



February 23, 2005

### **The Endocrine Society Joins Cognitive Specialties to Request Pay Raise from CMS**

The Endocrine Society, along with 26 other specialty societies, recently asked the Centers for Medicare and Medicaid Services (CMS) to take another look at how 41 evaluation and management (E/M) services are currently valued for reimbursement through Medicare. The request, which was sent in the form of a letter, informed CMS of the many reasons why E/M services are woefully undervalued in the current Medicare physician payment fee schedule. According to the letter, the work of providing E/M services has increased significantly in the 14 years since the current payment system was established. This system, known as the Resource-Based Relative Value System (RBRVS) determines payment rates for each code.

The purpose of this request is to ask the Agency to require the codes to be reviewed as part of the upcoming Five-Year Review of CPT codes.

*Part B News*, a widely distributed industry newsletter, highlighted the letter in a recent issue. In the article, The Endocrine Society, along with the other specialties, was designated as “Specialties Urging Boost in Pay for E/M Services.”

Citing the considerable differences in the practice of medicine since ten years ago (the last time E/M codes were subject to review), the letter stated that providing E/M services, which are primarily conducted by non-surgical specialties, has changed in a number of ways, some of which are summarized as follows:

1. **A greater expectation that physicians will be proactive in disease prevention as well as diagnosing and treating illness.** During the past ten years, Medicare has added a number of screening services for coverage. Moreover, Medicare added diabetes screening, screening cardiovascular blood tests and the “Welcome to Medicare” visit just this year.
2. **Additional documentation requirements added to physician work.** The 1995 and 1997 Medicare E/M documentation guidelines have increased demands related to stand-alone E/M services. These guidelines did not exist the last time the E/M codes were reviewed. In addition, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) also has increased its documentation requirements related to hospital visits.
3. **An increase in the complexity of data to be evaluated and care to be managed.** More proactive patient involvement, more polypharmacy, and an increase in the number

of clinical guidelines that provide good examples of what is considered optimal care have contributed to increased complexity of data for a physician to evaluate in the course of treatment.

4. **Patients presenting to the office with a greater expectation of participating in medical decision-making and with more information from the Internet and lay press.**
5. **The advent of online communications with patients.** Patients today routinely present to the office with information they have gleaned from the Web and questions to go along with it.

The letter was sent to CMS as part of the statutorily-mandated Five-Year Review process (see related article in January 20 *Endocrine Insider* article) calling on medical organizations to submit recommendations for codes that should be reviewed during this process.

### **NIH to Hold Conference on Managing Menopausal Symptoms [BR & CR & CP]**

On March 21 – 23, 2005, the National Institutes of Health (NIH) will hold a “State-of-the-Science Conference on Management of Menopausal Symptoms.” The National Institute on Aging and the NIH Office of Medical Applications of Research are the primary sponsors of this meeting.

During the first two days of the conference, experts will present information on the biology of the menopause transition, the nature of the symptoms women experience, and strategies for relieving the common problems associated with the menopause transition. After weighing all of the scientific evidence, an independent panel will prepare and present a state-of-the-science statement answering the following key conference questions:

- What is the evidence that the symptoms more frequently reported by middle-aged women are attributable to ovarian aging and senescence?
- When do the menopausal symptoms appear, how long do they persist and with what frequency and severity, and what is known about the factors that influence them?
- What is the evidence for the benefits and harms of commonly used interventions for relief of menopause-related symptoms?
- What are the important considerations in managing menopause-related symptoms in women with clinical characteristics or circumstances that may complicate decision-making?
- What are the future research directions for treatment of menopause-related symptoms and conditions?

On the final day of the conference, the panel chair will read the draft statement to the conference audience and invite comments and questions. A press conference will follow to allow the panel and chair to respond to questions from the media.

The conference will be held in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8 a.m. on March 21 and 22, at 9

a.m. on March 23, and will be open to the public. Advance information about the conference and conference registration materials may be obtained from American Institutes for Research of Silver Spring, Maryland, by calling 888-644-2667 or by sending e-mail to [menopause@air.org](mailto:menopause@air.org). American Institutes for Research's mailing address is 10720 Columbia Pike, Silver Spring, MD 20901. Registration information is also available on the NIH Consensus Development Program Web site at <http://consensus.nih.gov>.

### **Endocrine Society Clinical Guidelines Underway**

The Clinical Guidelines Subcommittee, chaired by Robert Vigersky, M.D., is spearheading the effort to produce the Society's first set of clinical guidelines, several of which are expected to be published in 2005 and 2006. Since its creation by Council in 2003, the CGS has identified several important topics in endocrinology where guidelines are either nonexistent, out-of-date, or inadequate and has begun to develop a set of Endocrine Society guidelines that will cover these topics.

