August 30, 2013

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-1600-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule and Other Revisions to Part B for CY 2014

Dear Administrator Tavenner:

The American Association of Clinical Endocrinologists (AACE) represents over 6,000 endocrinologists in the United States and abroad. AACE is the largest association of clinical endocrinologists in the world. Most AACE members are Board-Certified in Endocrinology and Metabolism and concentrate their work on the treatment of patients with endocrine and metabolic disorders including diabetes, thyroid disorders, osteoporosis, growth hormone deficiency, cholesterol disorders, hypertension, and obesity. AACE members are committed to providing the highest quality of care to the patients they serve.

AACE appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule and revisions to Medicare Part B payment policies under the Medicare Physician Fee Schedule (MPFS) for Calendar Year 2014, published in the July 19, 2013 Federal Register.

Our comments pertain to the following issues:

1. Proposed Changes to Practice Expense Inputs for Ultrasound Guidance for Needle Placement (CPT code 76942)
   a) Identification of CPT code 76942 as misvalued
   b) Proposed reduction in clinical and procedure time and equipment inputs for CPT code 76942

2. Request for Comments on Practice Expense Inputs for CPT code 76942
   a) What should be included in the definition of an equipment “room”
   b) How much does the machine used for ultrasound guided biopsies in the physician’s office cost?

3. Limiting Payment for Certain Services for which the MPFS non-facility payment is higher than the total payment for the same service in the facility setting (outpatient department or ASC)

4. Complex Chronic Care Management Services

5. Revisions to the Physician Quality Reporting System

6. Value Based Payment Modifier
1. Proposed Changes to Practice Expense Inputs for Ultrasound Guidance for Needle Placement (CPT code 76942)

Thyroid cancer is the fastest growing cancer in American women. One out of every two women over the age of 50 has a thyroid nodule. With early diagnosis rendered by high resolution neck ultrasound and ultrasound-guided fine needle biopsy, most thyroid cancer patients have outstanding outcomes. However, with delayed diagnosis and suboptimal surgical care, thyroid cancer can be disfiguring or lethal.

Endocrinologists are the experts in examining the thyroid with their hands and with ultrasound technology to pinpoint exactly where thyroid and lymph node nodules are and whether they are likely to contain cancer. If a thyroid nodule is suspicious, the endocrinologist performs a biopsy under ultrasound guidance by inserting a tiny needle to capture thyroid cells. The specimen is then expelled on to a glass slide for staining and subsequent viewing under the microscope. Accurate ultrasound guidance is essential for the success of this very complex and delicate procedure. A biopsy episode typically requires 3-5 passes per nodule, and frequently there are two or three nodules present that may require biopsy. However, only a single charge of CPT code 76942 is allowed by Medicare for each ultrasound guided biopsy episode.

With the advent of routine high resolution ultrasound, matrix probe technology, color flow doppler and ultrasound-beam steering technology in the 21st century, ultrasound guidance of thyroid biopsy has been dramatically facilitated. This gold standard of care for guidance requires endocrinologists to continue to upgrade their ultrasound skills and equipment. AACE has promoted the development of advanced ultrasound skills in the field of endocrinology by certifying over 400 members in neck ultrasonography (ECNU certification) since 2009 and, in conjunction with the American Institute of Ultrasound Medicine (AIUM), many AACE members have certified their ultrasound laboratory facilities.

AACE believes that current reimbursement for CPT code 76942 accurately reflects the complexity of thyroid fine needle aspiration biopsy in the 21st century. Patients having this procedure are typically scheduled at 60 minute intervals, rendering the procedure room and ultrasound equipment unavailable for any other patient service for the duration of that time. We agree that different ultrasound guidance applications require different codes based on complexity. However, the value of ultrasound-guided fine needle thyroid biopsy should not be reduced based on evaluation of other less complicated ultrasound guidance procedures for simpler, lower-risk tasks.

In this context, AACE views the fee schedule’s proposed rule that would reduce reimbursement for ultrasound guided thyroid needle biopsy by more than 50% as a threat to women’s health. We fear that an across the board Procrustean Bed approach to cutting the code’s reimbursement would incentivize a return to “blind” thyroid biopsy or encourage endocrinologists to use out-of-date ultrasound equipment which makes guidance less accurate and safe. The proposed reduction in reimbursement for CPT code 76942 in thyroidology is counter-intuitive to the promotion of safe thyroid nodule care, quality improvement and patient safety, and represents a pennywise and pound foolish policy that will undermine the Medicare program. As the Medicare population grows with the aging of the baby boomers, the need for proper thyroid cancer diagnosis and treatment will only grow.

