised practice expense RVUs calculated using the Physician Practice Expense Information Survey (PPIS), supplemented with additional data for oncology drug administration services.⁷ Although CMS proposes to increase the RVUs for chemotherapy drug administration services in 2011 relative to 2010, the fully-implemented RVUs for most chemotherapy administration services would be lower in 2013 than they were in 2010. These reductions, combined with likely cuts or no increase in the conversion factor, will mean that physicians will be paid less for chemotherapy administration 2013 than they were in 2010. Our members are deeply concerned that if these cuts to Medicare payments are implemented as proposed, they will have to shift more patients to hospitals and likely will have to reduce staff. Even if Congress acts to reverse the conversion factor reduction, the decreases in payment rates could 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 the result may be reduced patient access to oncology services. In addition, many members are concerned that private payers will implement similar reductions as most base their reimbursement on the Medicare PFS RVUs.

³ We refer to drugs, biologicals, and radiopharmaceuticals collectively as "drugs" throughout our comments.

⁴ Id. at 40088.

⁵ Id. at 40095.

⁶ Id.

⁷ Id. at 40048.

ACCC urges CMS to halt these proposed reductions and provide stable, adequate reimbursement for cancer care.

III. Continue to only apply the increase in the assumed utilization rate to certain diagnostic equipment priced at more than \$1 million.

Section 1848(b)(4)(C) of the ACA requires the use of a 75 percent utilization rate for expensive diagnostic imaging equipment in the methodology for establishing PE RVUs for procedures that use such equipment. CMS proposes to apply this provision to the same equipment and codes for which CMS began a transition to a 90 percent utilization rate in 2010 and to apply the provision to 24 additional Current Procedural Terminology (CPT) codes that use similar CT or MRI equipment priced at more than \$1 million.⁸ ACCC supports the proposed implementation of the ACA requirement, but we continue to believe that CMS should not revise the implementation rate assumption for other equipment.

IV. CMS should exercise caution as it evaluates potentially misvalued services and include representatives of providers and specialty societies in its review.

In the Proposed Rule, CMS describes its actions to review seven categories of potentially misvalued services under the PFS as directed by Social Security Act (SSA) section 1848(c)(2)(K)(ii), as added by section 3134 of the ACA.⁹ The seven categories of potentially misvalued codes are:

1. Codes and families of codes for which there has been the fastest growth.
2. Codes or families of codes that have experienced substantial changes in practice expenses.
3. Codes that are recently established for new technologies or services.
4. Multiple codes that are frequently billed in conjunction with furnishing a single service.
5. Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
6. Codes which have not been subject to review since the implementation of the RBRVS (the so-called 'Harvard-valued codes').
7. Other codes determined to be appropriate by the Secretary.¹⁰

ACCC urges CMS to exercise care in evaluating the RVUs for services identified as potentially misvalued based solely on rapid growth or new technologies. Many of the fastest growing codes represent newer, more innovative therapies in the field of oncology care, and increasing utilization may indicate improved quality of care. A reduction in reimbursement may lead to a decrease in patient access to these therapies. If CMS is concerned that a fast-growing code potentially is misvalued, ACCC recommends that the agency work closely with specialty societies in determining the proper value for these procedures.

⁸ Id. at 40054.

⁹ Id. at 40066.

¹⁰ Id.

V. CMS should not expand the MPPR policy any more than is required by the ACA.

As part of its review of “potentially misvalued codes,” CMS proposes to expand application of the MPPR policy to additional imaging services. Effective January 1, 2007, CMS adopted an MPPR of 25 percent for the technical component (TC) of certain diagnostic imaging procedures, applied to the second and subsequent services when more than one service is furnished using the same imaging modality on a contiguous body area in a single session. Effective July 1, 2010, section 3135 of ACA increased the imaging MPPR from 25 percent to 50 percent, further reducing the reimbursement rate for the lower-priced procedure when more than one imaging service is provided on contiguous body parts in a single session.