Currently, two guidelines, *Growth Hormone Deficiency in Adults*, chaired by Mark Molitch, M.D.; and *Androgen Deficiency in Men*, chaired by Shalender Bhasin, M.D., are in draft stage, with an anticipated publication date of Summer 2005. The CGS is tackling four others this year: *Metabolic Syndrome* (Jamie Rosenzweig, M.D., chair), *Thyroid Disease in Pregnant and Postpartum Women* (Leslie DeGroot, M.D., chair), *Pediatric Obesity* (Gilbert August, M.D., chair), and the *Role of Androgens in Women* (Margaret Wierman, M.D., chair).

The individual guidelines are being developed by task forces consisting of experts in the field, and the guideline development process is a rigorous one. A CGS member serves as task force chair and selects the task force members for each of the guidelines being developed. The guidelines task forces then rely on evidence-based reviews of the literature to provide support for their recommendations, using a state-of-the-art GRADE scheme for evidence grading which takes into account study design as well as the relative strengths and weaknesses of the best available evidence. Once drafted, each guideline will be reviewed by the CGS, the Clinical Affairs Committee, and Council. It will then be made available to Society members for comment via the Web. Finally, the guidelines will be submitted for publication in the *Journal of Clinical Endocrinology and Metabolism* and undergo peer-review.

The CGS comprises members with expertise in the major areas of endocrinology. In addition to Dr. Vigersky, the CGS members are: Gilbert August, M.D.; Shalender Bhasin, M.D.; George Bray, M.D.; Leslie DeGroot, M.D.; Lorraine Fitzpatrick, M.D.; Kathryn Martin, M.D.; Mark Molitch, M.D.; Jamie Rosenzweig, M.D.; and William Young, M.D.

Look for updates about the Society's clinical guidelines in future issues of *Endocrine Insider*, *Endocrine News*, and on the Society's Web portal.

### **The Endocrine Society Works with FASEB to Extend Duration of Visas Mantis Clearance**

The State Department announced a policy change last week that made a clearance valid for four years for students and two years for working scientists, making it easier for them to stay in the country for the duration of their study or research. FASEB was one of a coalition of

organizations, which also included The Endocrine Society that produced a statement calling on the State Department to implement this change.

The U.S. Department of State recently circulated a press release describing the Visas Mantis clearance process. The press release stated that visa applications for persons to study or work in certain sensitive scientific and technical fields are subject to an interagency clearance in Washington, DC, called Visas Mantis. Since 1998, the Visas Mantis clearance process has been used to screen against the illegal transfer of technology. Once the clearance process is complete and a visa is issued, the individual may apply for admission at a U.S. port of entry. Visas Mantis clearance and visa validity are different than the period of admission determined by a Department of Homeland Security officer at the port of entry.

The U.S. Department of State, in consultation with the U.S. Department of Homeland Security, has extended the validity of Visas Mantis clearances for the F (student), J (exchange visitors), H (temporary workers), L (intracompany transferees) and B (tourist and business) categories of visas. This means that if the original visa has expired and a new visa application is filed to return to the previous study or work program in the United States, another Visas Mantis clearance may not be required. Consular officers have the discretion, if warranted, to request a Visas Mantis clearance during any visa adjudication.

International students (F visas) who have received a Visas Mantis clearance and been issued a visa will benefit from having that clearance be valid for up to the length of the approved academic program, to a maximum of four years. If student changes academic programs, the clearance will no longer be valid and a Visas Mantis review would be required should the applicant reapply for a new visa.

Temporary workers (H visas), exchange visitors (J visas) and intracompany transferees (L visas) can receive a Visas Mantis clearance valid for the duration of their approved activity to a maximum of two years. If the nature of the visa holder's activity in the United States changes, the clearance will cease to be valid and a new Visas Mantis review would be required should the applicant reapply for a new visa.

Business visitors (B-1 visas) and visitors for pleasure (B-2 visas) can receive a Visas Mantis clearance valid for one year, provided that the original purpose for travel, as stated in the visa application, has not changed on subsequent trips.

In addition to the extension of validity for Visas Mantis clearances, the Department of State has made several other improvements in the Visas Mantis process in the past year. By increasing staffing, improving systems and working with our interagency partners, the Department has been able to decrease the average time to obtain Visas Mantis clearance to less than 14 days.

### **Medicare Announces Pay-for-Performance Program, Includes Endocrine-Related Quality Measures**

“It is time that we pay for the quality of the health care provided to our beneficiaries, not simply the amount,” said CMS Administrator, Dr. Mark McClellan, in reference to a CMS announcement to implement new initiatives to pay health care providers for quality of care they provide to Medicare beneficiaries. “We are working to apply this in every setting in which Medicare and Medicaid pays for care.”



