



AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

February 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244-1850

Dear Ms. Norwalk:

The American College of Physicians, which represents over 120,000 physicians who specialize in internal medicine and medical students, requests that the Centers for Medicare and Medicaid Services (CMS) address continuing difficulties regarding the use of Part D vaccines. While the College appreciates CMS's support of recent language in the Tax Relief and Health Care Act of 2006 that provided a means for physicians to be paid for the administration of these Part D vaccines, there remain substantial problems with the delivery of and payment for the actual vaccine. More specifically, the College is concerned about problems our members are encountering in their efforts to protect their Medicare patients from the significantly debilitating condition of Herpes-Zoster (shingles), and the consequences of post-herpetic neuralgia.

As you are aware, in May 2006 the Federal Drug Administration approved a Herpes-Zoster (H-Z) vaccine (Zostavax) for persons 60 years or older that was found in clinical trials to be safe and effective in preventing the condition and reducing the symptom intensity for patients who developed the condition. Subsequently, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC) passed a motion in October 2006 recommending that adults 60 years and older receive the H-Z vaccine. Unfortunately, our members are experiencing difficulties in making this vaccine accessible to their Medicare patients – the population most likely to benefit from its use. This is despite the fact that a May 8, 2006 memo by Abby Block, Director, Center for Beneficiary Choices at CMS to Part D Sponsors clearly states that all Part D plans “are required to provide access to vaccines not covered under Part B” and recent assurance from Dr. Jeffrey Kelman, Chief Medical Officer, Center for Beneficiary Choices at CMS that all Part D plans must have provisions for the delivery of and payment for this vaccine. The College offers the recommendations below to CMS to help correct this situation.

- The ACP recommends that CMS require all Part D plans to make clear on their websites and relevant printed materials their specific provisions for approving the payment for H-Z vaccine use, their process for providing the vaccine, and the procedures that must be



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followed for physicians (if they bill the plan directly) or beneficiaries to be reimbursed if the vaccine was provided out-of-network.

Rationale: The relatively high cost of the H-Z vaccine, approximately \$150 - \$200 a dose, serves as a significant barrier for the use of the vaccine for many Medicare beneficiaries. The fact that the medically necessary use of this vaccine is covered under the Part D benefit substantially removes this barrier. Unfortunately, the processes to obtain the necessary approval for the vaccine from the drug plans, and to obtain the vaccine and reimbursement for out-of-network supply of the vaccine, are far from transparent. Our members and their patients frequently encounter problems obtaining information from Part D plans regarding whether they actually cover the vaccine, as well as how the vaccine should be obtained and how the physician or beneficiary should be reimbursed if the vaccine comes from the physician's own supply. A clear statement by CMS (coupled with enforcement) that the plans must provide easily accessible information on their websites and other relevant printed materials on the issues outlined above would significantly improve this situation.

- The ACP recommends that CMS expedite the development and implementation of non-burdensome mechanisms to reimburse physicians and beneficiaries for the cost of the H-Z vaccine through Medicare Part D.

Rationale: Those College members who have been able to obtain the relevant delivery and payment information regarding the H-Z vaccine typically purchase the vaccine from the manufacturer, establish the necessary vaccine storage conditions (e.g. a freezer) in their offices, and bill the patient a usual and customary charge for the vaccine. The patient then is required to attempt to receive reimbursement from their Part D plan. At a minimum, this places the patient "at risk" for the full cost of the vaccine, and often adds a great deal of work for the physician and his/her office staff regarding obtaining information on the plan's approval process and assisting the beneficiary in obtaining the reimbursement. The May 8, 2006 memo referenced above outlined several alternative mechanisms to facilitate vaccine access and payment, including: in-network specialty pharmacy distribution of the vaccine to the physician's office; the creation of a model vaccine-specific notice that the plan enrollee could bring to their physician that provides all the information necessary for the delivery of and payment for the vaccine; and the development of a web-assisted electronic physician billing system, which would provide the physician with relevant patient, plan coverage and payment information regarding the Part D vaccine, and would allow the physician to bill the plan for the vaccine directly. While the College has previously communicated its preference for the web-based option in a June 29, 2006 letter sent to then CMS Administrator McClellan, and signed by a number of medical societies, the expedited implementation of any of these procedures at this time would help to improve the situation.

ACP

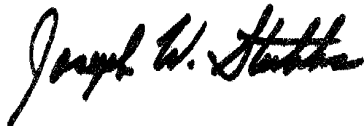
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- The ACP recommends that CMS publish a Medicare Learning Network (MLN) article/pamphlet that in one document provides physicians with all the information they need to know regarding delivery of and payment for Part D vaccines, and the vaccine's administration.

Rationale: Communication with our members reflects substantial confusion and lack of information regarding how they should provide their Medicare patients with Part D covered vaccines. These physicians are used to providing patients with Part B covered Influenza, Pneumococcal and Hepatitis B vaccines. The publication of a MLN document that addresses in a comprehensive manner delivery and payment issues regarding Part D vaccines would help to clarify this currently confusing service area and would help ensure that Medicare beneficiaries will receive these treatments when appropriate.

In summary, the recent approval of the H-Z vaccine offers an opportunity to protect the health and quality of life for our Medicare beneficiaries. The College believes that implementation of the above recommendations will go a long way to improve the access to this vaccine. Please contact Neil Kirschner, Senior Associate, Insurer and Regulatory Affairs at 202 261-4535 or nkirschner@acponline.org if you have any questions regarding these recommendations.

Sincerely,



Joseph Stubbs, MD, FACP
Chair, Medical Service Committee