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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-1612-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015)

Dear Administrator Tavenner:

On behalf of the Iowa Oncology Oncology (IOS), 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]

IOS represents more than 60 practicing hematology and oncology professionals who provide care to thousands of patients battling cancer across Iowa. IOS works to ensure that cancer patients have appropriate access to a broad range of approved and medically-accepted anticancer regimens. IOS is a chapter member of the Association of Community Cancer Centers, an affiliate of the American Society of Clinical Oncology, and the largest organization in the state representing oncologists.

In our comments below, we recommend that CMS:

- Work with Congress to permanently reform the Sustainable Growth Rate (SGR) formula
- Work with IOS and other organizations on the implementation of the off-campus provider-based modifier;
- Revise the maintenance factor used in the calculation of equipment costs;
- Ensure that reimbursement remains adequate to protect access to mammography;
- Not implement the proposed elimination of codes related to prostate biopsy exams;

- Not implement the proposal to delete the radiation treatment vault as a direct practice expense (PE) input;
- Not implement the proposal to delete existing codes for stereotactic radiosurgery (SRS);
- Use caution in reviewing and making changes to codes on the "potentially misvalued codes" list;
- Not implement the proposal to eliminate the continuing medical education (CME) exemption from Sunshine reporting requirements;
- Expand payment for secondary interpretation of images;
- Implement the proposal to include anesthesia services in the definition of "colorectal cancer screening;"
- Not implement the proposal to change the process for creating local coverage determinations (LCDs) for clinical diagnostic laboratory tests;
- Collaborate with IOS and other specialty societies on the implementation of the Value-Based Payment Modifier (VBPM); and
- Work with the American Medical Association (AMA) and stakeholders to improve the transparency of the process for developing values for new, revised, and potentially misvalued codes.

We discuss these recommendations in depth below.

I. CMS should continue to work with Congress to permanently reform 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. The Protecting Access to Medicare Act of 2014 (PAMA) extended the current zero percent update through March 31, 2015, but CMS notes that the update for the rest of 2015 will be affected if Congress does not act to prevent another payment cut.[1] IOS is concerned that, once again, the SGR formula may produce a drastic cut to the conversion factor if Congress does not act to prevent this reduction from taking effect.

These reductions, if implemented, 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 patients out of the physician office setting due to the sequestration cuts to reimbursement 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

[1] Id. at 40522.

reimbursement rates will be adequate, practices may not be able to plan for the future, make hiring decisions, and invest in new technology. We are encouraged that CMS is "committed to working with the Congress to permanently reform the SGR methodology for Medicare PFS updates,"[2] and we are further encouraged that there was bi-cameral and bi-partisan support earlier this year for a long-term reform bill. We hope the bill still will be viable later this year.

II. CMS should work with IOS and other organizations on the implementation of the off-campus provider-based modifier.

IOS thanks CMS for considering the comments it received in 2013 regarding the best method for collecting information that would allow the agency to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments. Based on its review of these comments, CMS proposes to create a Healthcare Common Procedure Coding System (HCPCS) modifier to be "reported with every code for physician and hospital services furnished in an off-campus provider-based department of a hospital."[3] IOS believes this is a less administratively-burdensome method for capturing data from off-campus departments than other mechanisms CMS could use, but we have a number of concerns that we would like CMS to address in the final rule.

First, CMS's definition of "campus" is "the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office."[4] Given the variety of designs of hospital campuses, and the potential for case-by-case exceptions, physicians may not be certain if their office is on campus or off-campus. For example, it may not be clear whether the physicians' office building is "immediately adjacent" to a cluster of "main buildings." We urge CMS to provide clear guidance to help physicians identify whether their office is on-campus or off-campus.

Second, CMS says that it is seeking "a better understanding regarding the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments affects payments under PFS and beneficiary cost-sharing."[5] However, when a physician practice is acquired by a hospital, the provider number could change, making it difficult to track data for that practice before and after the acquisition. CMS should work with IOS and other organizations to develop a mechanism that will collect the data needed to help CMS understand how these transactions affect Medicare payments and beneficiary cost sharing.

III. CMS should revise the maintenance factor used in the calculation of equipment costs.

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[2] Id.
[3] Id. at 40334.
[4] 42 C.F.R. § 413.65(a)(2).
[5] 79 Fed. Reg. at 40333-40334.

