September 4, 2012

Ms. Marilyn Tavenner  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1590-P  
P.O. Box 8013  
Baltimore, MD 21244-8013  

RE: CMS-1590-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face to Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013  

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. The majority of AACE members are certified in Endocrinology and Metabolism and concentrate 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 2013, published in the July 30, 2012 Federal Register.  

Our comments pertain to the following issues:  

1. Proposed Transitional Care Management Code  
2. Accreditation and Patient Attribution for Advanced Primary Care Practices  
3. Physician Quality Reporting System  
   a) General Comments  
   b) Proposed Osteoporosis Measure Group for 2014 and Beyond  
4. Value Based Payment Modifier  
5. Electronic Prescribing  
6. DXA Bone Density Scans  
7. Medicare Telehealth Services/Behavioral Therapy for Obesity  

1. Proposed Transitional Care Management Code  

Proposed Rule: CMS is proposing to create a new G-code to describe all non-face-to-face services related to the transitional care management furnished by the community physician or qualified non-physician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, long-term care hospital, skilled nursing facility, and inpatient rehabilitation facility.
AACE commends CMS for proposing the Hospital, SNF, or CMHC Post-Discharge Management G-code, GXXX1. AACE supports CMS’ effort in recognizing non face-to-face evaluation and management services provided by endocrinologists and other cognitive specialists that previously have not been reimbursed by Medicare. AACE acknowledges that this is new territory CMS is exploring and the new G code is the initial step in addressing reimbursement for non face-to-face evaluation and management services.

AACE also recognizes that that this code does not take into consideration the consultative work performed by endocrinologists and other cognitive specialists. It would be very difficult for most endocrinologists or other cognitive specialists to report this code because it requires the physician to take on the total care of the patient after they have been discharged from the facility. This is not a common scenario for cognitive specialists who typically render comprehensive care for single diseases or disease clusters like diabetes mellitus, hyperlipidemia and hypertension. This issue could be resolved if the code was disease-specific and the verbiage be revised to reflect a given disease state and more than one physician was allowed to bill it. Having said that, if there are endocrinologists that provide the full scope of services required under this new code, we urge CMS to consider them qualified to bill for these services.

AACE recommends that CMS revise their proposal, including the activities covered under the code, to create disease specific transitional care visit codes for each of the major chronic diseases, including diabetes. Within three (3) years, CMS should ask the Relative Value Update Committee (RUC) to re-evaluate these codes to determine if they have been billed appropriately and to assess the appropriate work relative value units per protocol. Prior to this review, AACE would urge CMS to revise their calculations regarding impact of these new codes on Medicare dollars being spent so as not to negatively impact the budget neutrality adjustment on the conversion factor.

2. Accreditation and Patient Attribution for Advanced Primary Care Practices

**Proposed Rule:** CMS is seeking public comment on the criteria and process that should be used to accredit advanced primary care practices under the Medicare program and how patients should be attributed to an advanced primary care practice.

**Accreditation**

An advanced primary care practice, or medical home, may be a viable practice model for an endocrinologist who serves as the primary care physician for diabetes patients or other patients that require close oversight and management of an endocrine-related condition. Often patients with uncontrolled diabetes see their endocrinologist many more times in any given year than they see a primary care physician. In these circumstances the endocrinologist serves as the medical home for a patient, developing a comprehensive plan of care and coordinating services with other health professionals for the patient’s treatment.

The rigorous standards, processes and costs involved for an endocrine practice to obtain accreditation from the national accreditation organizations listed in the proposed rule will make endocrine accreditation difficult and preclude most endocrinologists from obtaining advanced primary care practice status under Medicare (if these accrediting organizations are utilized by CMS). For example, National Commission for Quality Assurance (NCQA) standards require that 75% of the patients treated by a practice must receive the full spectrum of patient care from that practice in order for it to be recognized and accredited as a patient centered medical home. This threshold will be unachievable for most endocrinologists in solo or in a small endocrine group practice.

