September 6, 2013

Marilyn Tavenner
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-1600-P (Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014)

Dear Administrator Tavenner:

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) for calendar year (CY), published in the Federal Register on July 19, 2013 (the "Proposed Rule").[1]

ACCC represents more than 18,000 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.

In our comments below, we recommend that CMS:

- Work with Congress to develop a long-term fix to the Sustainable Growth Rate (SGR) formula and avert a 24.4 percent reduction to the conversion factor in 2014;
- Work with ACCC to study the issue of payment for services rendered in off-campus hospital-based departments;
- Apply adjustments to the work relative value units (RVUs) instead of to the conversion factor to reflect changes in the Medicare Economic Index (MEI);

[1] 78 Fed. Reg. 43282 (July 19, 2013).

- Exercise caution when reviewing codes it identifies as potentially misvalued;
- Not implement the proposed cap on PFS non-facility payments using facility rates calculated under the Hospital Outpatient Prospective Payment System (OPPS) or Ambulatory Surgical Center (ASC) payment systems;
- Implement the proposal to create a new G-code for complex chronic care management services that meet certain standards;
- Work with the stakeholder community on the use of Current Procedural Terminology (CPT) codes for stereotactic radiosurgery (SRS);
- Implement the proposed requirement that "incident-to" services be provided in accordance with state laws;
- Implement the proposed changes to the Clinical Laboratory Fee Schedule (CLFS) and also develop standards for new tests under the CLFS;
- Implement the provisions related to the Physician Quality Reporting System (PQRS) measures and the new reporting option to use approved registries; and
- Collaborate with ACCC and other specialty societies on the implementation of the Value-Based Payment Modifier.

We discuss these recommendations in depth below.

I. CMS should continue to work with Congress to develop a long-term fix to the SGR formula.

Many cancer patients turn to physician offices to receive their treatment and related care, and it is vitally important that physicians are reimbursed appropriately for these services in order for patients to continue to have access to them. ACCC is concerned that, once again, the SGR formula will produce a drastic cut to the conversion factor if Congress does not act to prevent this reduction from taking effect. The proposed cut of 24.4 percent would decrease the conversion factor to $26.8199, after application of a budget neutrality adjustment, from the current rate of $34.0230.[2] Physicians have also had to absorb an additional cut of two percent due to the federally mandated sequestration.[3]

These reductions would cause significant access issues for cancer patients, as many providers no longer would be able to treat Medicare patients in their offices. In fact, many providers already are shifting more patients out of the physician office setting due to the sequester and years of virtually no update to the conversion factor. An additional SGR cut on top of these pressures on physician payments may cause even more patients to be affected.

Although Congress has enacted several short-term measures to prevent payment cuts, significant uncertainty remains about future payment rates. Without confidence that future reimbursement rates will be adequate, practices may not be able to plan for the future, make

[2] Id. at 43518.
[3] Budget Control Act of 2011, Pub. L. No. 112-25, 125 Stat. 240.

hiring decisions, and invest in new technology. We are encouraged that CMS has stated it will continue to work with Congress to permanently reform the SGR methodology,[4] and we are further encouraged that the House Energy and Commerce Committee recently approved a long term SGR fix.[5] As this bill works its way through the House and Senate, we encourage CMS to be supportive of these efforts and to continue to work with specialty societies in developing a system to replace the SGR.

II. CMS should work with ACCC to study the issue of payment to services rendered in off-campus hospital based departments.

In the Proposed Rule, CMS recognizes the issue that as a result of consolidation of practices and hospitals, many more claims are being submitted under the OPPS, as opposed to the PFS. This change results in higher total Medicare payments, due to differences in reimbursement levels between physicians' offices and hospital outpatient departments, and also higher patient financial responsibilities. CMS would like to know how best to capture the data from these off-campus hospital-based facilities to determine if the higher payments are justified.[6]

ACCC appreciates the opportunity to work with CMS on this issue, and we also commend CMS for reaching out to the community to determine the best method to collect data. ACCC encourages CMS to proceed carefully, however, to ensure that the data collection efforts do not create an extra administrative burden on these facilities and providers. If CMS were to require the reporting of a payment modifier for all services offered in an off-campus department, ACCC would ask that it be administratively simple to implement through electronic health records. We also ask that CMS limit the data collection requirements to physician offices that recently became provider-based. For example, CMS could limit the reporting to off-campus facilities that had been, until sometime in the past five years, a facility billing under the PFS.