The maintenance factor used to calculate the per-minute cost for equipment is currently defined as 0.05, or 5 percent of the equipment price, as finalized in the CY 1998 rulemaking. In the Proposed Rule, CMS notes that several stakeholders have suggested that the maintenance factor should be variable, and solicits comment on reliable data on maintenance costs that vary for particular equipment items.[6] We agree that maintenance costs can vary by type of equipment, and we urge CMS to work with providers to understand these costs and ensure that they are accurately factored into the rate-setting calculations.

IV. CMS should ensure that reimbursement remains adequate to protect access to mammography.

CMS proposes to delete the codes that were created in CY 2002 to allow providers to bill for mammography services provided using digital technology (G0202, screening mammography digital; G0204, diagnostic mammography digital; and G0206, diagnostic mammography digital), and identify all mammography services with the Current Procedural Terminology (CPT®)[7] codes that have traditionally been used to identify film mammography services (77055, mammogram one breast; 77056, mammogram both breasts; and 77057, mammogram screening).[8] CMS notes that the typical mammography service is now furnished using digital technology, making the separate G-codes for digital mammography unnecessary. As a result, CMS proposes to delete the G-codes beginning in CY 2015 and to pay for all mammography services using the CPT codes. For CY 2015, CMS proposes to value these codes using the same RVUs as the G-codes and proposes to submit the codes for review as potentially misvalued.[9] Mammography is critically important for the screening and treatment of breast cancer, and we urge CMS to ensure that the reimbursement rate for it remains adequate to protect access to care.

V. CMS should not implement the proposed elimination of codes related to prostate biopsy exams.

CMS currently uses four HCPCS codes to identify prostate biopsy services: G0416 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 10–20 specimens); G0417 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 21–40 specimens); G0418 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 41–60 specimens); and G0419 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; greater than 60 specimens). CMS proposes to eliminate G0417, G0418, and G0419 and to maintain G0416 but revise the descriptor to define the service regardless of the number of specimens.[10] CMS asserts that the current coding structure may be confusing, especially

[6] Id. at 40327.
[7] CPT copyright 2013 AMA. All rights reserved. CPT® is a registered trademark of the AMA.
[8] Id. at 40330.
[9] Id.
[10] Id. at 40340-40341.

because the number of specimens associated with prostate biopsies is relatively homogenous, and G0416 represents the overwhelming majority of all Medicare claims submitted for the four G-codes. CMS therefore concludes that the codes for higher number of specimens are not needed. CMS also proposes to identify G0416 as a potentially misvalued code for review.[11]

We disagree with this proposal. Although most procedures involve fewer than 20 specimens and can be identified with G0416, some patients require biopsies of more than 20 specimens. We recommend that CMS retain the current codes so that biopsy procedures that require more than 20 specimens can be reimbursed appropriately, in recognition of the increased resources needed to perform these services.

VI. CMS should not implement the proposal to delete the radiation treatment vault as a direct PE input.

Following its review of information about the direct PE input for the "radiation treatment vault" used in several radiation treatment procedures, CMS proposes to delete the vault as a direct PE input.[12] CMS explains that the direct PE input should be deleted because the agency believes the vault is not in itself medical equipment that must be accounted for as a direct PE input but rather a structural component of the building required to house the radiation treatment equipment, which is accounted for in the indirect PE methodology just like other building and infrastructure costs for other PFS services. The radiation treatment vault therefore would be removed as a direct input for the following HCPCS codes: 77373, 77402-77416, 77418.

IOS strongly disagrees with this proposal and urges CMS not to implement it. Not only is the policy flawed, but we are deeply concerned about the resulting decreases in reimbursement for many radiation oncology and radiology services that would result from the change. Contrary to CMS's assertions, radiation treatment vaults are not similar to other attributes of the building, such as the electrical and plumbing specifications. Unlike the building's electrical and plumbing components that can accommodate any equipment installed in the space, the radiation treatment vault is constructed to protect against the risk of radiation exposure from a specific and individual radiation therapy machine. Building leases typically require radiation therapy centers to remove the vault at the end of their lease so that the space can be used by other medical practices. The cost also can be readily distinguished from the cost of the building. The Internal Revenue Service considers the value to be a depreciable medical expense, similar to the radiation therapy equipment. IOS requests that CMS not implement this proposal and retain the vault as a direct PE input for these codes.

[11] Id. at 40341.
[12] Id. at 40330-04331.

