August 30, 2011

Donald Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1503-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-1524-P: Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for Calendar Year 2012; Proposed Rule.

Dear Dr. Berwick:

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 2012, published in the July 19, 2011 Federal Register.

Our comments relate to the following issues:

1. Review of Evaluation and Management Codes
2. Process to Review Potentially Misvalued Codes
3. Multiple Procedure Payment Reduction
4. Electronic Prescribing
5. Physician Quality Reporting System
6. Physician Value-Based Payment Modifier
7. Third Year Transition to PPIS Practice Expense Values
8. DXA Bone Density Scans
9. Sustainable Growth Rate Formula

1. Review of Evaluation and Management Codes

Proposed Rule: Recommends RUC review of the major Evaluation and Management (E&M) codes due to an evolution toward a more comprehensive care management focus.

AACE believes the current E&M codes are undervalued and supports any process that will lead to the recognition of the highly-skilled, labor intensive cognitive care and care coordination that are part of the E&M services provided by endocrinologists. Access to high-quality endocrine care is currently in jeopardy for beneficiaries with hard to treat diabetes and other endocrine disorders. Patients with such complex medical conditions require a level of expertise that the referring primary care physician does not possess. The highly-
skilled, intensive cognitive care provided by endocrinologists has been significantly undervalued compared to procedural care. Recognizing and valuing the expert care that endocrinologists provide to their patients is essential for patients to continue to have access to high quality endocrine care.

Endocrinologists are experiencing the same economic disadvantages as primary care, resulting in difficulty in attracting residents into the specialty and creating concerns about the future ability to meet the nation’s healthcare needs, particularly given the growing diabetes epidemic. Many endocrinologists are now reimbursed less than primary care physicians for treating the same patients. This is due to the 10 percent incentive payment for designated primary care specialties enacted under the Patient Protection and Affordable Care Act (PPACA), which did not include endocrinology or other cognitive specialties.

AACE considers the review and re-evaluation of E&M codes as a critical immediate step to ensure patient access to care and to maintaining the viability of the endocrinology workforce. We strongly urge CMS to recognize and pay for the cognitive work performed by endocrinologists and other cognitive specialists, in addition to the work required in the coordination of care between the endocrinologist, the primary care physician and other members of the health care team. These services must be paid for if the health care reform goal of better coordination of care is going to be successfully achieved.

2. Process to Review Potentially Misvalued Codes

Proposed Rule: Eliminates future five-year reviews and incorporates the publically nominated reviews normally handled through that process into the annual potentially misvalued codes review process.

The consolidation of the five-year review of work and practice expense and the annual review of potentially misvalued codes will eliminate the opportunity for public input and comment that has been previously afforded through the five-year review process. Given the timing of the five year review comment period in the process, it also allows for proposed RVUs to be revised prior to the publication of the MPFS final rule for that year. In eliminating the five year review process, changes in values assigned to CPT codes may have to wait an additional 12 months. Furthermore, the five year review process allows for medical societies to nominate CPT codes for review that it believes need to be re-evaluated. To date, the misvalued code review process has been populated with codes that are identified by CMS. AACE is concerned that this proposal diminishes the consultative process between regulators and stakeholders and reduces the transparency of the review process, both of which have served to benefit and strengthen the Medicare program to date. AACE would urge CMS to hold a town hall meeting or other type of organized meeting with stakeholders to further refine and adapt this proposal before it is considered further.

3. Multiple Procedure Payment Reduction

Proposed Rule: Expands the 50% Multiple Procedure Payment Reduction (MPPR) for advance diagnostic imaging services to include the professional, or work, component.

CMS proposes to expand the multiple procedure payment reduction currently applied to the technical component for 119 advanced diagnostic imaging services to also apply to the professional interpretation of these imaging services, when two or more of these services are provided in the same session on the same day. CMS is also considering a future expansion of this policy to apply the 50% multiple procedure payment reduction to all imaging services, including standard imaging services such as ultrasound and x-ray, when two or more services are provided to the same patient on the same day. AACE believes this is a short-sighted, ill-conceived proposal and urges CMS to eliminate the proposal from the final rule for the 2012 Medicare Physician Fee Schedule.

This proposal appears to be premised on the misperception that Medicare payments for imaging services continue to grow unabated. The application of the 2005 Deficit Reduction Act imaging cuts caused a downward trend in the volume of imaging services beginning in 2007. According to the American Medical Association (AMA), in 2010 the volume for both standard and advanced imaging services per fee-for-service beneficiary actually fell below the 2009 levels. The AMA reports that some of these services have begun to
shift out of physician offices and into more expensive hospital outpatient departments, suggesting that another round of imaging cuts is not only unnecessary but could potentially place an additional cost burden on patients and increase Medicare program costs.