III. CMS should apply adjustments to the work RVUs instead of to the conversion factor to reflect changes in the MEI.

For CY 2014, CMS proposes to adjust the RVUs for all services to reflect a proposed change in the composition of the MEI.[7] CMS does not fully explain the adjustments to the RVUs in the Proposed Rule, but it appears that the agency reduces the practice expense (PE) and malpractice RVUs to reflect the reduced proportion of the MEI attributable to costs other than physician compensation. Instead of increasing the work RVUs to match the physician compensation share of the MEI, CMS applies an adjustment to the conversion factor. As a result of these adjustments, the total RVUs for most services are proposed to be reduced and the PE RVUs would be cut by almost ten percent. These cuts have a particularly harsh impact on payment for drug administration services and radiation therapy because the PE RVUs are

[4] 78 Fed. Reg. at 43511.
[5] Medicare Patient Access and Quality Improvement Act of 2013, H.R. 2810, approved by the House Energy and Commerce Committee on July 31, 2013.
[6] 78 Fed. Reg. at 43301-02.
[7] Id. at 43514.

responsible for the largest share of payments for these services. CMS estimates that these changes will reduce Medicare payments to hematologists and oncologists by 1 percent, to radiation oncologists by 2 percent, and to radiation therapy centers by 5 percent.[8] If implemented, the effect of these cuts will be felt beyond Medicare because other payers use the PFS RVUs to establish payments, as well.

ACCC understands that CMS reduced the conversion factor instead of the work RVUs when it rebased the MEI in 2011 in order to ensure the stability of the RVUs.[9] In 2011, CMS increased the PE and malpractice RVUs, resulting in increases in the total RVUs for most services. For 2014, CMS would reduce the PE and malpractice RVUs, increase the conversion factor, and leave the work RVUs unchanged. Instead of ensuring stability, this approach creates instability in payment by reducing the total number of RVUs assigned to each service. ACCC recommends that CMS increase the work RVUs instead of the conversion factor. If CMS does not adjust the work RVUs, we ask the agency to phase-in these adjustments over at least 2 years.

IV. CMS should exercise caution when reviewing codes it identifies as potentially misvalued.

In the 2014 proposed rule, CMS solicited the input of Medicare Contractor Medical Directors (CMDs) to identify potentially misvalued codes.[10] The Proposed Rule identifies 14 potentially misvalued codes identified in consultation with CMDs.[11] The rule explains that these codes were identified by the CMDs for a variety of reasons, including that the CMDs were concerned about the current valuation of physician work, that a more extensive code has lower work RVUs than less extensive codes, or that the current valuation for a procedure is based on the procedure being furnished by a physician even though the procedure is typically furnished by support staff with supervision.[12] In addition, CMS proposes several ultrasound guidance codes as potentially misvalued based on CMD comments that one such code is routinely billed with another code and on a more fundamental concern about the current payment giving an improper incentive to furnish ultrasound guidance.[13] ACCC asks that CMS exercise caution when reviewing these codes to ensure that any revisions in payment rates reflect the full costs of providing these services in the physician office setting.

[8] Id. at 43513-14.
[9] 75 Fed. Reg. 73170, 73276 (Nov. 29, 2010).
[10] 78 Fed. Reg. at 43305-06.
[11] Id.
[12] Id.
[13] Id.

V. CMS should not implement the proposed cap on PFS non-facility payments using facility rates calculated under the hospital OPPS or ASC payment systems.

CMS proposes to limit payment for more than 200 codes in the non-facility setting under the PFS to the sum of the Medicare payment under the PFS in the facility setting and the payment to either a hospital outpatient department under the OPPS or to an ASC.[14] In the Proposed Rule, CMS compared payments using the 2014 PFS non-facility payments, calculated using the 2013 conversion factor, and 2013 OPPS and ASC rates. This proposal would produce substantial reductions in payment for the affected codes, including reductions of 20 to 38 percent for several radiation therapy services.