In the Proposed Rule, CMS proposes to extend the MPPR policy even further to multiple imaging services provided across modalities, to non-contiguous body parts, and to four additional CPT codes for CT services (75571, 75572, 75573, and 75574). CMS proposes to make this change under section 3134 of the ACA, which allows the Secretary to make adjustments to “potentially misvalued codes,” including “multiple codes that are frequently billed in conjunction with furnishing a single service.” This change, if implemented, would reduce payment for 20 percent more services than the current MPPR policy under the PFS.¹¹ When combined with other changes in the PE RVUs, this would result in a decrease in Medicare payments to hematologists/oncologists and radiation oncologists of 5 percent when the PE RVUs are fully phased-in in 2013.¹²

We believe the proposed expansion of the MPPR is not justified and could harm access to appropriate cancer care. Imaging services are an essential part of diagnosing and treating cancer. At times, patients may need to have scans with different modalities performed during the same visit to best assess the state of their cancer. Performing scans using different types of equipment requires additional practice expense resources, such as staff and technician time to set up each machine, position and re-position the patient, explain each procedure, and administer any necessary contrast agents. Because the second scan requires the use of additional resources, a 50 percent reduction in payment is not justified for scans of different modalities. Moreover, CMS itself notes, “[b]ecause of the different pieces of equipment used for CT/CTA, MRI/MRA, and ultrasound procedures, it would be highly unlikely that a single practitioner would furnish more than one imaging procedure involving 2 different modalities to one patient in a single session where the proposed MPPR policy would apply.”¹³ CMS should not use the authority to adjust payment for “codes that are frequently billed in conjunction with furnishing a single service” to expand the MPPR to services that CMS acknowledges rarely are billed together. ACCC urges CMS not to finalize this proposal.

In addition, CMS should not expand the MPPR to imaging services performed on non-contiguous body parts until it has conducted a careful analysis of the resources used in performing these scans and provides stakeholders the opportunity to comment on both that

¹¹ Id. at 40075.

¹² Id. at 40232.

¹³ Id. at 40074.

analysis and any proposed expansion of the MPPR. As with scans conducted on different machines, scans of non-contiguous body parts often require significant additional work to reconfigure the equipment and reposition the patient. CMS expects that there would be efficiencies in performing two scans of the same modality on non-contiguous body parts, but it does not present any data to support this expectation. We urge CMS not to change the payment for these scans without first conducting an analysis of the data and sharing that analysis with stakeholders, giving them an opportunity to comment.

VI. CMS should not implement its proposal to use the General Services Administration (GSA) medical supply schedule to update price inputs for high cost supplies.

CMS also proposes to address the issue of “potentially misvalued codes” by implementing a new process for updating the prices of “high-cost supplies” (supplies priced at \$150 or more) that are used as direct PE inputs for services paid under the PFS. Under the new process, which would begin as soon as CY 2013, CMS would update the prices of these supplies every two years based on “the publicly available price listed on the GSA medical supply schedule” or, if a supply price were not publicly available on the GSA medical supply schedule, CMS would “reduce the current price input for the supply by a percentage that would be based on the relationship between GSA prices at that time and the existing PE database prices for similar supplies (currently an average 23 percent reduction).”¹⁴ CMS believes that the GSA medical supply schedule is an appropriate source of information because it is “public and transparent and reflects the best government contract price for a product.”¹⁵

ACCC agrees that use of accurate price inputs is essential to setting appropriate payments under the PFS. We are opposed to this proposal, however, because use of the “best government contract price” will not reflect prices available to private sector physicians. The GSA medical supply schedule consists of significantly discounted prices that the federal government achieves through its enormous purchasing volume, contractual requirements to disclose price information, and ability to audit vendors to ensure that it receives the best prices available to any purchaser.¹⁶ These requirements allow the government to achieve significant discounts below “typical market prices.” The Department of Veterans Affairs, exercising its authority to procure medical supplies for the GSA, is able to wield immense bargaining power by “exercising its audit rights and access to contractor data to pursue best prices aggressively for medical supplies and services.”¹⁷ Physicians, on the other hand, do not have these advantages and usually purchase supplies at higher prices than are available to the GSA. CMS should use a data source that

¹⁴ Id. at 40082.

¹⁵ Id. at 40081.

¹⁶ See, e.g., VA Acquisition Regulation (VAAR) Subpart 842.1 – Contract Audit Services (providing for pre-award and post-award audits); VA Contract Clause AS13, Examination of Records by VA (Multiple Award Schedule) (Feb. 1998) (providing for pre-award audits for up to two years after contract award); see also FAR 52.212-5 (Apr. 2010) (providing for post-award audits for up to three years after payment); FAR 52.215-2 (Mar. 2009) (same).