In recent years changes to Medicare payment policy have marginalized the role of the specialist in providing appropriate care to Medicare beneficiaries. Endocrinologists undergo extensive, specialized training in the
care and treatment of diabetes and other endocrine disorders during a two - three year endocrine fellowship following completion of an internal medicine residency program. Diabetes, for example, requires complicated, individualized treatment plans as well as comprehensive care coordination for associated risk factors. There are a multitude of treatment strategies for managing diabetes, and endocrinologists spend a significant amount of time determining what the best strategy is for each individual patient. The work of an endocrinologist to manage a patient’s diabetes is cognitive and extremely time and labor intensive.

Current Medicare policies also provide a disincentive for future medical residents to pursue fellowships and advanced study in endocrinology, a field that primarily provides patient evaluation and management services, as opposed to procedural-based services. Unless new delivery and payment models are structured to accommodate the unique characteristics of the endocrinologist’s practice, current physician shortages in endocrinology will be exacerbated and the healthcare workforce will become ever more ill-prepared to meet the nation’s medical needs, especially in the critical diabetes and obesity fields.

Endocrinologists who serve as the primary care physician for their patients will bill the same primary care cognitive codes for their work to evaluate the patient and develop a comprehensive, individualized treatment plan and coordinate the services required for that patient’s plan as any medical home physician would. Accordingly, we urge CMS to consider the unique characteristics of the endocrine practice when contemplating criteria for recognition and accreditation of advanced primary care practices. Adopting accreditation standards that are generalizable to endocrinologists providing comprehensive diabetes care would be extremely beneficial to patients and to the nation’s health care system.

Patient Attribution

We recommend that CMS decide the attribution of a patient to an advanced primary care practice by determining which practitioner delivers the majority of evaluation and management (E&M) services for that patient. This approach will allow all physicians, including endocrinologists, who are providing comprehensive care management to a patient to be recognized and appropriately compensated for their services.

3. Physician Quality Reporting System (PQRS)

Proposed Rule: CMS is proposing 264 individual measures and 26 measure groups for 2013 and 2014. CMS is also proposing to align reporting measures under the PQRS and Electronic Health Record incentive program, as well as aligning measures for reporting under the PQRS Group Practice Reporting Option (GPRO) web-interface with measures required under the Medicare Shared Savings Program. CMS is proposing to use participation in the PQRS by physician group practices of 25 or more in 2013 and 2014 in the implementation of the value-based modifier payment adjustment in 2015.

General Comments

According to CMS, the participation rate in the Physician Quality Reporting System (PQRS) program was only 26% of eligible professionals in 2010. The proposed rule seeks to implement several changes to the PQRS to increase participation to at least 50% of eligible professionals by 2015, the year the program starts initiating punitive payment adjustments for unsuccessful or non-reporting. If CMS reaches its target level of participation by 2015, that will still leave 50% of Medicare eligible professionals subject to a 1.5% payment reduction on all Medicare allowable Part B billed services. By 2015, if these same physicians are in group practices of 25 or more, they will suffer an additional 1% payment reduction due to the application of the value-based payment modifier.

Many physicians see PQRS as 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 give bureaucrats new data to massage, actual changes in care patterns are what our health
system requires. AACE believes that the current implementation of PQRS is largely wrong-headed, but if the system must be perpetuated, we offer the following suggestions.

First, we believe the proposed structure of the PQRS with different reporting criteria, depending on the physician group size and reporting method unnecessarily complicates the program and provides a strong disincentive for participation. If increased participation in PQRS is desired, we recommend that physicians should be able to report the required three quality measures that best align with the services they provide, regardless of reporting mechanism or size of the group practice to which they belong.

