



COMMONWEALTH OF PENNSYLVANIA
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Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 2003P-0029

Re: Impact on Medicaid of Proposed Rule Regarding Use of Ozone-Depleting Substances

To Whom It May Concern:

The Pennsylvania Medical Assistance (MA) Program is aware that the U.S. Food and Drug Administration (FDA) is in the process of determining the date that chlorofluorocarbon (CFC)-containing albuterol metered dose inhalers (MDIs) will be banned from the U.S. marketplace.

Throughout the past several years under the Pennsylvania MA program, nearly all albuterol MDIs that have been dispensed have been generic. However, until hydrofluorocarbon (HFA) inhalers come off patent and generic alternatives are permitted to enter the U.S. market, the phase-out of CFC inhalers will effectively force the Pennsylvania MA program to dispense more costly branded inhalers thereby adding costs to an already strained budget. Additionally, the affordability of albuterol MDIs for those MA recipients with no prescription benefits will be questionable at best thus placing the health and life of low-income patients at risk.

We believe the FDA is aware that the cost of branded inhalers is *double* that of the generic inhalers; their cost is approximately \$40 per inhaler whereas generic CFC inhalers are approximately \$20. Not only will the sole availability of branded albuterol MDIs make access to rescue therapy cost-prohibitive, but those patients who can no longer afford their inhalers will inevitably be forced to seek emergency department care, further burdening the health care system.

From February 2003 through February 2004, there were 102,758 claims for all types of albuterol inhaler drug products, totaling a cost of approximately \$2,000,000.00 to the Pennsylvania Fee-For-Service (FFS) MA program. The FFS delivery system covers approximately one third of our total MA population or roughly 500,000 lives. The remaining one million covered lives are served through our managed care delivery system. Were the same number of claims for FFS recipients fulfilled solely with

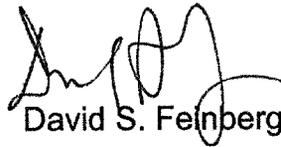
2003P-0029

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branded HFA inhalers, the total cost would have been \$4,000,000.00. As you can see, this change will have a significant fiscal impact on the already strained Pennsylvania MA program.

We are aware that the comment period for this rulemaking has closed; however, we hope the FDA will consider this request to postpone the phase-out until generic albuterol alternatives are permitted to enter the U.S. market.

Sincerely,



David S. Feinberg