VII. CMS should not implement the proposal to delete the HCPCS codes for SRS.

CMS proposes to delete two of the codes that have been used to bill for SRS services provided using robotic methods for many years, G0339 (Image-guided robotic linear accelerator based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment), and G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment).[13] Taking into account comments received in response to a request for comments in last year's rulemaking, CMS concludes that the CPT codes for SRS, 77372 (Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based) and 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions), accurately describe both robotic and non-robotic SRS services, and that the direct PE inputs included in the CPT codes accurately reflect the typical resource inputs in providing either type of SRS service. Thus, CMS proposes to recognize only the CPT codes for payment of SRS services and to delete the G-codes. The CPT codes have RVUs based on the recommendations of the AMA Relative Value Update Committee (RUC), and the G-codes currently are contractor priced.

IOS is greatly concerned about the significant reductions in reimbursement that would occur for services currently identified by G0339 and G0340 if these proposals are implemented. Physicians could experience cuts of up to 66 percent compared to the rates currently established by the Medicare Administrative Contractors (MACs). These drastic reductions cannot be absorbed by physicians and would threaten access to care. IOS urges CMS to review the resources associated with these procedures carefully and not implement the proposed changes in coding or reimbursement for CY 2015.

VIII. CMS should use caution in reviewing and making changes to codes on the "potentially misvalued" list.

In the Proposed Rule, CMS proposes to evaluate approximately 65 codes as potentially misvalued because they represent high expenditure services across specialties with Medicare allowed charges of $10 million or more, which CMS identifies as a prioritized subset of the new statutory category "codes that account for the majority of spending under the physician fee schedule."[14] CMS arrived at this list by identifying the top 20 codes for each specialty in terms of allowed charges, then removing any codes proposed as potentially misvalued since CY 2009 and any evaluation/management (E/M) codes. IOS is concerned because this list includes the codes for several drug administration services: 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular), 96375 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential

[13] Id. at 40332.
[14] Id. at 40337.

intravenous push of a new substance/drug (List separately in addition to code for primary procedure)), 96401 (Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic), and 96409 (Chemotherapy administration; intravenous, push technique, single or initial substance/drug).

These drug administration services are at the core of many cancer treatment regimens. Given the increasing incidence of cancer in the Medicare population, it is understandable that these codes have high utilization simply because there are more patients being treated for cancer. Physician's ability to treat patients depends on whether these codes are valued to reflect the true costs of care, including the costs of safely handling complex drugs and biologicals. We urge CMS to exercise caution in reviewing these codes and ensure that the payment rates continue to reflect the costs of providing these services.

IX. CMS should not implement the proposal to eliminate the CME exemption from Sunshine reporting requirements.

CMS proposes certain limited revisions to the regulations adopted to implement Section 6002 of the Patient Protection and Affordable Care Act (ACA), commonly known as the Sunshine Act, that requires manufacturers of covered drugs, devices, biologicals, and medical supplies to publicly report payments and other transfers of value that they make to physicians and teaching hospitals. Most notably, CMS proposes to delete the special rules for reporting of payments provided to CME program sponsors as compensation for physician speakers.[15] CMS explains that this proposal is intended to address its concern that the existing CME exemption could be read as a CMS endorsement of the specific CME providers named in the regulation. CMS also suggests that the explicit CME exemption is not necessary because when a manufacturer provides funding to a CME provider and does not select the speaker or provide a distinct, identifiable set of covered recipients to be considered as speakers, CMS will consider such a payment to be excluded from reporting under the separate exclusion for payments made indirectly through a third party where the manufacturer is unaware of the identity of the covered recipient. CMS also requests comment on two alternative proposals to modify the existing CME exemption, either by expanding the list of accredited organizations by name or by replacing the named list with a list of criteria that any organization must meet to be accredited for purposes of the exemption.

IOS requests that CMS maintain an explicit exemption for CME and modify the exemption as proposed by replacing the list of named organizations with a set of criteria that any CME provider could meet for purposes of fitting within the exemption. Although we appreciate CMS's statement that the indirect payment exclusion applies to manufacturer payments to CME sponsors where the manufacturer does not select or influence selection of the speaker, we believe that it is important for CMS to clearly delineate the scope of manufacturers' reporting obligations by including an exemption for CME in the text of the regulation itself. In addition, we believe that expanding the exemption to include any CME

[15] Id. at 40383.

provider that meets a standard set of criteria will address CMS's concern about not endorsing a particular organization while also eliminating a great deal of confusion and ensuring that physicians retain the ability to obtain CME credits broadly.