¹⁷ U.S. Government Accountability Office, GAO-04-718, Contract Management: Further Efforts Needed to Sustain VA’s Progress in Purchasing Medical Products and Services (June 2004), <http://www.gao.gov/new.items/d04718.pdf>.

reflects prices available to the physicians who are paid under the PFS, not the GSA medical supply schedule prices that are available only to the federal government. ACCC urges CMS to continue to work with stakeholders to identify an appropriate source of pricing information for high-cost supplies and not implement the proposal to base these inputs on the GSA medical supply schedule.

VII. 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, including screening pap tests, screening pelvic examinations, screening mammography, colorectal cancer screening, and prostate cancer screening.¹⁸ 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 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.

VIII. CMS should implement the PQRI changes enacted in ACA because they will lead to increased participation in the program and 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 as required by ACA section 1848(m)(1)(B).¹⁹ We believe that extending the bonus-based model through 2014, along with other improvements to the reporting and record keeping requirements, will promote increased participation in the program.

ACCC specifically supports ACA sections 3002(e) and 3002(f)(2), which allow for timely feedback to providers and for an informal appeals process whereby eligible professionals (EPs) can seek a review of a determination that they did not successfully report data in order to qualify for the bonus payment.²⁰ One of the most common complaints about the PQRI program to date is that EPs would spend the resources to participate in the PQRI program, yet would

¹⁸ Id. at 40131-40135.

¹⁹ Id. at 40168.

²⁰ Id. at 40169.

receive neither bonus payments, nor feedback as to why they were not getting such payments. We believe that these changes will lead to increased participation in the program.

ACCC supports efforts by CMS to make the reporting process easier for providers, by, among other things, providing for electronic health record (EHR) reporting, registry-based reporting, and implementing the group practice reporting option.²¹ These changes should not only allow more providers to participate in the program and thus earn bonus payments, but should also 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.

IX. CMS should continue to allow providers to bill for overfill and should not include overfill in the calculation of ASP-based payment limits.

CMS proposes to update its regulations “to clearly state that Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label.”²² CMS also proposes to update its regulations “to clearly state that payment for amounts of free product, or product in excess of the amount reflected on the FDA-approved label, will not be made under Medicare.”²³ ACCC supports the proposed revision to the regulations regarding calculation of the ASP payment limits, but we oppose the proposed change to the regulations regarding payment for the use of overfill. CMS’s proposal is based on several misunderstandings about overfill and its role in providing drug therapies to Medicare beneficiaries in the most efficient manner. Should CMS nevertheless decide to finalize the major policy change it proposed, we urge the agency to ensure that the rule is applied and enforced prospectively only. In addition, if CMS concludes that overfill is free product, notwithstanding the explanation below demonstrating that it is not, we ask CMS to state affirmatively that any new policy restricting the billing for use of overfill apply only in the physician office setting. In hospitals or other provider settings, CMS never has said a drug must be a cost in order to be billed, and there is no basis for such a policy.

A. Physicians should be allowed to bill for use of overfill.

1. Overfill is part of the product purchased by the physician and is not free product.

In the Proposed Rule, CMS explains its understanding that “when a provider purchases a vial or container of product, the provider is purchasing an amount of drug defined by the product packaging or label,” and “any excess, free product (that is, overfill) is provided without charge to the provider.”²⁴ This is incorrect. When a physician purchases a vial or container of product, he or she purchases the entire vial or container of product, including the amount of drug on the

²¹ Id.

²² Id. at 40155.

²³ Id.

²⁴ Id.

label, the vial or syringe in which the drug is packaged, any diluent needed to reconstitute the product, and any intentional overfill included to ensure that the drug is prepared and administered properly. The overfill is included in the cost of the drug to the physician, just as the diluent or syringe is included in the cost. Intentional overfill does not represent free goods to the physician any more than does the diluent or the vial or syringe holding the drug. Any overfill included in the vial is a cost to the physician, and therefore if the physician is able to extract any of the overfill, it may be included in the physician's bill.

2. Use of overfill benefits Medicare and beneficiaries.

We recognize that, for some products and in some cases, it may be possible for a physician to extract more units per vial or container than CMS used to calculate the payment limit. When this happens, the physician is simply using in the most efficient manner the drug he or she purchased. This is consistent with CMS's policy, as stated in the Claims Processing Manual, of "encourag[ing] physicians, hospitals and other providers and suppliers to care for and administer to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner."²⁵ CMS recognizes that there are some circumstances in which physicians are not able to use the full quantity of drug in a single use vial, and in those cases, Medicare allows payment for the discarded drug.²⁶ On the other hand, if the physician is not able to use the full quantity of drug in the vial due to the physician's error, including spillage or the physician's inability to extract the full volume for administration, Medicare does not pay the physician for the vial's full volume. By not paying for lost volume due to the physician's error or inefficiency, Medicare appropriately provides an incentive for physicians to handle drugs carefully and use them in the most appropriate manner.

