



November 16, 2006

Leslie Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave, SW #316G
Washington, DC 20201

Dear Administrator Norwalk:

The Biotechnology Industry Organization (BIO) is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO is committed to ensuring beneficiary access to innovative biological therapies including vaccines and asks that you revisit current policy towards dispensing fees under Medicare Part D. BIO believes that the current narrow definition of dispensing fees compromises Medicare beneficiary access to life saving vaccines.

BIO understands that CMS will soon issue a Notice of Proposed Rulemaking (NPRM) addressing some technical issues under Medicare Part D. Specifically, BIO urges CMS to include in any forthcoming Part D NPRM a proposal to include vaccine administration fees within the scope of the Part D dispensing fee. The preamble to the final Part D regulation clearly implies that the definition and scope of dispensing fee is at the discretion of CMS and further states that the statute is ambiguous on the meaning of the term.¹

CMS chose a definition of dispensing fee that is very narrow – including only those pharmacy and professional costs associated with the transfer of possession of a covered Part D drug from the pharmacy to the beneficiary.

¹ Final Part D Regulation. Federal Register Vol. 17, #18, January 28, 2005. page 4234

CMS proposed and then rejected two other definitions of dispensing fees that would have allowed for broader coverage of professional services related to providing covered Part D drugs, including vaccine administration fees.² The preamble specifically recognized the problems created by omitting coverage of vaccine administration.

"Given the definition of a dispensing fee we have incorporated in the final rule, the costs of Part D vaccine administration could not be covered as part of a dispensing fee. Neither could those costs be covered as separate administration fees, since as discussed elsewhere in this preamble, other than medication therapy management programs.....we do not expect medical or clinical services to be included." ³

The preamble goes on to explain that doctors will be able to bill Medicare Part B for administration of Part D vaccines to compensate for the narrow dispensing fee definition. However, subsequent to issuing the final Part D rule, CMS clarified that Medicare Part B can only pay for administering vaccines covered under Medicare Part B—reversing its statement from the preamble and inhibiting access to vaccines.

CMS has the authority to re-visit the definition of the Part D dispensing fee and must do so in light of the policy reversal on the availability of Part B for billing of physician administration of Part D vaccines. CMS chose its original dispensing fee definition and the Part B policy precisely to make sense of the clear intent of Congress – that physician administered vaccines are a covered Part D drug. Given that another solution has not emerged, BIO strongly believes that CMS now has an obligation to re-visit the series of issues and policies around vaccine administration in order to be consistent with statutory intent.

While CMS and others may have concerns about broadening the definition of dispensing fee to one of the two other options first suggested in the Part D proposed rule, we believe there is yet another option. Dispensing fees could be expanded solely to include vaccine administration fees to align with the

² The Final Part D Regulation included three dispensing fee definition options. The first is the definition currently in use which limits coverage to activities related to transfer of possession. The second would have added coverage of supplies and equipment necessary for the covered drugs to be effectively administered. The third proposed definition would have also included activities to ensure proper administration of a covered drug. (page 4234, Fed Reg 1/28/05)

³ Final Part D Regulation. Federal Register Vol. 17, #18, January 28, 2005. page 4231

express statement of vaccine coverage found in the statute. This would be a new approach that is narrower than previously rejected options.

We urge CMS to include this proposal in any forthcoming proposed Part D NPRM. Appropriate, complete, and rational coverage of the costs associated with Part D vaccines is important for beneficiary access which will otherwise be impeded – particularly for low income subsidy beneficiaries -- if administration fees become a wholly uncovered service.

BIO supports the Final Rule and Congressional intent and further believes that it is good public policy to ensure beneficiary access to vaccines. We look forward to your consideration and resolution of this very important policy issue.

Sincerely,

/s/

Jayson Slotnik
Director, Medicare Reimbursement
& Economic Policy
Biotechnology Industry Organization (BIO)

CC:

Jeffrey Kelman, Chief Medical Officer, Center for Beneficiary Choices
Larry Kocot, Senior Advisor, CMS
Herb Kuhn, Acting Deputy Administrator