AACE urges CMS to withdraw the proposed changes to ultrasound guided needle placement (CPT code 76942) in the proposed rule until this code is surveyed later this year for submission to the RUC in April, 2014. We believe that the RUC deserves an opportunity to carefully review all implementations of the code. Specifically, the proposed removal of ultrasound guided fine needle aspiration of joints from the list of “biopsy” procedures performed under 76942 should make the upcoming survey much more representative of the correct and true use of the code. We discuss the specific proposed changes below.

a) Identification of CPT code 76942 as misvalued

Proposed Rule: CMS has included ultrasound guidance for needle placement (CPT code 76942) in a list of potentially misvalued codes because a contractor medical director identified a high frequency of co-billing with CPT code 20610 (major joint arthrocentesis). We would point out the fine needle aspiration of joint fluid under
US guidance (FNA) is completely different from fine needle aspiration biopsy of thyroid, breast or prostate (FNAB) and should never have been reimbursed under the same code in the first place.

A joint fine needle aspiration for fluid injection or retrieval, requiring a single pass, is not a high-risk procedure that requires sophisticated technology to perform. Bundling CPT code 20610 and CPT code 76942 is appropriate due to the lack of complexity and minimal time required for this fine needle aspiration procedure. We understand that a code change proposal has been submitted to the CPT Editorial Panel to bundle CPT codes 20610 and 76942. If approved, fine needle aspiration biopsy of breast, thyroid and prostate will then become the typical procedures for use with ultrasound guidance and the rationale stated above for reducing the value of CPT code 76942 will be moot. Preparations are already underway by AACE and other specialty societies that utilize CPT code 76942 to survey the code and provide data to the RUC in April, 2014. AACE urges CMS to delay any action on CPT code 76942 until the multi-specialty society survey is completed and data is reviewed by the RUC to determine any efficiencies and technology improvements that have developed since the code was last reviewed.

b) Proposed reduction in clinical and procedure time and equipment inputs for CPT code 76942

Proposed Rule: CMS proposes to reduce the clinical and procedure time for CPT code 76942 based on an analysis of the underlying procedures with which this code is used and to change the equipment input for CPT code 76942 from EL015 (general ultrasound room) to EQ250 (portable ultrasound machine).

We do not believe that changes in clinical and procedure time and equipment inputs for ultrasound guided thyroid needle biopsies should be made based on assessments of less complicated ultrasound guidance procedures. As we have noted, preparations are already underway by AACE and other specialty societies to survey CPT code 76942 and provide data to the RUC in April, 2014. New practice expense inputs bill be developed as part of the survey. AACE urges CMS to delay any action with respect to CPT code 76942 until the survey is completed and the data is reviewed by the RUC.

2. Request for Comments on Practice Expense Inputs for CPT code 76942

a) What should be included in the definition of an equipment “room”

CMS states in the proposed rule that, “Ordinarily under the PFS, direct PE input packages for “rooms” include only equipment items that are typically used in furnishing every service in that room”. This definition is not consistent with the precedent established by CMS in past rulemaking and AACE disagrees with this definition because not all of the equipment in the room will be used for every service in the room, but if it is used for a typical service furnished in that room it should remain. AACE supports the position of the RUC on this issue and urges CMS to adopt the following definition for an equipment room: “Equipment packages called rooms should include all items that are typically in the room and cannot be used for another patient, in order to furnish all typical services performed in that room.”

b) How much does the machine used for ultrasound guided biopsies in the physician’s office cost?

It is difficult to obtain paid invoices for equipment and supplies, especially for large equipment items like ultrasound systems that are bought very infrequently due to the large investment cost. However, AACE is concerned about the credibility of the information from published media reports cited in the proposed rule and the perception that the current machine costs are greatly over-valued. We question whether these published costs incorporate all the components of an ultrasound package, or if they include the cost of machine maintenance. In addition, new costs associated with transmission of ultrasound data and reports into EMR environments are substantial and must be included in the survey assessment. AACE will work through the RUC with the other specialties that utilize ultrasound biopsy guidance to provide equipment invoices to CMS as soon as possible.
3. Limiting Payment for Certain Services for which the MPFS non-facility payment is higher than the total payment for the same service in the facility setting (outpatient department or ASC)

**Proposed Rule:** CMS proposes to begin capping payments for services performed in the non-facility setting when those payments are greater than what is paid when the same service is performed either in the hospital outpatient or ambulatory surgical center facility setting.