X. CMS should expand payment for secondary interpretation of images.

In the Proposed Rule, CMS describes the current conditions under which Medicare will pay for secondary interpretation of an EKG, X-ray, or other image, and raises several questions for comment about payment for secondary interpretation of images.[16] Currently, Medicare payment is available for a secondary interpretation, either as a separate payment using a modifier for unusual circumstances requiring a secondary interpretation or as part of another payment, such as payment for certain E/M services. CMS notes that technological advances have enabled greater sharing of existing images between providers and questions whether Medicare payment for secondary interpretation of images should be expanded. CMS poses several questions about whether and how Medicare should provide reimbursement for secondary interpretations in more routine circumstances.

IOS feels that, given the technological advances that have made sharing of images easier, it would be better and more efficient for the healthcare system and its patients for physicians to be reimbursed for the secondary interpretation of images. Imaging is critical to cancer care, and in many cases, multiple physicians are involved in the patient's care and need to review the patient's images. For example, a surgeon and a medical oncologist may treat the same patient and would need access to the same images to plan the patient's care and monitor the patient's progress. Providing payment for these interpretations will encourage greater collaboration among members of the patient's care team and help to discourage use of duplicative imaging services.

XI. CMS should implement the proposal to include anesthesia services in the definition of "colorectal cancer screening."

Under 42 C.F.R. § 410.37, Medicare covers colorectal cancer screening tests under certain conditions. CMS proposes to revise the definition of "colorectal cancer screening test" under that provision to include anesthesia that is separately furnished in conjunction with a screening colonoscopy.[17] CMS states that this revision will have the effect of extending the waiver of coinsurance and deductibles to anesthesia or sedation services furnished in conjunction with a screening colonoscopy, and thereby encouraging Medicare beneficiaries to seek these services. If it finalizes the proposal, CMS will create an appropriate modifier for use when billing under the relevant anesthesia codes in conjunction with screening colonoscopy.

IOS supports this proposal and believes it will create greater beneficiary access to this important, potentially life-saving screening tool for more patients. We ask CMS to implement it in the final rule.

[16] Id. at 40370.
[17] Id. at 40369.

XII. CMS should not implement the proposal to change the process for creating LCDs for clinical diagnostic laboratory tests.

In response to the requirement in PAMA for MACs to issue coverage policies for clinical diagnostic laboratory tests in accordance with the process for making an LCD, CMS reviewed this process and proposes changes to it to make the process "better fit the needs of this particular area of medicine."[18] Specifically, for draft LCDs on clinical diagnostic laboratory tests published on or after January 1, 2015, CMS proposes to shorten the public comment period from 45 days to 30 days, make Carrier Advisory Committee (CAC) meetings optional, remove the requirement for open stakeholder meetings, require publication of the final comment/response document and final LCD within 45 days of the end of the comment period, and make these final LCDs effective on the date of publication, rather than 45 days later.[19]

IOS appreciates CMS's efforts to ensure that the process for developing LCDs for clinical diagnostic laboratory tests operates smoothly and with opportunity for comment. We urge CMS to retain the current 45-day comment period, CAC meetings, requirement for open stakeholder meetings, and 45-day notice period before an LCD takes effect, however. These elements of the process help to ensure that stakeholders are able to comment meaningfully on a proposed LCD, respond to comments from others, and prepare for implementation. CMS asserts that 30 days is a sufficient comment period based on the national coverage determination (NCD) process that allows only 30 days for comment.[20] We disagree and note several critical differences between the NCD process and the LCD process. First, the NCD process typically involves two 30-day comment periods, one on the tracking sheet and one on the proposed decision, allowing stakeholders additional time to learn about CMS's concerns about a service or technology and prepare comments. Even with this additional time, however, a 30 day comment period may not be enough time to gather all of the relevant data for CMS's decision. Second, a pending NCD also tends to be well-publicized by CMS and in the trade press, in contrast to announcements from the numerous MACs, which tend not to be distributed as broadly. A 45-day comment period that allows more time for stakeholders to become aware of the proposed decision and respond to it is more suitable for the LCD process.

We also disagree that new communication technologies obviate the need for open public meetings. Instead of holding public meetings to discuss the evidence and respond to questions, CMS states that MACs can address questions or follow-up information from a specific comment through conference calls or email.[21] These communication methods may be more efficient, but they deny stakeholders the opportunity to be aware of and respond to comments from others during the process. CMS also believes that the required summary of comments received and responses to comments provides adequate explanation of the

[18] Id. at 40378.
[19] Id. at 40380.
[20] Id. at 40378.
[21] Id.

evidence considered and the reasons for the MAC's final decision.[22] Unfortunately, some of the MACs' summaries are too brief and lack sufficient detail to provide any clarity about the reasons for the decision. We strongly recommend that CMS retain these opportunities for meaningful dialogue between stakeholders and the MACs.

