

August 29, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1403-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1403-P Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2009

Dear Acting Administrator Weems:

On behalf of The Endocrine Society (Society), representing more than 14,000 physicians and scientists in the field of endocrinology, we appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed revisions to the payment policies under the Physician Fee Schedule for calendar year 2009. The Society looks forward to working closely with the Agency as this proposed rule moves toward implementation.

Founded in 1916, the Society represents physicians and scientists engaged in the treatment and research of endocrine disorders, such as osteoporosis, diabetes, hypertension, infertility, obesity, and thyroid disease. The following comments focus on four areas of particular importance to our members:

- 1) Independent Diagnostic Testing Facilities
- 2) Resource-Based Practice Expense Relative Value Units – Equipment Time in Use
- 3) Preventive Services under MIPPA Section 101
- 4) Expanding Access to Primary Care Services under MIPPA Section 133

Independent Diagnostic Testing Facilities

The Endocrine Society would like to state its opposition to the CMS proposal requiring physicians and non-physician practitioners who perform diagnostic testing services in a non-facility setting to enroll as independent diagnostic testing facilities (IDTF) and comply with most of the standards now required of these stand-alone testing facilities. We believe that requirements set forth in the recently passed Medicare Improvements for Patients and Providers Act (MIPPA), which create accreditation requirements in order to provide advanced diagnostic imaging services, are more than sufficient. We ask that CMS focus on implementation of MIPPA provisions instead of moving forward with the IDTF proposal outlined in this proposed rule. We welcome the results of the Government Accountability Office (GAO) study to be conducted on the effects of MIPPA accreditation requirements, and suggest that further regulations on IDTF and imaging procedures are unnecessary.

In the event that CMS chooses to move forward with further IDTF regulations, we offer these additional comments:

Our interpretation of the proposed rule indicates that only radiology-certified professionals would be eligible to perform or oversee these diagnostic procedures under the proposed rule changes. We believe that the outcome of this requirement would ultimately reduce patient access to important diagnostic services, something that previous federal requirements, including the provisions included in the Welcome to Medicare exam, have attempted to eliminate.

Two procedures frequently performed by endocrinologists are thyroid ultrasound and dual-energy x-ray absorptiometry (DXA) scans. These procedures are crucial for the detection of endocrinologic disorders such as thyroid nodules, parathyroid tumors, recurrent thyroid cancer, and osteoporosis. Currently, 40 percent of thyroid ultrasound exams are performed by radiologists and only 12 percent of DXA scans are performed by radiologists. Obtaining the appropriate qualified personnel required to meet these new IDTF standards will not only be cost prohibitive to many endocrinologists currently providing these services, but will not provide increased quality to patients or greater savings to the Medicare program. These requirements would reduce the number of practitioners who provide these services, limiting patient access. Thyroid ultrasound performed by endocrinologists is often more cost effective than when the procedure is done by radiologists. This is particularly the case when diagnostic imaging alone is done on a first procedure that identifies a nodule, leading to a recommendation to the referring physician for ultrasound-guided biopsy, necessitating a second patient visit to the radiologist. On the contrary, both initial imaging and needle aspiration biopsy are performed by endocrinologists at the same encounter. In addition to these concerns, we also question the implementation of required IDTF site inspection requirements. If physician practices are required to become registered IDTFs, greater numbers of site inspections will be necessary. Without CMS having the capacity to conduct these inspections in a timely manner, patient access to services could become significantly compromised.

CMS has asked for comments related to limiting IDTF enrollment requirements to include less than the full range of diagnostic testing services. As stated above, a majority of thyroid ultrasound and DXA scan procedures are not currently performed by radiologists. Requiring physician compliance with IDTF requirements will likely reduce access to these services for patients – a change that would be detrimental to the health of Medicare enrollees. Limiting access by increasing certification requirements would only increase costs to the Medicare program for potentially dangerous thyroid nodules and major osteoporotic fracture complications in the future. We request that these IDTF provisions be applied only to advanced imaging services.

