

May 28, 2010

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Tavenner:

On behalf of the physician and medical student members of the undersigned organizations, we are submitting our comments and recommendations concerning the Centers for Medicare and Medicaid Services' (CMS) Interim Final Rule (IFR) *Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring and Documentation Requirements; and Changes in Provider Agreements* [CMS-600-IFC]. In general, we look forward to working closely with you and CMS to implement the varied program integrity measures contained in the Patient Protection and Affordable Care Act of 2010 (PPACA). Our collaboration will ensure a smooth transition to and adoption of processes, procedures, and systems that will enhance the agency's ability to limit improper payments as well as combat fraud without hindering physicians who are legitimately engaged in delivering high quality care to patients.

We are acutely aware of the challenges that the government has faced in combating fraud in the area of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) and home health services. We agree with previous statements by the Administration that taking a targeted approach and adding additional safeguards to vulnerable areas is the best way to address program integrity issues. **However, we have significant operational and implementation concerns with the provision in the IFR that requires all physicians who order or refer to be enrolled in Medicare by July 6, 2010. While we understand CMS is exploring ways to make this policy more flexible, we strongly urge CMS to reconsider the IFR provision accelerating this enrollment deadline and limit the policy to physicians who order or refer DMEPOS and home health services specifically named in the law.** Enrollment has perennially been an area where CMS contractors have struggled to implement agency changes with limited resources and within artificially short deadlines.

Timing of July 6, 2010 Deadline

Our chief concern is the timing associated with the IFR provision mandating that all physicians who order and refer most covered items and services for Medicare beneficiaries enroll in Medicare and have their enrollment information in the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) by July 6, 2010.

Under Section 6405 of PPACA, physicians who order and refer DMEPOS or home health services are required to be enrolled with Medicare by July 1, 2010. While the law only requires physicians who order or refer DMEPOS or home health services to be enrolled by July 1, CMS is mandating that physicians who also order or refer imaging, laboratory, and specialist services be enrolled by July 6, 2010. The IFR contains an exception to this requirement for physicians who have validly opted out of the Medicare program. However, such physicians must have a valid opt-out record in PECOS (but such physician is not required to submit an enrollment application). We have begun to field inquiries from physicians who have opted out expressing concern that they can no longer order and refer. As a result, an information campaign is required for these physicians as well.

The change in policy is a significant departure from the January 3, 2011, deadline established by CMS prior to the passage of PPACA for enrollment in PECOS of all referring and ordering physicians. Originally, the date was December 31, 2009, but CMS has delayed it twice—first to April 3, 2010 and then to January 3, 2011—once the agency agreed that more time was needed for outreach and to provide contractors with sufficient time to handle this change and other ongoing enrollment initiatives.

Past changes to the Medicare enrollment process, particularly ones involving substantial policy changes such as this one, have proven the need for a thoughtful and sufficient implementation timetable. Significant outreach has already been undertaken by CMS and our organizations to communicate to clinicians the January deadline. With an implementation date that is just over five weeks away, we are deeply concerned that implementing this policy to include anything more than physicians who order or refer DMEPOS and home health services will create significant confusion and bottleneck contractor customer service lines. Our concern over expanding the July deadline beyond physicians who refer or order services besides DMEPOS and home health is heightened by the other enrollment initiatives also underway which are already straining the current process. Physicians are now being asked to “revalidate” their enrollment information or to re-enroll if they have not done so in the past six years to ensure all their information is up to date. Physicians also continue to report to us serious problems accessing customer services hotlines and problems getting correct answers to their enrollment questions.

We are furthermore very concerned that implementing this policy could cause serious cash flow interruptions for “downstream” physicians who could see Medicare patients referred to them by physicians who are not yet enrolled/re-enrolled in the program and as a result impede access to care for patients. While PPACA requires physicians who refer or order DMEPOS or home health to be enrolled, it does not require them to be enrolled in PECOS. To reduce the potentially negative impact on downstream physicians, CMS could focus enrollment efforts on those who order and refer DMEPOS and home health who have never been enrolled in Medicare and allow physicians who are enrolled but not yet in PECOS until January to become re-enrolled. By providing those who are already enrolled additional time could further reduce the strain on the contractors as well.