CMS suggests that the cost data is more reliable in the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) compared to the cost data collected under the resource – based relative value scale (RBRVS) for the physician fee schedule. This suggestion and the proposed payment policy undermines the concept of the RBRVS and the significant time and resources spent by AACE and other medical specialties that provide expert analysis to recommend accurate resource data for each service reviewed by the RUC. As CMS knows, the two payment system methodologies are very different. The cost structure for a small non-facility office practice is very different from a hospital and outpatient clinic, with regard to scope of services and volume of services provided. It is reasonable to assume that hospitals could cover lower payments for many of the services on which the proposed cap will apply because they are such low volume. Hospital payment systems are designed to over pay some services and under pay others with the overall cost of services averaging out over time. CPT code 10021, fine needle aspiration without ultrasound guidance, is used for the diagnosis of thyroid cancer and other thyroid conditions. The payment for this procedure will be reduced by 14% in the physician office if this proposed payment policy is implemented. Physicians cannot offset losses of this magnitude from payments for other services based on actual costs that are provided under the physician fee schedule. AACE requests that CMS withdraw the proposal to cap non-facility payments at either the OPPS or ASC rate and instead allow the RUC to review these codes.

**CPT code 95250 (Continuous Glucose Monitoring) -** One of the 211 procedure codes listed in the proposed rule that would be subject to the payment cap is CPT code 95250, the technical component of Continuous Glucose Monitoring (CGM), which covers patient training, glucose sensor placement, monitor calibration, use of a transmitter, removal of sensor, and downloading of data. AACE believes CPT code 95250 meets the exemption criteria contained in the proposed rule and that this code is included in this list in error. According to an analysis of 2011 Medicare claims data, over ninety-nine percent (99%) of the time that these services are provided they are performed in the physician office. The proposed rule contains criteria that excludes any service from the proposed cap for which 5% or less of the total number of services furnished are in the OPPS setting relative to the total number of PFS/OPPS allowed services. We respectfully request that CMS publish the data that provides the basis for including CPT code 95250 in the list of 211 codes proposed to be subject to the cap and not decrease the payment until this is done. Also, frequently hospitals do not charge for all of the equipment components included in this code, such as the sensor, which makes their costs lower than actual.

4. Complex Chronic Care Management Services

**Proposed Rule:** CMS proposes to establish a separate payment beginning in 2015 for complex chronic care management services provided to patients with multiple complex chronic conditions.

Under the proposal, physicians could bill two new separately payable G codes for providing and coordinating care for complex chronic care conditions that are expected to last at least 12 months or until patient death and place the patient at significant risk of death, acute exacerbation/decompensation or functional decline. CMS proposes significant practice capability requirements to bill for these codes, e.g. communication access 24 hours per day, 7 days a week. CMS also require that beneficiaries consent to receive these services that would be provided in 90 day increments.

AACE supports CMS’ effort in recognizing non face-to-face evaluation and management services required for providing well-coordinated, high quality care to patients with multiple complex chronic conditions that are currently not reimbursed by Medicare. However, the proposed rule does not take into consideration the consultative work performed by endocrinologists for complex chronic endocrine diseases, such as uncontrolled diabetes. It would be very difficult for most endocrinologists to report these codes because it requires the endocrinologist to take on the total care of the patient. This is not a common scenario for endocrinologists who
typically render comprehensive care for single diseases or disease clusters, such as diabetes, hyperlipidemia and hypertension.

AACE recommends that CMS revise this proposal to create disease specific complex chronic care codes for each of the major chronic diseases, including diabetes. The capabilities and services necessary to bill these codes should address all of the requirements related to the patient care plan for the specific disease.

5. Revisions to the Physician Quality Reporting System

Proposed Rule: CMS proposes a number of changes to the Physician Quality Reporting system (PQRS) as viable options to satisfy reporting requirements to receive a 0.5% bonus payment in 2014 and to avoid the 2.0% PQRS penalty in 2016, which will be based on the 2014 performance year.

The most recent CMS Report on PQRS Reporting Experience, which is from 2011, suggests that of the 5,174 endocrinologists nationwide eligible to participate in PQRS, only 1,716 (33%) did so and 1,415 (82%) of those earned some level of bonus payment. We note that the minimum 2011 bonus payment reported for the specialty of endocrinology was $0.37, and the average bonus payment was $854.63. It appears from the report that endocrinology participation rates in PQRS align closely with physician participation rates in general, which in 2011 were 32% of eligible physicians nationwide.

