Texas Society of Clinical Oncology

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Marilyn Tavenner
Acting 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-1590-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2013)

Dear Administrator Tavenner:

On behalf of the Texas Society of Clinical Oncology (TxSCO), 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 30, 2012 (the "Proposed Rule").[1]

TxSCO represents more than 450 practicing hematology and oncology professionals who provide care to thousands of patients battling cancer across Texas. TxSCO works to ensure that cancer patients have appropriate access to a broad range of approved and medically-accepted anticancer regimens. TxSCO is the largest organization in the state representing oncologists.

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 27.4 percent reduction to the conversation factor in 2013;
- Exercise caution when making any changes to the relative value units (RVUs) for drug administration services;

[1] 77 Fed. Reg. 44722 (July 30, 2012).

  - Implement the proposal to create a new G-code to describe post-discharge transitional care management services performed by a community physician or qualified non-physician practitioner and

clearly specify that specialists, such as medical oncologists and hematologists, may bill the new code;

- Do not implement the proposed changes to the time inputs for Current Procedural Terminology (CPT)[2] codes 77418 and 77373;
- Do not implement the proposed change to the interest rate assumption;
- Work with the relevant specialty societies to review each of the new molecular pathology codes to determine whether each code should be reimbursed under the PFS or the Clinical Laboratory Fee Schedule (CLFS);
- Implement the provisions related to the Physician Quality Reporting System (PQRS) and the Electronic Prescribing (eRx) Incentive Program; and
- Collaborate with TxSCO 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. TxSCO 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 27.4 percent would lower the conversion factor to $24.7124 from the current rate of $34.0376.[3] Physicians also face an additional cut of two percent under sequestration.

These reductions would present significant access issues for cancer patients, as many providers would no longer be able to treat Medicare patients in their offices. Although Congress has acted several times in recent years to enact short-term measures to prevent payment cuts, there remains significant uncertainty about future payment rates. Without confidence that future 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 has stated it will continue to work with Congress to permanently reform the SGR methodology,[4] and we urge CMS 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.

[2] CPT is a trademark of the American Medical Association (AMA).
[3] 77 Fed. Reg. at 44727
[4] Id. at 45032.

II. CMS should exercise caution when making any changes to the RVUs for drug administration services.

As part of its review of "potentially misvalued" codes, in the final rule for CY 2012, CMS asked the American Medical Association's (AMA) Relative Value Update Committee (RUC) to review certain high PFS expenditure CPT codes, including several drug administration codes.[5] This review will look at whether the physician times, work RVUs, and direct practice expense (PE) inputs for these codes are appropriately valued. CMS plans to include any revised valuations in the CY 2013 final rule with comment period.[6]

TxSCO strongly recommends that CMS exercise caution when making any changes to the RVUs for these services. Drug administration services are essential to cancer care, and appropriate reimbursement, based on consideration of all of the work and supplies associated with these services, is essential to protecting beneficiaries' access to cancer treatments. Oncology drugs in particular often require additional time and resources to prepare and administer safely. In addition, as the number of drugs subject to Risk Evaluation and Mitigation Strategies (REMS) increases, so does the amount of time physicians must spend administering those drugs. Before administering a drug subject to a REMS, the physician may be required to review a medical guide with the patient, obtain special training, and enter the patient into a registry. The RUC's review and CMS's evaluation of the results must include these additional time and work requirements. TxSCO urges CMS to review carefully any proposed revaluation of the drug administration codes to ensure that the time and practice expense inputs accurately reflect the services required to provide anti-cancer therapies to beneficiaries.

III. CMS should implement the proposal to create a new G-code to describe post-discharge transitional care management services performed by a community physician or qualified non-physician practitioner and clearly specify that specialists, such as medical oncologists and hematologists, can bill the new code.

