

# FLORIDA MEDICAID



JEB BUSH, GOVERNOR

ALAN LEVINE, SECRETARY

February 3, 2005

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Division of Dockets Management  
U. S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 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 Florida Medicaid 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 Florida Medicaid 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 Medicaid to dispense only the more costly branded inhalers or not dispense them at all, placing the health and life of low-income patients at risk. We believe that FDA is aware that branded CFC free inhalers cost more than double—their retail cost is approximately \$47 per inhaler whereas generic CFC inhalers are approximately \$18. Not only will the sole availability of branded albuterol MDIs make access to rescue therapy cost-prohibitive, but also 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 January 1, 2004 through December 31, 2004, there were 305,733 claims for all types of albuterol inhaler drug products, totaling a cost of \$5,543,401 to the Florida Medicaid program. Were the same number of claims fulfilled solely with branded HFA inhalers, the total cost would have been \$20,057,907. This would amount to a \$14,514,505 (361.83%) increase to Florida's Medicaid program for this type product if the CFC inhalers are phased out.

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

Sincerely,

Thomas W. Arnold  
Deputy Secretary for Medicaid

03P-0029



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