### **CMS Releases E-Prescribing Proposed Rule, To Hold Special Open Door Forum**

On Tuesday, March 1, CMS will host a Special Open Door Forum conference call focusing on clarification and discussion of the E-prescribing proposed rule, from 2:00 pm to 4:00 pm Eastern Time.

The E-prescribing rule proposes to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). These proposed standards would be the foundation standards or the first set of final uniform standards for an electronic prescription drug program under the MMA.

The purpose of the two-hour Open Door Forum is to clarify providers' understanding of the proposed rule and provide an overview of some of the key elements contained within it. The call leaders will discuss the timeline for the adoption of E-prescribing standards, the proposed foundation standards, and CMS' plan to conduct a pilot project to test additional standards, as mandated by the MMA.

In addition to participating in this Open Door Forum, Society staff also will review the proposed rule to determine its impact on clinician members of the Society. Look for details in future issues of the *Endocrine Insider*.

To participate in the call dial: 1-800-837-1935 and reference conference ID: 3860280.

If you are unable to participate on March 1, you may listen to a recording of the call through the CMS ENCORE system. Dial 1-800-642-1687 and enter conference ID #3860280. The recording begins 2 hours after the call, and expires after 4 business days.

To view the proposed rule, which was published in the *Federal Register* on Friday, February 4, 2005, please use the following web link:

<http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-1773.pdf>

For automatic emails of Open Door Forum schedule updates and to view Frequently Asked Questions go to the CMS website at: [www.cms.hhs.gov/opendoor](http://www.cms.hhs.gov/opendoor)

### **FDA Plans New Board to Monitor Drug Safety**

On February 15, 2005, the Food and Drug Administration (FDA) announced it will create a new independent Drug Safety Oversight Board to oversee the management of drug safety issues. In addition, the Agency will provide new and emerging information to health providers and patients about the risks and benefits of medicines. Health and Human Services (HHS) Secretary Mike Leavitt announced that the move is an effort to restore public confidence in the nation's prescription drug supply. The new proposals focus on making the FDA's review and decision-making processes more independent and transparent.

The proposal includes creating an independent Drug Safety Oversight Board (DSB). The DSB will seek to enhance the independence of internal deliberations and decisions regarding risk/benefit analyses and consumer safety. The Board will oversee the management of important drug safety issues within the Center for Drug Evaluation and Research (CDER).

The DSB comprises of members of the FDA and medical experts from other HHS agencies and government departments (e.g., Department of Veterans Affairs) who will be appointed by the FDA Commissioner. The Board also will consult with other medical experts and representatives of patient and consumer groups. However, it will not include FDA medical officers or drug review officers, who might be reluctant to overturn their own earlier decisions.

The Agency is also proposing a new "Drug Watch" Web page for emerging data and risk information and increased use of consumer-friendly information sheets written especially for healthcare professionals and patients. The Agency will be soliciting public input on how FDA should manage potential concerns associated with disseminating emerging information prior to regulatory action. The Agency will issue draft guidance on procedures and criteria for identifying drugs and information for the Drug Watch Web page. In addition, FDA will actively seek feedback from healthcare professionals and patients on how best to make this information available to them. The Society will continue to monitor the development of the new programs and offer input when appropriate.

**CMS Releases Updated Memo:  
Infusion Pumps: C-Peptide Levels as Criteria for Use**

The Centers for Medicare and Medicaid Services (CMS) recently released a transmittal informing physicians, suppliers, and other providers that a new diagnostic criterion for the use of insulin infusion pumps is now covered under Medicare. According to CMS Transmittal 471, beta cell autoantibody testing, as an alternative diagnostic per the updated C-peptide testing requirement for the use of insulin infusion pumps, is effective for services performed on or after December 17, 2004.

In addition to meeting already established criterion, the beneficiary with diabetes must be insulinopenic per the fasting C-peptide testing requirement, or, as an alternative, must be beta cell autoantibody positive. Insulinopenia is defined by CMS as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. For patients with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine)  $\leq 50$  ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose  $\leq 225$  mg/dL. Levels only need to be documented once in the medical records.

The transmittal emphasizes that levels need only be documented once in the patient's medical records.

For billing purposes, Medicare carriers will accept, effective for services on or after December 17, 2004, CPT code 84681 (C-peptide) or CPT code 86337 (insulin antibodies) when diagnosis codes 250.00-259.93 are also reported on a claim.

Go to [www.cms.hhs.gov/manuals/transmittals/comm\\_date\\_dsc.asp](http://www.cms.hhs.gov/manuals/transmittals/comm_date_dsc.asp) to download a copy of the transmittal from the CMS web site.

For questions regarding articles listed in *Endocrine Insider* or information on advocacy and policy activities within The Endocrine Society, contact the Programs & Policy Affairs department:

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