Congress specifically applied the MPPR on the technical component for “Advanced Imaging Services,” defined in the statute as magnetic resonance imaging (MRI), computed tomography (CT), PET, and nuclear cardiology. Ultrasound and x-ray are considered, ‘standard imaging,’ and their physician work reimbursement is considerably less, with most ultrasound procedures being reimbursed at a level of $18 - $30. In a 2008 study by the General Accounting Office (GAO), standard imaging, ultrasound and x-ray, was found to be growing at a much slower rate versus MRI or CT.

AACE is concerned about CMS’ proposed policy to reduce by 50% the physician work component of the lower reimbursed imaging services that are furnished to the same patient on the same day, in the same session. We do not believe this policy promotes the appropriate use of imaging services and instead continues to reinforce growth in more expensive imaging services. Enactment of this proposed policy would be counter-productive to the work of medical societies regarding clinical practice guidelines and it does not support increased value in imaging services for Medicare beneficiaries. Expanding a policy that supports the use of more expensive diagnostic testing is not in the best interest of continued solvency for the Medicare program.

Most importantly, when a physician interprets an image, there is no significant efficiency of interpreting and reporting separate studies, regardless of whether they were performed on the same patient in one encounter. The implementation of the multiple procedure payment reduction has the potential to decrease patient compliance, coordination of care, and increase the hassle factor as some physicians may resort to scheduling a patient for a second or subsequent visit to perform an imaging service in order to circumvent the 50% reduction in payment. The potential consequences of this policy are counterproductive to the goals of enhancing quality and reducing cost. As Medicare physician payments continue to be cut, physicians are struggling to continue to serve beneficiaries and keep their practices viable. The implementation of this policy to all imaging and diagnostic testing services will only provide an additional incentive for physicians to “opt-out” of the Medicare program. AACE strongly urges CMS to reconsider this issue and reject this proposal now and in the future.

4. Electronic Prescribing

CMS Proposed Rule: Defines requirements for incentive bonus payments and penalty adjustments for the continuation of the Electronic Prescribing (e-Rx) program ending in 2014 and provides additional hardship exemptions for eligible professionals to request to avoid the 2012 e-Rx penalty.

AACE supports efforts to help facilitate system-wide use of electronic prescribing and electronic health records; however, we remain very concerned about the accelerated penalty phase of the e-Rx program. Financial penalties totaling 1% of a physician’s total estimated Medicare Part B allowed charges furnished during the 2011 reporting period are going to be imposed for failure to participate in the 2011 e-Rx incentive program if a physician did not qualify for an exemption. Requiring reporting the year before the penalty program starts, not creating adequate exemption categories and last minute modifications have created confusion, resulting in insufficient time to educate physicians on steps they need to avoid e-Rx penalties next year.

As was stated in AACE’s comment letter on the 2011 MPFS proposed rule, we continue to believe there should be no penalties applied until 2013, for lack of e-Rx in 2012, consistent with the provisions in the Medicare Improvements for Patients and Providers Act of 2008 establishing the e-Rx program.

The e-Rx program rules were promulgated in the 2011 MPFS final rule published in November, 2010, which did not allow sufficient time to conduct educational and informational activities for a program that was initiated on January 1, 2011. We believe there will be a significant number of endocrinologists, and physicians overall, who receive a 1% payment penalty for failure to report in the 2011 reporting period. An e-Rx program payment reduction coupled with a 29.5% SGR formula payment cut, and ongoing investments required for transitioning to electronic health records (EHRs), reduced payments under new care delivery and payment
systems and other potential payment reductions resulting from the 2011 Budget Control Act, will force physicians out of the Medicare program and create an access to care crisis. AACE urges CMS to undertake the following modifications to reduce the administrative and economic burdens of the e-Rx program:

- add a second reporting period in 2012 to provide an additional opportunity for physicians to meet the requirements of the 2011 reporting period and avoid an e-Rx penalty;
- recognize EHR technology certified under the Medicare/Medicaid EHR incentive program as a qualifying system under the e-Rx program so physicians do not have to purchase two separate systems to avoid penalties;
- provide additional clarification about the existing and proposed program exemptions and maintain these exemption categories throughout the duration of the e-Rx program;
- implement an additional exemption for physicians who are currently eligible for Social Security retirement benefits or will be eligible by 2014, to eliminate an economic burden for physicians who intend to retire in the next four years and should not be burdened with installing an e-Rx system for such short-term use;
- extend the deadline for applying for a program exemption to the end of the year since the proposed deadline is October 1, 2011, and not all proposed program exemptions will be finalized by that date; and
- establish an appeals process for eligible professionals to pursue if their request for a significant hardship exemption has been denied.

5. Physician Quality Reporting System

CMS Proposed Rule: Proposes to make a number of modifications to the Physician Quality Reporting System (PQRS), including adding 26 new individual measures and 10 new measure groups, and providing interim feedback reports for those reporting through claims based reporting, among other things.