Given the 2011 reporting experience for endocrinology we note that, 1) the majority of participants received a poor return on their investment for participation, and 2) there is likely to be a significant number of endocrinologists penalized in 2015 and 2016 for either unsuccessful or non-participation in PQRS.

Poor participation rates by endocrinologists largely reflect the view that PQRS is yet another well intentioned government program that does nothing to improve patient care while increasing physician pre-occupation with senseless point and click coding. While such reporting may provide new data to report, actual changes in care patterns are what our health system requires.

We also maintain that the PQRS measures do not provide an accurate and reliable method for evaluating the quality or value of the highly-skilled, labor intensive cognitive care provided by an endocrinologist acting as a consultant to treat patients with complex endocrine diseases and disorders. AACE favors indicators that are more process oriented and reflective of physician efforts rather than measures that depend mostly on patient adherence as the basis for a performance-based payment system that provides bonuses and penalties.

With respect to the changes proposed for PQRS in 2014, we believe the expanded reporting options via registries and efforts to align CMS reporting programs so physicians who do report will only do so once to satisfy PQRS and demonstrate electronic health records meaningful use will be helpful to some PQRS participants. However the proposal to increase the number of measures that must be reported from three to nine measures, while lowering the applicable patients a physician must report on from 80% to 50%, is unlikely to be an incentive for individual physicians to start reporting who currently do not do so.

AACE is concerned about the impact of the punitive PQRS program and its impact on practices and patient access to endocrinologists. There is a shortage of endocrinologists in this country to treat patients with diabetes and pre-diabetes, including the 27% of Medicare beneficiaries (about 10.9 million Americans) currently diagnosed with diabetes who account for 32% of Medicare spending. We believe that unfunded mandates and punitive reporting programs under the guise of value-based payment, such as the PQRS, will only exacerbate the current shortage of endocrinologists, restrict patient access to highly-specialized diabetes care and undermine the Medicare program. For these reasons, AACE urges CMS to postpone the 2014 penalty under PQRS until successful participation rates are achieved to prevent access issues and further disruptions in patient care.
6) Value-Based Payment Modifier

Proposed Rule: CMS is proposing to apply the value-based payment modifier to physicians who practice in groups of 10 or more beginning in 2016, based on their reported data on PQRS measures from 2014. Payments for affected physicians would be cut by 2% in 2016 unless they successfully participate in one of the PQRS group reporting options or unless 70% of the physicians and other eligible professionals in the group participated in PQRS as individuals. Group practices of 100 or more would be subject to both the PQRS penalty and a downward adjustment under the value-based payment modifier in 2016 if it is determined that they provide low-quality, high-cost care. All other physicians will be subject to the value-based payment modifier in 2017.

AACE continues to oppose the value-based payment modifier (VBPM) as a flawed concept for many of the same reasons that we oppose providing bonuses and penalties under the PQRS. While we applaud any evidence-based attempt to reward quality and the improvement of care in the Medicare system, there is simply no evidence that PQRS or the VBPM have accomplished or will accomplish those goals.

By applying the VBPM to physicians who practice in groups of 10 or more in 2016, CMS proposes to extend this arbitrary payment adjustment to an estimated 58% of physicians. We believe this is cause for significant concern based on the current data reflecting physician participation in PQRS, upon which the VBPM is based. We recognize the restraint CMS has shown by not proposing a downward payment adjustment in 2016 for group practices of less than 100 under the VBPM. The proposed rule instead would subject practices of this size to either an upward or neutral adjustment. We note that practices of 100 or more will be subjected to a downward adjustment if it is determined that they provide low-quality, high-cost care.

Like the PQRS, AACE believes a fully-implemented VBPM program will have harmful consequences for the endocrine practice and patient access to care. Because CMS is required by statute to implement the VBPM, AACE urges that you implement the VBPM on a voluntary basis, with an emphasis on large groups that are already successful PQRS program participants, until Congress repeals this ill-conceived initiative or a significant majority of physicians have become successful reporters under PQRS.

Once again, thank you for the opportunity to comment on the proposed rule for the 2014 Medicare Physician Fee Schedule. If you have any questions about the comments contained in this letter, please contact Sara Milo, Director of Legislation & Governmental Affairs at smilo@aace.com or 904-353-7878 ext. 148.

Sincerely,

Jeffrey I. Mechanick, MD, FACP, FACE, FACN, ECNU
President