Consistent with its policy of encouraging efficient and clinically appropriate use of drugs, Medicare should allow payment for use of intentional overfill when the physician is able to extract it for use. Physicians are not always able to use the overfill in a vial due to variations in the amount of overfill included in the vial and the requirements for safe preparation of drugs, but when they can, the physician's efficiency benefits Medicare, the patient, and the physician. This can be seen if we look at the following example: a physician has five patients who each need an 85 mg dose of a drug that is packaged in a 100 mg single use vial with 10 mg overfill. There are several ways the physician could schedule the patients to receive the drug and appropriately bill Medicare. First, the physician could schedule each patient to receive the drug on separate days. In many cases, this might be necessary to accommodate the patients' clinical needs and schedules. The physician would bill Medicare for the 85 mg administered and would bill for the 15 mg discarded using the JW modifier, as described in the Claims Processing Manual. In this case, Medicare and the patient pay for 100 mg of drug. The physician would use five vials of drug and would bill Medicare for 500 mg of drug, including 75 mg of drug that was discarded.

Patient	Amount Administered	Amount Discarded	Amount Billed
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²⁵ Medicare Claims Processing Manual, ch. 17, § 40.

²⁶ Id.

A	85 mg (from vial 1)	15 mg	100 mg
B	85 mg (from vial 2)	15 mg	100 mg
C	85 mg (from vial 3)	15 mg	100 mg
D	85 mg (from vial 4)	15 mg	100 mg
E	85 mg (from vial 5)	15 mg	100 mg
Total amount billed			500 mg

This approach is permitted by Medicare and may be the only feasible way to schedule the patients to receive their drugs. It is not the most efficient approach, however, because it results in additional charges to both Medicare and the beneficiary, additional drug for the physician to purchase, and additional discarded drug that must be disposed of safely.

Second, if clinically appropriate for the patients, the physician could schedule all of the patients to receive the drug on the same day and use the remaining 15 mg in each vial for patients B, C, D, and E. In this example, the physician would need 5 vials of drug, but would bill Medicare for only 440 mg of drug. As in the first example, the physician would need to discard 75 mg of drug.

Patient	Amount Administered	Amount Discarded	Amount Billed
A	85 mg	0 mg	85 mg
B	85 mg (15 mg from vial 1 plus 70 mg from vial 2)	0 mg	85 mg
C	85 mg (30 mg from vial 2 plus 55 mg from vial 3)	0 mg	85 mg
D	85 mg (45 mg from vial 3 plus 40 mg from vial 4)	0 mg	85 mg
E	85 mg (60 mg from vial 4 plus 25 mg from vial 5)	75 mg	100 mg
Total amount billed			440 mg

Third, if the physician is able to schedule all five patients on the same day and the physician is able to recover 7 mg of the 10 mg overfill in the vial, the physician could treat the patients using only four vials of drug and would bill Medicare and the patients for only the 425 mg used and would not bill for any discarded drug. This approach reduces total costs to Medicare and the beneficiaries and results in no discarded drugs.

Patient	Amount Administered	Amount Discarded	Amount Billed
A	85 mg	0 mg	85 mg
B	85 mg (22 mg from vial 1 plus 63 mg from vial 2)	0 mg	85 mg
C	85 mg (41 mg from vial 2 plus 44 mg from vial 3)	0 mg	85 mg

D	85 mg (63 mg from vial 3 plus 22 mg from vial 4)	0 mg	85 mg
E	85 mg (85 mg from vial 4)	0 mg	85 mg
Total amount billed			425 mg

Physicians may not always be able to recover usable drug from the overfill and may not always be able to align patients treatment schedules to use drugs most efficiently, and for this reason, Medicare appropriately makes payment in the first and second scenarios. However, when overfill can be used, CMS should not discourage physicians from putting it to use because the overfill is included in the total cost of the drug to the physician.