AACE recognizes that CMS is trying to address the numerous concerns with the PQRS program since the inception of the Physician Quality Reporting Initiative in 2007. We applaud the recent and proposed program enhancements including the maintenance of certification program incentive, efforts to synchronize the PQRS program and the Electronic Health Records (EHR) incentive program and the proposal to provide interim PQRS feedback reports to eligible professionals reporting individual measures and measure groups via claims for 2012 and beyond.

We are concerned, however, that physicians will receive a payment penalty totaling 1.5% of their allowed Part B charges beginning in 2015 based on their PQRS reporting in calendar year 2013. Given the operational issues that continue to plague the program in its fifth year of existence, it defies logic that the PQRS program will have resolved all issues one year from now so that physicians and the public will have the confidence that CMS can accurately determine physicians who fail to successfully report and are subject to a payment penalty. AACE strongly urges CMS to push back the reporting period for the 2015 PQRS penalty adjustment to calendar year 2014 to provide additional time to address the administrative operational issues that adversely impact the physician’s ability to successfully report.

AACE supports the proposed new PQRS core quality measures related to diabetes, ischemic vascular disease, tobacco use and cessation intervention, blood pressure and preventive care. We note that CMS is also proposing 10 new measure groups, including elevated blood pressure and cardiovascular prevention.

AACE requests that CMS add a new core measure group for the management of thyroid disease and disorders. More than 25 million Americans have some form of thyroid disorder and half remain undiagnosed. The prevalence of thyroid disease in the elderly is twice that of the younger population and symptoms are often different than those seen in younger patients. Once a thyroid disorder has been diagnosed and a treatment plan has been initiated, it is important that patients continue to see their endocrinologist or physician regularly to make sure their thyroid hormone levels are in check. AACE members who are thyroidologists have been unable to participate in the PQRS program due to the absence of quality measures in this disease area. It is
important that patients with thyroid disease and disorders receive the same high quality care as other beneficiaries. AACE urges CMS to incorporate a thyroid core measure group in the PQRS program.

6. Physician Value-Based Payment Modifier

**Proposed Rule:** Solicits input on the potential use of quality measures from the 2012 PQRS and the EHR incentive programs in addition to outcomes measures such as morbidity, patient safety, complications, functional status, care coordination and patient experience for measuring performance or value in calculating the value-based payment modifier. Comments are also solicited on using a total per capita cost measure and per capita cost measures for 4 conditions: chronic obstructive pulmonary disease, heart failure, coronary artery disease and diabetes. CMS proposes to use calendar 2013 as the performance period for applying the modifier in 2015.

The PPACA requires that a payment modifier be established that provides for differential payment to a physician or group of physicians based upon the quality of care furnished compared to the cost. The proposed use of the quality performance measures from the PQRS, among other measures, raises some interesting questions.

Most importantly, AACE believes the proposed diabetes measures do not provide an accurate and reliable method for evaluating the quality and value of care performed by an endocrinologist. Specifically, the diabetes measures focus on short-term outcomes, measured through indicators that include Hemoglobin A1c, blood pressure control, tobacco non-use and aspirin use. These measures 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. If that were the case then endocrinologists would not receive referrals of hard to treat diabetes patients for whom the family practitioner is unable to effectively manage. Using diabetes as a cost measure may inadvertently disadvantage certain endocrinologists who treat the hardest to manage diabetes patients, unless appropriate and effective risk adjustments are applied. The cost of services required for a well-controlled diabetes patient who is compliant with a prescribed dietary, lifestyle and medication treatment plan is going to have costs that reflect a fraction of the cost of care provided to a patient whose blood glucose is uncontrolled and is experiencing medical complications such as neuropathy, vision problems, cardiovascular disease or kidney disease. How will CMS calculate and apply risk adjusters to account for such factors?

The CMS proposed implementation of the value-based modifier raises a number of questions, including those listed below. AACE urges CMS to address these and other issues raised in comments in an interim final rule before issuing a final rule on the implementation of the physician value-based payment modifier.

- How will a physician’s performance be measured and calculated into the modifier if CMS determines that they are not successfully reporting under the PQRS program by calendar year 2013?
- How will a physician’s performance be measured and the modifier calculated if a physician does not participate in the PQRS program?
- How are a physician’s costs to be calculated into the modifier if there are no costs attributed to the physician that relate to the 4 conditions proposed?
- How will performance be measured for physicians who are near retirement age and have chosen not to make the infrastructure investments to participate in PQRS or the EHR incentive program because they determined it was not cost-effective?
- How does the value-based modifier impact payments for services provided by physicians whose status under Medicare is “non-PAR” if at all?
7. Third Year Transition to PPIS Practice Expense Values