ACCC strongly opposes this misguided proposal. CMS incorrectly asserts that the costs of care generally should be higher in the hospital outpatient or ASC setting than in the physician office, and CMS believes that the OPPS and ASC payment rates may be more accurate than the PFS rates.[15] These conclusions ignore legitimate differences in physicians' and facilities' costs. For example, physicians often do not have access to the same discounts on drugs, equipment, and supplies as hospitals, and they do not have the option of spreading the cost of costly equipment across several departments of a hospital. CMS also disregards differences in its own payment systems that inhibit direct comparisons of payments across systems. The PFS establishes rates for individual services and can include services provided within a global period. The OPPS payment rates are based on mean costs for groups of services assigned to the same ambulatory payment classification (APC). These rates may be higher or lower than the cost of providing any particular service assigned to the APC. The OPPS rates can vary significantly from year to year depending on hospitals' cost reporting practices and changes in Medicare's packaging policies. The ASC rates are calculated as a percentage of the OPPS rates and do not directly reflect ASCs' costs of furnishing care.

CMS also proposes to apply the cap when as little as five percent of the total volume of services are furnished in the hospital outpatient setting.[16] Analysis of the proposed rates indicates that CMS often set the cap using the ASC rates, even though the volume of services in that setting was far below five percent. This extremely low threshold does not help to ensure that the capped rates accurately reflect typical costs for providing the service in either the physician or facility setting. When the Medicare Payment Advisory Commission (MedPAC) recommended that CMS cap certain hospital outpatient payments at the rates applicable in physician offices or ASCs, it recommended a threshold of 50 percent of claims in the setting used to establish the cap to ensure that payment rates are sufficient to protect access to care.[17]

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[14] Id. at 43296.
[15] Id.
[16] Id. at 43297.
[17] MedPAC, Report to the Congress: Medicare and the Health Deliver System, June 2013, at 37, available at: http://medpac.gov/documents/Jun13_EntireReport.pdf.

ACCC strongly opposes the proposed cuts in physicians' payment, but if CMS decides to implement a cap, we urge the agency to use only rates that reflect a substantial volume of claims. We also recommend that CMS compare physician and OPPS rates for the same year to capture the most recent cost data, and not to use the ASC rates at all because they are not based directly on providers' costs.

VI. CMS should implement the proposal to create a new G-code for complex chronic care management services that meet certain standards.

In the Proposed Rule, CMS proposes to establish separate payment under the PFS for certain complex chronic care management services.[18] To receive separate payment, these services must be furnished to patients with multiple complex chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. The services would be billable under two new alphanumeric G-codes: GXXX1, to cover services provided in the initial 90 days, and GXXX2, to cover services in the subsequent 90 days.[19] The scope of services would include provision of 24/7 access to care; systematic assessment of the patient's medical, functional, and psychosocial needs, including a plan of care; and management of care transitions. All of these services, as relevant to the patient, would need to be furnished to bill for either code.[20] Practices would need to provide at least 60 minutes of complex chronic care management services per 90 days to bill these codes.[21] CMS intends to propose RVUs for these services in future rulemaking.[22]

ACCC appreciates CMS' efforts to recognize these services with the creation of new G-codes. These services often are delivered by oncology providers without the proper recognition of the time and resources they take. These services will continue to increase with the advent of Accountable Care Organizations and Oncology Medical Homes, both of which are expanding through CMS and private payer initiatives. In order to meet the needs of patients in a medical home, practices are implementing many of the requirements to bill these codes, such as: certified electronic health records (EHR), employment of advanced practice nurses or physician assistants with job descriptions including provision of complex chronic care management services, and use of appropriate written protocols.

ACCC supports the creation of these codes and looks forward to working with CMS to establish appropriate reimbursement for them.

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[18] 78 Fed. Reg. at 43339.
[19] Id.
[20] Id. at 43338.
[21] Id. at 43340.
[22] Id.