Without the ability to bill Medicare for even a few weeks small practices, particularly those serving a large Medicare population, could be significantly disrupted. The new deadline also has significant repercussions for residents and teaching physicians. Since most residents are not permitted to enroll in Medicare because most do not have a full license, CMS is requiring the resident's teaching physician to be named on the claim as the referring or ordering physician. Teaching hospitals are now in the process of re-enrolling thousands of physicians, a process that is expected to take the remainder of the year. And, we are also concerned that the IFR accelerated deadline will impact beneficiaries and those medical practices already struggling to learn about, understand, and then implement the numerous program integrity provisions contained in the new health system reform law, particularly those with retroactive effective dates.

In order to give physicians sufficient time to enroll/re-enroll and for contractors to absorb this additional workload we urge CMS to:

- 1) Restrict the July 6 date solely to those named in the law, DMEPOS and home health, and permit physicians who order lab, imaging services, or specialist services to enroll/re-enroll by January 3, 2011;**
- 2) Not deny any claims for referrals or orders for imaging services, laboratory, or specialist services prior to January 2011 solely on the basis that the referring/ordering physician is not yet in PECOS;**
- 3) Increase contractor resources to:**
 - a. Support the Medicare contractors' enrollment workload to ensure backlogs are avoided, customer service lines are answered promptly (including the lines for the web-based PECOS and for the National Provider Identifier (NPI)), and information submitted by physicians is not lost; and**
 - b. Improve customer service training so that physicians consistently receive correct information;**
- 4) Develop an aggressive outreach enrollment campaign for physicians; and**
- 5) Work collaboratively with the medical community to ensure physicians clearly understand their enrollment responsibilities.**

If the deadline is not changed, we urge the agency to immediately provide contractors with a supplement for the specific purpose of physician outreach and enrollment processing. We urge CMS to direct contractors to set-up dedicated lines to expedite inquiries and problems related to enrollment and PECOS. In addition, we request that CMS begin sending out alerts through all electronic means, set-up open door meetings, and utilize other HHS communications tools to ensure physicians are aware of the accelerated deadline and have the ability to meet the requirements by the deadline.

Finally, we urge CMS to develop a contingency plan if the number of claims after July 6 begin to climb dramatically not as a result of fraud, but related to the enrollment deadline.

Other Concerns

In addition to the foregoing, the IFR contains provisions implementing PPACA section 6406 requiring physicians participating in Medicare to provide documentation on referrals to programs at high risk of waste and abuse. The IFR specifies that this provision will be expanded beyond DMEPOS and home health, and will also be applied to laboratory, imaging, and specialist services. The IFR, however, does not include an adequate analysis of the impact of this newly expanded requirement on physicians, particularly practicing clinicians in small practices. While maintaining the documentation may be consistent with business practices, providing access to both electronic and written documents to potentially a wide of array of program integrity and fraud auditors and investigators is not. Providing documentation in the regular course of business to contractors for claims processing is part of a regular administrative work flow. In contrast, repeated audits over a seven year range of time is not part of a regular administrative work flow and will cause considerable financial burden, absorb staff time and require investment in the maintenance of documentation. The foregoing necessitate resources that small practices do not have.

We are also concerned that the requirements for document retention vary considerably depending upon different components of the Medicare program. We receive numerous inquiries each year from physicians about how long they need to retain certain records. These requirements vary considerably depending on the purpose and physicians remain unclear on how long they need to retain documents.

We urge CMS to:

- 1) Reconsider the resources small practices will need to meet this new obligation to provide access to documentation to an expanded category of services over a seven- year period of time; and**
- 2) Provide education to physicians on document retention requirements that span the various components and programs of CMS so that physicians have a clear understanding of what they are.**

We would like to discuss what resources will be deployed to conduct extensive outreach and to build up contractor and agency capacity to rapidly and efficiently process enrollment applications and to communicate the new program integrity provisions contained in PPACA. We appreciate the opportunity to bring these concerns to your attention.

Sincerely,

American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Home Care Physicians
American Academy of Ophthalmology
American Academy of Otolaryngology– Head and Neck Surgery

American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Emergency Physicians
American College of Gastroenterology
American College of Osteopathic Surgeons
American College of Physicians
American College of Radiation Oncology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Medical Association
American Osteopathic Academy of Orthopedics
American Psychiatric Association
American Society for Radiation Oncology
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of Hematology
American Society of Nuclear Cardiology
American Thoracic Society
American Urological Association
Child Neurology Society
College of American Pathologists
Congress of Neurological Surgeons
Heart Rhythm Society
Infectious Diseases Society of America
Joint Council of Allergy, Asthma and Immunology
Medical Group Management Association
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Critical Care Medicine
Society of Hospital Medicine
Society of Interventional Radiology
The Endocrine Society