In the Proposed Rule, CMS explains that while it believes current hospital and nursing facility discharge management codes adequately capture care management activities involved in discharging a beneficiary from a hospital or skilled nursing facility, it does not believe that the current evaluation and management (E/M) office or other outpatient visit CPT codes appropriately describe comparable care management work for the beneficiary post-discharge. As a result, CMS proposes to create a new G-code for CY 2013 that specifically describes post-discharge transitional care management services, including all non-face-to-face services related to transitional care management furnished by a community physician or qualified non-physician practitioner within 30 calendar days following the date of discharge to community-based care from an inpatient acute care hospital, psychiatric hospital, long-term care hospital, skilled

[5] 76 Fed. Reg. 73026, 73066 (Nov. 28, 2011).
[6] Id. at 73065.

nursing facility, inpatient rehabilitation facility, hospital outpatient for observation services or partial hospitalization services.[7]

TxSCO supports the creation of this new G-code, and we ask CMS to clarify that specialty physicians will be able to bill for the code. CMS anticipates that most community physicians will be primary care physicians,[8] and oncologists and hematologists are primary care physicians for cancer patients. In many cases, the patient's first stop after leaving a hospital will be the office of his or her medical oncologist or hematologist. Theses physicians and their staff provide extensive care management services to their patients, including coordinating care among the providers who treat and serve cancer patients, such as physical therapists, durable medical equipment suppliers, and radiation therapy centers, and help to connect the patient to other essential community resources, such as support groups and transportation services. Therefore, these and other specialists should be able to bill this new code to coordinate the patients' care. To ensure that this code helps to encourage better care management, CMS should provide clear instructions that oncologists, hematologists, and other specialists may use the new code.

IV. CMS should not implement the proposed changes to the time inputs for CPT codes 77418 and 77373.

CMS identifies CPT codes 77418 (Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session) (IMRT) 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) (SBRT) as two "potentially misvalued" codes due to possible overestimates of the procedure time in the direct practice expense (PE) inputs.[9] Although the direct PE inputs reflect procedure time of 60 minutes for IMRT and 90 minutes for SBRT, CMS found information disseminated to the public that indicates a procedure time of 10-30 minutes for IMRT and 60 minutes for SBRT. As a result, CMS proposes to reduce the procedure time assumption for IMRT to 30 minutes and for SBRT to 60 minutes and requests AMA RUC review and public comment on the proposal. As a result of this change, Medicare's payment for 77418 would decline by almost 40 percent, and payment for 77373 would decline by 28 percent. Total payments to radiation oncologists would be reduced by 7 percent, and payments to radiation therapy centers would decline by 8 percent.[10] When combined with other proposed changes to the PFS, payments to these providers would be reduced by 15 and 19 percent, respectively.[11]

[7] 77 Fed. Reg. at 44777.
[8] Id.
[9] Id. at 44742.
[10] Id. at 45036-37.
[11] Id.

TxSCO strongly disagrees with this proposal and asks CMS not to implement the change in payment rates and procedure times. Any changes in the time inputs should be based on validated data provided by a representative sample of physicians and providers. Our members report that the amount of time for each treatment can vary significantly from site to site depending on the equipment used and the cancers being treated. CMS must consider these variations, as well as the full array of other direct PE inputs involved in these treatments, before changing the time inputs. We ask that CMS not change the RVUs for CPT codes 77418 and 77373 for 2013 until the AMA and the RUC complete their review of all of the inputs associated with these codes. If CMS finds, after the RUC's review, that significant decreases in RVUs are justified, it should phase-in any such changes over several years to prevent disruptions in access to care. At a time of great uncertainty about future Medicare reimbursement rates, CMS should not implement drastic payment cuts for these services, particularly because they use significant capital equipment that may take years for physicians to repay.

Based on its concerns about the time inputs for CPT codes 77418 and 77373, CMS also proposes to request that the RUC re-review many other radiation therapy codes.[12] TxSCO urges CMS to exercise care in evaluating the RVUs for these services identified as potentially misvalued based solely on information not verified by the AMA or the RUC. Inappropriate reductions in reimbursement may lead to a decrease in patient access to these therapies. Reductions of the scale proposed for CPT codes 77418 and 77373 simply would be unsustainable for patients and providers.