VII. CMS should work with the stakeholder community on the use of CPT codes for SRS.

In the Proposed Rule, CMS explains that because it believes there is no longer a need to distinguish between robotic and non-robotic SRS services, the existing Healthcare Common Procedure Coding System (HCPCS) G-codes that currently are used to describe robotic versus non-robotic SRS no longer are necessary and that the CPT codes 77372 and 77373 can be used in the future to bill for these services. CMS does not propose to eliminate these G-codes for PFS payment in CY 2014.[23]

CMS is soliciting comments on whether the direct PE inputs used to develop PE RVUs for CPT codes 77372 and 77373 accurately reflect the typical resources used in furnishing the services that would be reported in the non-facility setting if the G-codes were phased out and there were no distinction in payment between robotic and non-robotic SRS.[24] ACCC urges CMS to work with stakeholders to ensure that the CPT codes accurately describe these services and that the payment rates for those codes fully reflect the costs of providing these important treatment options.

VIII. CMS should implement the proposed requirement that "incident-to" services be furnished in accordance with state laws.

The Proposed Rule would establish new requirements for services and supplies provided "incident to" a physician's professional services. CMS proposes to make it an explicit condition of payment for services and supplies furnished and billed as "incident to" services that the non-physician practitioners who provide such services do so in accordance with the requirements of the state in which the services are furnished.[25] The new requirement that "incident to" services be provided in accordance with applicable state law also would apply to Rural Health Clinics and Federally Qualified Health Centers.[26] ACCC supports this requirement.

IX. CMS should implement the proposed changes to the CLFS and also develop standards for new tests under the CLFS.

CMS proposes to implement a process to adjust payment amounts under the CLFS based on changes in technology, intended to address the significant technological advances in clinical laboratory testing since implementation of the CLFS, including point-of-care testing, brand new tests, and laboratory-developed tests.[27] Under this proposed process, CMS would review certain codes on the CLFS to determine whether payment for those codes should be adjusted due to

[23] Id. at 43296.
[24] Id.
[25] Id. at 43335-6.
[26] Id. at 43336.
[27] Id. at 43351.

technological changes, beginning with the CY 2015 PFS proposed rule. Such adjustments could be both upward (to reflect new high cost technologies) or downward (to reflect reduced costs through increased efficiency). CMS proposes to review all CLFS codes, beginning with those that have been on the CLFS the longest and proceeding forward, and then to review codes again every five years as time and resources allow.[28] ACCC supports this initiative.

In addition, ACCC believes that CMS should develop a new standard for inclusion of new tests onto the CLFS. Specifically, ACCC is concerned with the current gapfilling procedure, as we explained in the comments we submitted to CMS on July 5, 2013.[29] ACCC believes that the current process lacks transparency and that many of the reimbursement levels for specific tests are not adequate to cover the costs of performing them. These problems may inhibit access to appropriate tests and may stifle innovation, particularly in the field of molecular testing.

X. CMS should implement the provisions related to the Physician Quality Reporting System (PQRS) measures and the new reporting option to use approved registries.

ACCC supports many of CMS's proposals related to PQRS in the 2014 Proposed Rule. ACCC also supports the requirement that for CY 2014, in accordance with § 414.90(c)(3), eligible professionals who satisfactorily report data on PQRS quality measures will be eligible to receive an incentive equal to 0.5 percent of their total Medicare Part B allowed charges.[30]

In addition, ACCC supports CMS's proposed creation of new measure groups, including the radiation dose optimization measures group encompassing six quality measures. The included measures are: utilization of a standardized nomenclature for CT imaging; count of high dose radiation; reporting to a radiation dose index registry; availability of CT images for follow-up/comparison; search of CT images through a secure, authorized, media-free, shared archive; and CT follow-up for incidental pulmonary nodules.[31]

ACCC also supports the creation of general surgery measures group including procedures such as ventral hernia, appendectomy, cholecystectomy, mastectomy, lymphadenectomy, or lumpectomy/breast biopsy.[32]

Finally, ACCC supports the proposals related to a new PQRS reporting mechanism: the qualified clinical data registry reporting mechanism that would be available for use beginning in

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[28] Id.
[29] ACCC comments on 2013 Gapfill Payment Amounts for New Molecular Pathology CPT Codes, July 5, 2013, available at: http://www.accc-cancer.org/advocacy/pdf/2013-ACCC_Comments_mol-testing-gapfilling.pdf.
[30] 78 Fed. Reg. at 43358.
[31] Id. at 43448.
[32] Id.