**Proposed Rule:** Implement the third year of a four year transition to the Physician Practice Information Survey (PPIS) new Practice Expense Relative Value Units (RVUs)

AACE supports the continued implementation of the American Medical Association’s (AMA) Physician Practice Information Survey (PPIS), now in the third year of the four year transition period to full implementation. The PPIS was designed as a nationally representative survey of physicians, from 51 specialties and health care professionals, which were randomly drawn from the AMA’s Physician Masterfile. A total of 3,657 physicians and health care professional records were used in the PE/hour computations, which included the subspecialty of endocrinology. Previous practice expense calculations used until calendar year 2010, based on the 1995 – 1999 AMA Socioeconomic Monitoring System (SMS) survey, were outdated and did not accurately reflect office practice expense. AACE believes that the PPIS survey results more accurately reflect the increase in practice expense in an endocrinologist’s practice and are consistent with the increased practice expense costs across most specialties.

8. DXA Bone Density Scans

**Proposed Rule:** For Calendar Year 2012, payment for CPT codes 77080 (DXA bone density study) and 77082 (vertebral fracture assessment) will be based on resource-based RVUs instead of the imputed RVUs provided under the PPACA for use through 2011. CMS also requests RUC review of codes 77080 and 77082.

A DXA bone density scan used for the early diagnosis, prevention and treatment of osteoporosis is an example of a high quality, low-cost point of care service provided by an endocrinologist. A DXA procedure is the imaging test accepted by the medical community as the “gold standard” for diagnosing osteoporosis. Providing a DXA scan in the office allows an endocrinologist to identify patients at high fracture risk and immediately implement a treatment plan if required. A DXA test is also used to monitor the effectiveness of medical therapy to prevent and treat osteoporosis.

Access to community-based osteoporosis screening and diagnosis has been the driving force behind the modest increases in osteoporosis screening rates over the past decade. While offering testing in the physician office has helped to increase screening rates by making testing more convenient, DXA tests are woefully underutilized.

Prior to the phase-in of Medicare’s cuts in DXA payment beginning in 2007, the proportion of women aged 65 years and older who received any type of bone density measurement increased from 8.4% in 1999 to 12.9% in 2005, and from 0.6% to 1.7% in men. Recent CMS claims data suggests that the DXA utilization rates have remained stagnant since then.

We hope that provisions of the PPACA that promote prevention and beneficiary access to preventive services will incentivize beneficiaries to have their bone density tested. Under the PPACA, DXA is a covered service when provided once every two years as part of the Annual Wellness Visit, in addition being part of the Welcome to Medicare exam, and beneficiaries will no longer have responsibility for any cost-sharing for this preventive benefit. A bone density test will also be a preventive service covered without cost sharing for younger women whose fracture risk is equal or greater than that of a 65 year-old white woman under health insurance plans offered through the Health Exchanges beginning in 2014.

AACE is very concerned about adequate access to this important preventive benefit. Medicare payments over the last four years have not covered the cost of providing these services and have caused many physicians to discontinue providing DXA and VFA and some mobile van units serving rural and underserved areas to go

---

completely out of business. CMS should encourage endocrinologists and other physicians who perform DXA scans to continue to provide this valuable service in their offices by ensuring the reimbursement is fair and accurately reflects the cost of providing the test. Federal prevention efforts will succeed only if patients have convenient access to preventive services from a health care professional they know and trust.

9. Sustainable Growth Rate Formula Cuts

Proposed Rule: Confirms the conversion factor used to calculate Medicare physician payments will be cut from the current $33.97 to $23.96 – a cut of 29.5% -- for the 2012 MPFS.

AACE is very concerned about the viability of the Medicare program, given the magnitude of cuts physicians currently face due to the flawed Sustainable Growth Rate (SGR) formula and the prospect of even deeper cuts as a result of the additional deficit reduction mandated by the Budget Control Act of 2011. We appreciate the Administration’s proposals to rebase the Sustainable Growth Rate (SGR) formula baseline in recent budget requests, however, there appears to be a lack of political will to do this given the anxiety over the federal budget deficit and the strong distaste for extending the debt ceiling to cover the nation’s financial obligations.

AACE believes the current Medicare physician payment situation is a crisis that endangers the nearly 48 million beneficiaries that rely on the program for medical care. Since the SGR formula was not addressed in the PPACA, we urge the Administration to make this issue a high priority and work with Congress to find a resolution to this issue.

Once again, thank you for the opportunity to provide comments on these important issues. If you have any questions or need more information, please contact Sara Milo, Director of Legislation and Governmental Affairs at smilo@aace.com.

Sincerely,

Yehuda Handelsman, MD, FACP, FACE
President

R. Mack Harrell, MD, FACP, FACE, ECNU
Chair, Socioeconomic Committee

Jonathan D. Leffert, MD, FACP, FACE
Chair, Legislative & Regulatory Committee