Second, we suggest that it makes no sense to apply payment adjustments to sub-specialty physicians for whom there are no relevant quality measures. AACE members whose practices are primarily or solely based on thyroid disease and related conditions are unable to successfully participate in PQRS due to a complete lack of thyroid quality measures. As a matter of fairness and in the interest of program integrity, AACE believes physicians who do not have relevant quality measures to report based on their sub-specialty should be exempt from payment adjustments from both PQRS and the value-based payment modifier until relevant quality measures are added to the program. If CMS is going to continue with the proposed implementation of this program, AACE urges a call for the submission and creation of new quality measures for 2014 and beyond. CMS should specifically solicit medical sub-specialty areas that have no relevant quality measures in the present system.

Sadly, the PQRS diabetes measures do not accurately assess the quality and value of diabetes care delivered by an endocrinologist. The measures contained in the proposed Diabetes Mellitus Measures Group for 2013 and beyond are not reflective of the highly-skilled, labor intensive cognitive care provided by an endocrinologist over a long period of time to treat patients with uncontrolled diabetes. To apply these measures to both the primary care family practitioner and the endocrinologist suggests that there is no difference in the intensity, skill and quality of care provided by either professional when treating a diabetes patient. Further, use of the current measures provides an incentive for primary care physicians to “cherry pick” diabetes patients who have well-controlled diabetes and to request endocrinologic care for difficult and complicated patients. We discuss below how the use of the current PQRS measures to evaluate quality and cost in applying the new value-based payment modifier unfairly disadvantages endocrinologists.

Proposed Osteoporosis Measure Group for 2014 and Beyond

With regard to other measures of endocrine interest, we question why many of the proposed osteoporosis measures are recommended for “patients 18 and older, with a diagnosis of osteoporosis, osteopenia or prior low impact fracture,” as well as for women over 64 and men over 69 years of age. Fractures due to osteoporosis most commonly occur in the Medicare age range. We are concerned that extending the proposed measures to include younger people with fractures will obscure their value, since most young patients who have fractures will not have osteoporosis. Specifically our fear is that extending the measures to include patients less than 50 will unwittingly encourage inappropriate diagnostic tests and therapy for osteoporosis in patients who do not have osteoporotic bones. Our comments about individual measures proposed in the osteoporosis measures group are the following:

Osteoporosis: Screen for Falls Risk Evaluation and Complete Falls Risk Assessment and Plan of Care – It is unclear to us what is meant by “a complete risk assessment for falls and a falls plan of care,” and we recommend that you further clarify or define these terms, if this measure is retained.

Osteoporosis: Current Level of Alcohol Use and Advice on Potentially Hazardous Drinking Prevention - The measure appears to suggest that anyone whose alcohol use was documented (not just those engaging in potentially hazardous drinking) should receive counseling within 12 months. We recommend further clarification or refinement of the wording of this proposed measure.

Osteoporosis: Dual-Emission X-Ray Absorptiometry (DXA) Scan – The correct terminology is dual-energy x-ray absorptiometry, not dual-emission x-ray absorptiometry. We would not recommend a DXA test for younger
people who have a fracture because, again, it is unlikely that younger people will have osteoporosis. Based on the measure, the presumption is that all patients above the age of 17 who have a fracture should be considered for DXA testing and AACE does not support this testing philosophy.

Osteoporosis: Pharmacologic Therapy – There is no FDA approved indication for pharmacologic treatment of osteoporosis in younger adults (women before menopause or men 49 or younger) except for patients on chronic supra-physiologic dose of glucocorticoids. Therefore, we would recommend either removing this measure or raising the age of patients for whom this measure is reported.

4. Value-Based Payment Modifier

Proposed Rule: CMS is proposing to apply the value-based payment modifier to physicians who practice in groups of 25 or more beginning in 2015 and then in 2016, based on their reported data on PQRS measures from 2013 and 2014. All other physicians will be subject to the value-based payment modifier in 2017. For applicable group practices in the first year of implementation, those that successfully participated in PQRS can choose a value-based payment modifier of 0.0%, which would not affect their Medicare payments. Alternatively, successful PQRS participants can choose to be evaluated through a three-tiered system that incorporates both cost and quality, with subsequent upward or downward payment adjustments based on their results. Physician groups that did not successfully participate in PQRS will receive a 1% reduction in payment for the value-based payment modifier in addition to a 1.5% reduction for unsuccessfully reporting or non-reporting under PQRS.