CY 2014 for purposes of the CY 2014 PQRS incentive as well as the CY 2016 payment adjustment. The American Taxpayer Relief Act of 2012 provides that CMS shall treat eligible professionals as satisfactorily submitting data on quality measures if they satisfactorily participate in a qualified clinical data registry. Accordingly, CMS proposes that eligible professionals who satisfactorily participate in a qualified clinical data registry for the full calendar year 2014 will be treated as having satisfactorily reported data on quality measures for purposes of the PQRS incentive.[33] "Satisfactory participation" would be defined for the CY 2014 PQRS incentive and the CY 2016 PQRS payment adjustment as reporting at least nine measures available for reporting under the qualified clinical data registry, covering at least three of the National Quality Strategy domains, and report each measure for at least 50 percent of the eligible professional's applicable patients, including at least one outcome measure.[34]

ACCC requests that CMS make the process to nominate a qualified registry as simple as possible, and to have it clearly defined as early as possible, to encourage use of this new reporting mechanism.

XI. CMS should collaborate with ACCC and other specialty societies on the implementation of the Value-Based Payment Modifier.

In the Proposed Rule, CMS continues implementation and expansion of the value-based payment modifier with the goal, as required by the ACA, of applying the modifier to all physicians and groups of physicians starting in 2017.[35]

In CY 2014 (and thus for purposes of the CY 2016 value-based payment modifier), CMS proposes to expand the value-based payment modifier to groups of physicians with ten or more eligible professionals.[36] CMS estimates that this will mean almost 60 percent of physicians will be subject to the modifier.[37] In addition, CMS proposes to make the quality-tiering methodology mandatory beginning in CY 2014, except that groups of 10-99 eligible professionals (meaning those who had just become subject to the modifier) only would be subject to a neutral or upward adjustment. Groups of 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments.[38]

In addition, CMS proposes to refine the definition of the two categories used to determine how the value-based payment modifier applies. Under the Proposed Rule, Category 1 would include groups of physicians that meet the criteria for satisfactory reporting under the PQRS via

[33] Id. at 43477.
[34] Id. at 43365.
[35] Id. at 43485.
[36] Id. at 43588.
[37] Id.
[38] Id.

the GPRO reporting option, as well as groups that do not participate in the GPRO but at least 70 percent of whose physicians meet the PQRS reporting criteria as individuals.[39]

The Proposed Rule also would increase the amount of payment at risk due to the value-based payment modifier from one percent to two percent.[40] Thus, if a group falls into Category 2, it would be subject to an automatic two percent reduction. If a group falls into Category 1, the maximum downward adjustment would be two percent for groups with low quality and high cost, and one percent for groups with average quality and high cost or low quality and average cost. Likewise, the maximum upward adjustment would be two percent for groups with high quality and low cost, and one percent for groups with average quality and low cost or high quality and average cost. Upward adjustments would be subject to an adjustment factor based on the total number of downward adjustments that are applied.[41] Finally, CMS proposes to include the Medicare Spending Per Beneficiary measure (as slightly modified) as a sixth cost measure in the value-based payment modifier cost composite beginning with the calculation of the CY 2016 modifier.[42]

ACCC is concerned that providers may not be aware of the value based modifier, or be aware that they may not be required to report beginning in 2014. ACCC asks that more information be shared with providers through Medicare Administrative Contractors, Electronic Health Record companies, and other interested stakeholders to ensure compliance with the new requirement.

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,

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[39] Id. at 43489-90.
[40] Id. at 43588.
[41] Id. at 43490-91.
[42] Id. at 43495-96.