We also recommend that CMS continue to require a 45-day notice period before the final LCD takes effect so that physicians and providers can learn about the final decision and prepare for implementation.

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

In the Proposed Rule, CMS continues implementation and expansion of the VBPM with the goal, as required by the ACA, of applying the modifier to all physicians and groups of physicians starting in 2017.[23] The 2015 modifier (based on 2013 Physician Quality Reporting System (PQRS) reporting) will be applied only to groups of physicians with 100 or more eligible professionals. CMS will apply the modifier depending on whether the group falls into Category 1 or Category 2. Category 1 is composed of groups that have self-nominated for the PQRS GPRO and have reported at least one measure or have elected the PQRS administrative claims option for CY 2013. These groups will have two options: (1) accept a zero percent modifier for 2015 PFS payments; or (2) if the group satisfactorily reported for the PQRS incentive or chose the administrative claim reporting mechanism for CY 2013, follow a quality-tiering approach under which the group's 2015 PFS payments will increase for high quality and low cost performance or decrease for low quality and high cost performance, with a maximum reduction of 1 percent. If the group does not fall into Category 1, then it falls into Category 2 and will receive a -1 percent modifier for 2015 PFS payments.

The 2016 modifier (based on 2014 PQRS reporting) will be applied to groups of physicians with 10 or more eligible professionals. For the 2016 modifier, the quality-tiering methodology will be mandatory, but groups of 10-99 eligible professionals (meaning those who had just become subject to the modifier) will be subject only to a neutral or upward adjustment. Groups of 100 or more eligible professionals will be subject to upward, neutral, or downward adjustments. In addition, Category 1 was revised for the 2016 modifier to include groups of physicians that meet the criteria for satisfactory reporting under the PQRS via the GPRO reporting option, as well as groups that do not participate in the GPRO but at least 50 percent of whose physicians meet the PQRS reporting criteria as individuals. The amount of payment at risk from the 2016 modifier increased from 1 percent to 2 percent.

IOS is concerned that providers still may not be aware of the VBPM, and when it will apply to their payments. IOS asks that more information be shared with providers through MACs, electronic health record companies, and other interested stakeholders to ensure

[22] Id. at 40379.
[23] Id. at 40492.

compliance with the new requirement.

XIV. CMS should work with the AMA and stakeholders to refine its proposals to improve the transparency of the process for valuing new, revised, and potentially misvalued codes.

Finally, in the Proposed Rule, CMS discusses a proposal to refine the process for setting payment rates for revised and misvalued codes.[24] CMS responds to comments and concerns raised by stakeholders about its current practice of implementing values for new, revised, and potentially misvalued codes on an interim final basis. This process causes new and revised values to remain in place for at least one year, until CMS responds to comments on those interim final values in the final rule for a subsequent year. Stakeholders asked for the opportunity to receive notice of the new values and provide comment on them before they take effect.

CMS proposes a new process that would allow stakeholders to comment on values for new, revised, and potentially misvalued codes beginning with the 2016 rulemaking cycle. CMS would include the proposed values in the proposed rule if the agency receives them from the AMA by January 15 of that year. If CMS does not receive the recommended values from the AMA RUC by January 15, CMS would delay revaluing the code for at least one year. If CMS does not receive recommendations for codes that are revised or deleted through the annual CPT coding changes by January 15, CMS would create G-codes to describe the predecessor codes to the deleted or revised codes for use until the new or revised codes can be addressed in a proposed rule.

We support CMS's efforts to improve the transparency of this process and allow for consideration of stakeholder comments before implementing new or revised values. Because patient access to care depends on the appropriateness of Medicare's payment for physician's services, it is essential that these services be valued correctly. We are concerned; however, that CMS's January 15 deadline would allow recommendations from only one CPT meeting per year to be included in the proposed rule. We urge CMS to work with the AMA and other stakeholders to develop a timeframe for review that works well for all parties and permits the inclusion of the maximum number of new and revised values in the proposed rule for each year.

XV. Conclusion

IOS 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 IOS can be of further assistance. Thank you for your attention to these very important matters.

[24] 79 Fed. Reg. at 40359.

Sincerely,

Mark Hermann, MD
President