The value-based payment modifier is flawed and may cause unintended harmful consequences to both providers and patients. AACE opposes the proposed implementation of the value-based payment modifier for many of the same reasons we oppose the current PQRS program. While we applaud any evidence-based attempt to reward care quality in the Medicare system, there is not a shred of evidence that PQRS or the Value Based Payment Modifier have accomplished or will accomplish that goal. The PQRS program has been plagued by problematic operational issues since its implementation five years ago and, to no one’s surprise, still experiences poor participation. Furthermore, we cannot conceive how CMS could propose physician payment adjustments when the agency has not adopted any quality measures that encompass that same physician’s area of practice.

We are also concerned that CMS has yet to explain how they will implement effective strategies to risk adjust the method of calculation for the value-based modifier. As we mentioned above, use of the PQRS diabetes group measures to calculate both quality composite data and cost composite data will incentivize “cherry picking” of patients, especially in the diabetology field. Endocrinologists who will be referred the most complicated and difficult to manage diabetes patients will be unfairly penalized unless accurate and appropriate risk adjustments are applied. The attached graph reflects the pervasive primary care selection process by which healthier patients are retained and high-risk, high-cost patients are “dumped” into specialty practices (Attachment 1). While sub-specialty referral of complicated and difficult patients may be appropriate, payment schemes must offer more generous reimbursement to physicians who accept responsibility for these high risk individuals.

CMS has decided to base the application of the value-based payment modifier in 2015 and 2016 on PQRS reporting and other cost composite data from calendar years 2013 and 2014. AACE continues to oppose the decision made by CMS to back-date both the reporting requirements under the PQRS penalty program and the time period used in calculating the value-based modifier, because of the aforementioned issues.

Because CMS is required by statute to implement the value-based payment modifier, we urge consideration of implementation over the first two years on a voluntary basis, with an emphasis on large groups that are already successful PQRS program participants. This approach would allow CMS to test the proposed quality-tiering approach and ensure the accurate collection and application of the cost composite data used to calculate payment adjustments under the program. Another option would be to delay implementation to allow for further
development and study of truly accurate and reliable quality/cost measures for use as the basis for the value-based payment modifier.

5. Electronic Prescribing

Proposed Rule: In the Electronic Prescribing (e-Rx) program, CMS defines a group as a single tax identification number (TIN) with 2 or more eligible professionals and has increased the reporting requirement to 225 times during the 12-month period, January 1, 2013 – December 31, 2013. The agency has added two new hardship exemptions for 2013- 2014 for eligible professionals or group practices who achieve meaningful use during e-Rx payment adjustment reporting periods and who demonstrate intent to participate in the Electronic Health Record (EHR) incentive program while adopting certified EHR technology.

AACE continues to support efforts to help facilitate system-wide use of electronic prescribing and electronic health records. AACE commends CMS for reducing the number of e-prescribing measures from 625 to 225 for small group practices (2-24 eligible professionals) and adding the new hardship exemptions for eligible professionals or group practices. The reduction in the number of e-prescribing measures for small group practices should increase participation in this incentive program. The addition of hardship exemptions should temporarily reduce practice administrative red tape. AACE strongly supports efforts by CMS to further streamline the incentive programs reporting requirements.

AACE requests that CMS address the e-prescribing reporting requirements for solo practitioners who were not included in the proposed rule.

6. DXA Bone Density Scans

Proposed Rule: The proposed rule does not specifically address bone density scans provided with a dual-energy x-ray absorptiometry (DXA) machine, other than the use of a DXA as a quality measure in the proposed osteoporosis measures group for 2014 and beyond.

Sixty one million people in the U.S. are projected to have osteoporosis and low bone mass by 2020. Certainly our nation must maintain and preserve its capacity to treat this costly, debilitating and near-epidemic health threat. Evidence indicates that people at risk for osteoporosis who receive bone density tests survive longer and live better, experiencing fewer fractures, and saving money for all payers including Medicare, Medicaid and the private sector.

