November 7, 2000

Dear State Medicaid Director:

The Health Care Financing Administration periodically publishes Federal upper limits (FUL) on certain Medicaid drugs to ensure that the Federal government acts as a prudent buyer of drugs.

I am writing to inform you that the June 2000 revised FUL issuance you received in April, along with the enclosed changes, should be implemented no later than December 7, 2000. I want also to summarize for you the efforts that we have taken in conjunction with your help to assure that this list is accurate. This has been a significant undertaking and we are grateful for the efforts and cooperation provided by officials from all States.

The FUL list includes those drugs where the Food and Drug Administration (FDA) has determined there are sufficient generic equivalents and where national drug pricing compendia (e.g., First Data Bank, Medical Economics and MediSpan) demonstrate there are sufficient drug suppliers listing the drug for sale nationally as set forth in 42 CFR 447.332.

The authority to set upper limits for services available under the Medicaid program is provided under Federal regulations at 42 CFR 447.332, in accordance with section 1902(a)(30)(A) of the Social Security Act. (See 52 FR 28648 dated July 31, 1987 and 51 FR 29560 dated August 19, 1986.) As a general rule, in accordance with the regulations, the FUL is based on an amount that is equivalent to 150% of the published price for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules. The 150% threshold assures a sufficient range so that pharmacists can purchase the drug from multiple sources. Also note that this is an aggregate upper limit. (See 42 CFR 447.332(b)). You can continue to adjust the prices of individual drugs at the State level as long as your aggregate expenditures do not exceed the amount you would have otherwise spent by applying these specific limits plus a reasonable dispensing fee.

HCFA last issued an FUL price list effective September 1998. In April 2000, HCFA issued an update that was intended to take effect in June 2000. However, in response to the update, some States and representatives of the chain drug stores and other pharmacy providers identified data problems with the commercial pricing compendia used in the preparation of the FUL list. To respond to these concerns we prepared an amended list, which we initially believed addressed these concerns, and sent it to State Medicaid Agencies and pharmacy organizations on June 15 with an effective date of August 1. Concern

was again raised by the National Association of Chain Drug Stores, long term care pharmacy providers, and some individual pharmacy chains about the publication of the FUL prices and data problems with commercial pricing compendia. To allow us to validate the accuracy of these concerns, the August 1, 2000 FUL effective date was delayed.

As discussed below, consistent with the regulations, we believe we have addressed the concerns raised. Further, we have taken steps to update our FUL list and have made every effort to address all comments on specific drugs. Specifically, we have responded to State and pharmacy concerns by:

polling all State Medicaid Agencies to receive specific drug concerns on the amended FUL listing and subsequently addressed all concerns raised by States;

addressing specific concerns raised by the National Association of State Medicaid Directors, the Pharmacy Technical Advisory Group, National Association of Chain Drug Stores, long term care pharmacy providers, pharmacy organizations and manufacturers;

responding to all specific pharmacy requests to review the price set for certain drugs by contacting manufacturers, suppliers and the pricing compendia to assure our information is up to date;

eliminating the listing of multiple drug package sizes; and

working with drug pricing compendia to publish the source used in determining the FUL price and to make available the specific NDC used to establish the FUL price.

Because of the complexity of the drug marketplace, it is possible that pricing or the inclusion of individual drugs on the FUL list may still need to be revised. The FUL publication has always included a process for updates and corrections as new information becomes available and that process will continue to be in place. As revised information on market conditions, cost or availability becomes available we will amend the list to reflect these changes as may be necessary.

I apologize that the completion of this latest FUL list has taken so long. However, I believe we have reviewed the list, responded carefully, and made every effort to assure that in accordance with the statute and regulations this FUL list is correct so that no Medicaid beneficiaries are denied pharmacy services and the Medicaid program pays a fair price for these drugs. We are also committed to continue to work with you and the pharmacy industry to assure that data used to develop the FUL are accurate. If you have any questions please contact Sue Gaston at (410) 786-6918 or Sgaston@hcfa.gov or Cindy Pelter at
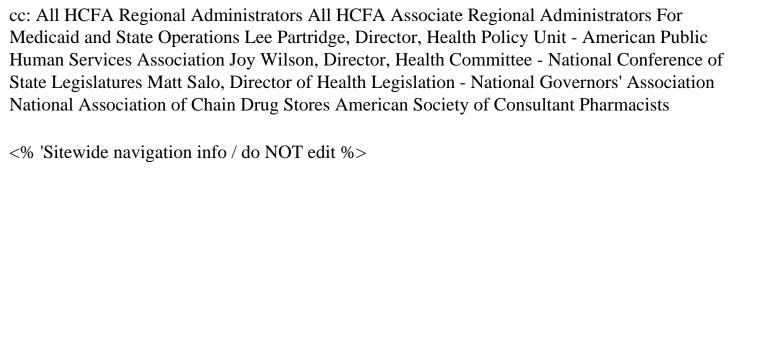(410) 786-1176 or Cpelter@hcfa.gov.

Sincerely,

/s/

Timothy M. Westmoreland
Director

Enclosures:

Enclosure A
Enclosure B

cc: All HCFA Regional Administrators All HCFA Associate Regional Administrators For Medicaid and State Operations Lee Partridge, Director, Health Policy Unit - American Public Human Services Association Joy Wilson, Director, Health Committee - National Conference of State Legislatures Matt Salo, Director of Health Legislation - National Governors' Association National Association of Chain Drug Stores American Society of Consultant Pharmacists

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