

June 25, 2009

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Access to Preventive Vaccines under Medicare

Dear Secretary Sebelius:

The undersigned organizations are writing to request that you take steps to help ensure that Medicare beneficiaries have meaningful access to all recommended adult vaccines. Specifically, we are writing to request that the Department of Health and Human Services (HHS), acting through the Centers for Medicare and Medicaid Services (CMS), use the authority granted by Section 101 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) to include all recommended preventive vaccines within the “additional preventive services” eligible for coverage under Medicare Part B.

As you know, Medicare beneficiaries have ready access to the influenza, pneumococcal and hepatitis B vaccines under Medicare Part B. CMS also does a good job of working with its partners to educate beneficiaries and physicians about the importance of these vaccines, as well as how to access coverage and payment under Medicare Part B.

Unfortunately, the record is significantly less successful for vaccines covered under the Part D Prescription Drug Benefit. As you may know, coverage of, and access to, vaccines under the Part D retail pharmacy benefit is complex and problematic. In large part, this is because these vaccines are typically physician-administered while Part D is designed as a retail pharmacy benefit.

There are a host of Part D associated technical and operational issues that make beneficiary access to immunizations difficult. Of particular concern, individual patients generally are required to pay the entire cost of physician-administered vaccines out-of-pocket in the physician office setting (an out-of-network provider) and then attempt to gain reimbursement from their Part D plan through a paper claim process. This creates a significant barrier to access, especially for low-income beneficiaries. In addition, coverage of the administration fee for Part D vaccines is variable, and depends on the Part D carrier.

As a result of the adverse impacts on patient access that arise from these issues, a recent national survey of physicians regarding their practice with respect to herpes zoster vaccine sponsored by the Centers for Disease Control and Prevention (CDC) demonstrated that a significant number of patients are purchasing Part D vaccines from

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in-network pharmacies and then transporting the product to their physician's office. However, this so-called "brown bagging" approach is dangerous for many preventive vaccines that must be frozen or refrigerated until immediately prior to use and it is difficult for the physician to verify the storage chain from the pharmacy to his/her practice.

Despite efforts to address some of these issues, CMS has been unable to identify effective solutions to the underlying programmatic issues that interfere with access to vaccines under Medicare Part D. As a result of the fundamental problems with access to vaccines under Part D, the Medicare Payment Advisory Commission (MedPAC) recommended in June of 2007 that appropriate preventive vaccines be covered under Medicare Part B instead of Part D. In support of this recommendations, in 2008, the American Medical Association, Infectious Diseases Society of America, and other medical societies (including many that have also signed onto this letter), urged that vaccines be covered under Medicare Part B rather than under the Part D plans.

However, the Part D benefit is now in its third year of operation and there is no indication that the vaccine issue is remotely close to being resolved. There is currently a new opportunity to improve access to, and coverage of, new adult vaccines. Specifically, Section 101 of MIPPA authorizes the Secretary to cover additional preventive services that are not expressly named within the Social Security Act. To qualify, the services must first be recommended by the U.S. Preventive Services Task Force (USPSTF) and then assessed under Medicare's national coverage determination process.

The USPSTF – an independent panel of experts in primary care and prevention – regularly reviews scientific evidence to develop recommendations designed to help clinicians evaluate clinical preventive services. The USPSTF includes by reference in its *Guide to Clinical Preventive Services* the recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP). The CDC's ACIP, in turn, is comprised of immunization experts selected by the HHS Secretary to provide recommendations for the routine administration of vaccines to children and adults, including age and dosage recommendations.

The ACIP is the only entity in the federal government that makes such recommendations regarding vaccines. In fact, ACIP's recommendations for the coverage of preventive vaccines are considered to be the "gold-standard" for coverage policies. For instance, within its Call Letter to Medicare Part D plans in April 2007, CMS indicates plans should facilitate access to ACIP-recommended vaccines.

In conclusion, under MIPPA, Congress provided the necessary mechanism for HHS and CMS to provide Medicare beneficiaries with meaningful access to preventive vaccines under Medicare Part B. This is important in light of reports of limited access to vaccines covered under Part D, especially for Part D enrollees with low incomes. Given that the USPSTF incorporates the recommendations of the CDC's ACIP on vaccines by reference, we urge HHS and CMS to interpret Section 101 of MIPPA to provide for

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coverage of vaccines recommended by ACIP. CMS' actions to consolidate all vaccines under Medicare Part B will promote the interests of Medicare beneficiaries by further advancing Medicare's focus on prevention. We further urge that such consolidation be considered the result of a change in law (i.e., MIPPA), so that the resulting costs to Medicare Part B are appropriately accounted for in the calculation of the Sustainable Growth Rate going forward.

We ask that you quickly review this issue and move to use the authority granted by Section 101 of MIPPA to include all recommended preventive vaccines within the "additional preventive services" eligible for coverage under Medicare Part B. As you review this matter, we would appreciate the opportunity to meet with your staff to discuss this important issue further. Such a meeting can be arranged through Sandy Marks at American Medical Association at sandy.marks@ama-assn.org or 202-789-4585.

Thank you for your time and prompt consideration of this matter. We look forward to your response.

Sincerely,

American Academy of Allergy, Asthma and Immunology
American Academy of Family Physicians
American College of Allergy, Asthma and Immunology
American College of Chest Physicians
American College of Obstetricians and Gynecologists
American College of Osteopathic Internists
American College of Physicians
American College of Preventive Medicine
American Gastroenterological Association
American Geriatrics Society
American Medical Association
American Medical Directors Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Society of Clinical Oncology
American Society of Hematology
American Society of Plastic Surgeons
American Thoracic Society
Infectious Diseases Society of America
Joint Council of Allergy, Asthma and Immunology
Medical Group Management Association
Partnership for Prevention
Society of Hospital Medicine