Medicare has made great strides in promoting preventive service utilization by eliminating beneficiary cost-sharing for these services and aggressively promoting the importance of prevention through early diagnosis and treatment. Unfortunately these initiatives are not supported by corresponding efforts to ensure the availability of easy-access preventive technology like DXA. Medicare payment for DXA bone density services dropped by nearly 50% effective on March 1st of this year when Congress did not extend the 2011 Medicare payment rates for osteoporosis testing and treatment services. Many endocrinologists have had no choice but to discontinue providing DXA in their offices. Prior to the Medicare reimbursement change, 80% of the DXA’s performed in this country were done in the office setting. Undoubtedly, the ongoing elimination of DXA technology in the out-patient setting will diminish patient access to this vital technology. Appropriate reimbursement for prevention services, such as DXA bone density tests, is necessary if we hope to fulfill our national commitment to preventive services as outlined in the “Welcome to Medicare” brochure.

AACE urges CMS to use its discretionary authority to adjust the payment level for DXA bone density scans, which we believe is currently misvalued.
7. Medicare Telehealth Services – Behavioral Therapy for Obesity

Proposed Rule: CMS proposes to add several new preventive services to the telehealth benefit, including behavioral therapy for obesity.

CMS’ obesity prevention coverage policy is aligned with the action taken by AACE’s Board of Directors at its meeting in July 2011, declaring obesity as a disease state. Sadly, obesity has been widely viewed as a lifestyle choice rather than a disease. However, a significant body of literature now implicates a number of hormonal and regulatory disorders in the pathogenesis and progression of the obese state to diabetes and other co-morbid conditions such as cardiovascular disease. Recognizing the hormonal results of obesity and the dire consequences, AACE has officially declared obesity as a disease state and plans to develop multiple preventive educational resources promoting lifestyle change, nutrition and exercise, and physician-managed pharmacological treatment for this disease.

AACE supports the role of the primary care physician in this new initiative as defined by CMS. However, we believe that, as experts in the treatment of metabolic disease, endocrinologists are critical to our nation’s concerted efforts to prevent and treat obesity. Endocrinologists are frequently the physicians who actually address and treat obesity. Many endocrinologists have developed cost-effective, organized obesity treatment programs that are not available in most primary care practices. Effective healthcare delivery demands the right care, at the right time, and in the right place. For many patients the right place is the endocrinologist’s office, and CMS payment policies should reflect this fact. Given the health implications of obesity, including its progression to type 2 diabetes, cardiovascular disease and other metabolic disease, AACE urges CMS to expand the list of providers who can be reimbursed for behavioral therapy services like obesity prevention and telehealth service, to include endocrinologists.

Once again, thank you for the opportunity to comment on the proposed rule for the 2013 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,

Alan J. Garber, MD, PhD, FACE
President

R. Mack Harrell, MD, FACP, FACE, ECNU
Vice President
Chair, Legislative & Regulatory Committee

Jonathan D. Leffert, MD, FACP, FACE
Chair, Socioeconomic and Member Advocacy Committee
Average HbA1c by provider specialty, in group where results reported to provider  
Date Range - January 1, 2012 - July 31, 2012  

Average: 7.87  6.91  7.07  6.91  6.52
NOTES:

ALL IM & SUBSPECIALITY IM PROVIDERS IN GROUP

RESULTS REPORTED TO IM PHYSICIANS.

This demonstrates that Endocrinology physicians are seeing a selected subset of patients with diabetes mellitus, as they should. Endocrinologists are seeing the most difficult patients, and the IM group is referring them if the A1c is high, which keeps their A1c averages lower.

This group pattern has existed since we started measuring it in 2008.

The endo group averages do not even overlap with any other specialty.

The ‘OTHER’ physicians are in specialties of Neurology, Pulmonary, and Infectious Disease, and their number of A1c tests is very low.