3. Enforcement of CMS’s proposed policy would be unclear and extremely burdensome for CMS and physicians.

CMS proposes to “update” the regulations to “clearly state that payment for amounts of free product, or product in excess of the amount reflected on the FDA-approved label, will not be made under Medicare.”²⁷ Not only would this new policy discourage efficient use of drugs, it also would impose significant new burdens on CMS, its contractors, and physicians. To demonstrate that each drug administration used no more than the volume on the label for the vial, the physician would have to record exactly how many vials of the drug were purchased and used for each patient along with the labeled amount on each vial to prove that no overfill was used. CMS then would have to examine patients' records to verify that no overfill was used too. These additional requirements would not advance Medicare’s interest in providing efficient, appropriate care to beneficiaries; instead, they would make treatment less efficient and subject physicians to potential law enforcement actions. CMS policymaking should be driven by the goals of improving the quality of care for Medicare beneficiaries and encouraging providers to deliver efficient, appropriate care rather than those of law enforcement.

B. Overfill should not be included in the calculation of payment limits under SSA § 1847A.

CMS also proposes to update the regulations to state “that Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label.”²⁸ ACCC supports this proposal. When CMS calculates a payment amount per billing unit, as required by SSA section 1847A, it divides the total average cost of the vial or container by the number of billing units in the vial or container according to the FDA-approved label. This is the most simple and straightforward approach, particularly in light of variations in the amount of potentially useable overfill that could be found in each vial or container and variations in drug packaging. Indeed, the amount of overfill included in a vial or container of a drug may vary depending on the type of container (vial, syringe, or other container), the size of the container, and whether the product is packaged as single use or multiple use. The OIG reached a similar conclusion in its study of dialysis facilities’ acquisition cost for dialysis drugs, after the OIG

²⁷ 75 Fed. Reg. at 40155.

²⁸ Id.

noted that survey respondents indicated varying amounts of overfill for two drugs, ranging from 7 percent to 14 percent. The OIG decided to not include overfill in its acquisition cost calculations because “the amount of overfill varies, and because facilities may have different practices regarding the utilization of overfill.”²⁹ For the same reason, CMS should not include any intentional overfill in the volume used to calculate a drug’s ASP.

X. CMS should implement reimbursement for patient education about cancer therapy by physicians and nurses.

ACCC believes that CMS should establish reimbursement for the time physicians and nurses spend educating patients and their caregivers about the symptoms and side effects associated with cancer treatment, including surgery, chemotherapy, and radiation therapy. Patient education helps to optimize treatment outcomes, decreases adverse events, office visits, and hospitalizations, and substantially reduces costs in an already burdened health system.

Currently, there is no dedicated payment for a period of treatment education for people with cancer and their caregivers, prior to the onset of treatment. Medicare allows for only 48 minutes, amortized over an average of six cycles, of patient education during infused chemotherapy and also provides for some post procedure education for those receiving infused chemotherapy.³⁰ However, the time and payment allocated for this education does not cover the cost and is not sufficient to cover the requisite initial and ongoing teaching. In addition, payment is available for this kind of education during administration of infusion therapies but not surgery, radiation therapy, or oral chemotherapy.

By providing distinct reimbursement under the PFS for a one-hour cancer patient treatment education session delivered by a physician or a registered nurse under the supervision of a physician, CMS can help address this disparity in access to care and ensure that all patients, irrespective of treatment modality or treatment setting, have access to the information they need to minimize adverse events and maximize their quality of life and outcomes.³¹

XI. CMS should work with ACCC and other providers and specialty societies on the creation of the CMI and its goal of transitioning to value-based purchasing.

Finally, section 3021 of the ACA requires CMS to establish a CMI to study new payment and service delivery models. One topic CMS might consider studying is an alternative to the current “buy and bill” system for acquisition and reimbursement of drugs administered in physicians’ offices. ACCC and its member institutions would be happy to work with CMS and CMI staff as they work on such a study or any other alternative payment and service delivery models that involve cancer care. We believe that input from physicians and providers will be essential to developing and testing new payment models, and we encourage CMS to call on us

²⁹ OIG, Medicare Reimbursement for Existing End-Stage Renal Disease Drugs, May 2004, OEI-03-04-00120, at 16-17.

³⁰ Correspondence from the Oncology Nursing Society (ONS) to Amy Bassano, CMS, from May 27, 2010.

³¹ Id.

and other stakeholders for advice as it moves forward with creating the CMI and transitioning to value-based purchasing.

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,

A handwritten signature in black ink that reads "Al B. Benson III". The signature is written in a cursive style with a horizontal line through the "III".

Al B. Benson III, MD, FACP
President

Association of Community Cancer Centers (ACCC)