V. CMS should not implement the proposed change to the interest rate assumption.

CMS factors in an assumed interest rate for capital equipment when calculating the practice expense costs used to establish RVUs. Currently, this interest rate is 11 percent. CMS proposes to use a "sliding scale" approach based on the current Small Business Administration (SBA) maximum interest rates for different categories of loan size (price of the equipment) and maturity (useful life of the equipment).[13] These rates range from 5.5 to 8 percent. CMS also proposes to update this assumption through annual PFS rulemaking to account for fluctuations in the prime rate or changes to the SBA's formula to determine maximum allowed interest rates.

TxSCO is concerned that these changes, along with other proposals affecting in radiation oncology, will lead to massive reimbursement reductions that likely will affect patient access to treatments. Radiation oncology and freestanding radiation facilities face reductions of 15 and 19 percent, respectively, due to the combined effects of this proposal, the proposed changes to IMRT and SBRT, the fourth year of the transition to use of the Physician Practice Information Survey data, and other proposals.[14] These reductions, along with the possibility of more

[12] Id. at 44743.
[13] Id. at 44731.
[14] Id. at 45036-37.

reductions due to the SGR update formula and sequestration, will be incredibly difficult for radiation oncologists to absorb. One TxSCO member reports that, "radiation therapy delivery services (in the more rural areas of the state) may be crippled by these proposed cutbacks."

Stable and predictable reimbursement rates are critical to allowing physicians to invest in providing innovative cancer therapies to their patients. The proposed changes in reimbursement will discourage physicians from making these services available. To protect continued access to care, TxSCO requests that CMS not implement the proposed changes to the interest rate assumption for 2013.

VI. CMS should work with the relevant specialty societies to review each of the new molecular pathology codes to determine the whether each code should be reimbursed under the PFS or the CLFS.

In the Proposed Rule, CMS responds to the creation of 101 new molecular pathology CPT codes for genetic testing and seeks comments on whether these codes should be assigned for payment under the CLFS or PFS.[15] TxSCO recognizes that each of these tests is unique, and each test should be evaluated individually to identify the fee schedule assignment that will result in appropriate payment. We recommend that CMS work with the relevant specialty societies to identify codes with a physician work component that should be reimbursed under the PFS. CMS also should recognize the important role that non-physician practitioners and scientists, such as Ph.D. geneticists, play in providing these services. The agency should take care to ensure that the payments under the PFS and CLFS appropriately recognize the costs of these professionals' services in order to protect beneficiaries' access to these molecular pathology tests.

We also understand that molecular pathology is a rapidly evolving field, and we expect that more new codes will be created in the coming years. We urge CMS to develop a predictable and transparent process for reviewing codes and assigning them to the appropriate fee schedule to enable timely access to these services.

VII. CMS should implement the provisions related to the PQRS and the eRx Incentive Program.

TxSCO supported the creation of the Physician Quality Reporting Initiative (PQRI) (now the PQRS) by Congress in 2006. We believe that the implementation of pertinent quality reporting measures can lead to improved quality of care for patients. TxSCO also supported the extension and expansion of the PQRS program as required by the ACA.[16] We believed that extending the bonus-based model through 2014, along with other improvements to the reporting and record keeping requirements, would promote increased participation in the program.

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[15] Id. at 44783.

[16] Patient Protection and Affordable Care Act (ACA) § 3002, Pub. L. No. 111-148 (2010).

TxSCO supports the proposed addition of an oncology measures group for 2013.[17] The group encompasses eight quality measures including hormonal therapy for estrogen receptor/progesterone receptor (ER/PR) positive breast cancer; chemotherapy for stage III colon cancer; influenza immunization; documentation of current medications in the medical record; quantification of pain intensity for cancer patients treated with chemotherapy or radiation therapy; plan of care for pain for cancer patients treated with chemotherapy or radiation therapy; documentation of cancer stage for breast, colon, and rectal cancer patients; and screening and cessation counseling for tobacco use.[18]

We recommend that CMS finalize these measures. We also recommend 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.