Resource-Based Practice Expense Relative Value Units – Equipment Time in Use

CMS has again proposed that the equipment utilization rate of 50 percent be applied across-the-board to all procedures. Imaging procedures utilized in single-disease states, such as dual energy x-ray absorptiometry (DXA) and vertebral fracture assessment (VFA) for osteoporosis, have substantially lower relative rates of utilization. The 2006 Medicare data reflect the fact that 99 percent of DXA studies are performed in an office setting, and approximately 78 percent of studies are performed by non-radiologists. These data indicate that primary care physicians perform DXA on patients as part of routine medical care in their practice, versus the high volume imaging centers that may exhibit significantly higher utilization rates. We believe that a more appropriate utilization rate for DXA and VFA services to be approximately 13 percent. In CY 2008, CMS altered the utilization rate for two codes – 93012 and 93217 – increasing the utilization rate from 50 percent to 100 percent. As such, we ask that CMS consider reducing the utilization rate for CPT codes 77080, 77081, and 77082 as the across-the-board utilization of 50 percent is not reflective of this particular equipment. We strongly encourage CMS to consider this issue in its final rule.

In July, CMS staff advised specialty societies that certain provisions of the recently-enacted Medicare Improvements for Patients and Providers Act (MIPPA) will be implemented in 2009 even though the associated regulatory language was not included in the proposed rule. As a result, CMS recommended

that specialty societies include comments on certain areas of the MIPPA provisions while commenting on the proposed 2009 fee schedule. The Endocrine Society would like to specifically comment on Sections 101 and 133 of MIPPA.

Improvements to Coverage of Preventive Services, Section 101

Section 101 outlines the expansion of coverage for additional preventive services not currently covered under the Medicare program, and the criteria by which these additional preventive services should be evaluated for inclusion. We agree that preventive care should be expanded in the Medicare program, and strongly support CMS' recommendation to do so. In particular, we believe that in order to prevent and detect osteoporosis in men, dual energy x-ray absorptiometry (DXA) scans should be available to men with increased fracture risk. Although the U.S. Preventive Services Task Force (USPSTF) has not released recommendations on this population to date, two topics on osteoporosis are currently in progress at the USPSTF, and we ask that men be included in these recommendations. Today, in order to qualify for a DXA bone measurement test under the Medicare program, patients must meet criteria which include a diagnosis of osteoporosis, osteopenia, or vertebral bone fracture. While these are vital indications for conducting bone mass measurement, The Endocrine Society advocates widening the scope of Medicare coverage to include preventive bone density scans for individuals with medical conditions placing them at risk of developing osteoporosis or osteopenia in the future. One such example would be therapy with steroids or other medications whose long-term use is associated with osteopenia or osteoporosis. We believe that screening men for future fracture risk is vital to the long-term health of this population, and ask that when the USPSTF completes their recommendations, CMS consider including DXA scans for men with risk factors for osteoporosis under the Medicare program.

Expanding Access to Primary Care Services under MIPPA, Section 133

Additionally, The Endocrine Society would like to comment on MIPPA Section 133 – Expanding Access to Primary Care Services. In particular we would like to state our support for the change in application of the budget neutrality adjustor from the work relative value units to the conversion factor. As with primary care physicians, endocrinologists use E/M codes heavily in billing for the services they provide. The change outlined in MIPPA will help to reverse the negative impact that the budget neutrality adjuster has had on physician payment in the past, and is a change that endocrinologists and others in the physician community applaud.

In conclusion, the Society appreciates the opportunity to submit these comments regarding CMS' 2009 Physician Fee Schedule. As always, the Society is grateful to CMS staff for the hard work that went into drafting this proposed rule. Please do not hesitate to contact Janet Kreizman, Senior Director of Government & Public Affairs, at jkreizman@endo-society.org, if we may provide any additional information or assistance as CMS moves forward in developing this rule.

Sincerely,



Robert M. Carey, MD, MACP
President
The Endocrine Society