With regard to the eRx Incentive Program, the Proposed Rule would modify the electronic prescribing measure, in accordance with proposed modifications to the PQRS Group Practice Reporting Option (GPRO), to define a group practice as a practice comprising at least two eligible professionals.[19] CMS also proposes that groups of two to 24 eligible professionals would need to satisfy an additional criterion for the 2013 eRx incentive – reporting the electronic prescribing measure's numerator code during a denominator-eligible encounter for at least 225 times during the 2013 incentive reporting period – and an additional criterion for the 2014 payment adjustment – reporting the electronic prescribing measure's numerator code at least 225 times for the six-month 2014 payment adjustment reporting period.[20] We appreciate CMS's efforts to adjust the reporting requirements for small groups, and we ask CMS to implement these proposals for 2013.

CMS also proposes to revise the significant hardship exemption finalized in the CY 2012 final rule to add two additional significant hardship exemption categories for the 2013 and 2014 eRx payment adjustments: (1) eligible professionals or group practices who achieve meaningful use during certain eRx payment adjustment reporting periods; and (2) eligible professionals or group practices who demonstrate intent to participate in the Electronic Health Record (EHR) Incentive Program and adoption of Certified EHR Technology. TxSCO supports these proposals for 2013 and asks CMS to finalize them.

[17] 77 Fed. Reg. at 44964.
[18] Id. at 44976-77.
[19] Id. at 44806.
[20] Id. at 44984.

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

In the PFS rule for CY 2012, CMS began the process of implementing the Value-Based Payment Modifier required by section 3007 of the Patient Protection and Affordable Care Act (ACA). In the Proposed Rule, CMS continues its efforts to implement this modifier by making additional proposals to identify the eligible physicians, quality measures, and payment adjustments under the initial phase of the program. CMS proposes that the program will start on January 1, 2015 with groups of physicians with 25 or more eligible professionals.[21] Groups that met the proposed criteria for satisfactory reporting of data on PQRS quality measures for the 2013 and 2014 incentive or the proposed criteria for satisfactory reporting using the administrative claims-based reporting mechanism, applicable to the 2015 and 2016 PQRS payment adjustment, could choose to have their value-based payment modifier calculated based on a quality-tiering approach that could result in positive or negative payment adjustments.[22] Groups that have not met those reporting criteria would receive a negative 1.0 percent payment adjustment.[23]

CMS proposes to calculate a composite score for each group based on its performance on quality measures and measures of total per capita cost and per capita cost for beneficiaries with four specific chronic conditions (chronic obstructive pulmonary disease, heart failure, coronary artery disease, and diabetes).[24] CMS also proposes to include all measures in the PQRS GPRO web-interface, claims, registries, and EHR reporting mechanisms for 2013 and beyond.[25] This choice of measures would "align the value-based payment modifier with the PQRS and utilize Medicare claims data in order to reduce administrative burden on groups of physicians."[26]

TxSCO appreciates the careful and transparent approach that CMS is taking in implementing the Value-Based Payment Modifier. We encourage CMS to continue to seek stakeholder input on the program, including the quality measures and the cost calculations. The payment modifier will succeed at incentivizing quality care at lower cost only if relevant and up-to-date quality measures are used and the full costs and benefits of treatment options are considered in evaluating physicians' performance. Quality measures should recognize the constantly evolving nature of cancer treatment and protect against incentives to select care based on cost rather than clinical appropriateness. Cancer care often involves resource-intensive therapies, and value can be measured only by assessing costs over the full course of treatment.

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[21] Id. at 44995.
[22] Id. at 44996.
[23] Id.
[24] Id. at 45007.
[25] Id. at 44998.
[26] Id. at 44992.

CMS also must provide ample educational opportunities as it works toward the January 1, 2015 implementation date. Oncologists, hematologists, and radiation oncologists often practice in large groups and will have many questions about how a value-based payment modifier that is calculated based on treatment of non-oncology conditions will affect their reimbursement.

IX. Conclusion

TxSCO appreciates the opportunity to offer these comments, and we look forward to continuing to work with CMS to address these vital issues. Please contact Sydney Abbott at 301-984-9496, ext. 223 or sabbott@accc-cancer.org, if you have any questions or if TxSCO can be of further assistance. Thank you for your attention to these very important matters.

Respectfully submitted,

William Jordan, DO
President