## MEDICARE PART A BULLETIN

January 7, 1997 General Medicare Bulletin G-256

TO: All Medicare Providers

FROM: Andy DePirro, Director, Program Relations

SUBJECT: REVACCINATION OF BENEFICIARIES WHO RECEIVED RECALLED

INFLUENZA VIRUS VACCINE (FLUOGEN)

**ATTENTION MEDICARE BUSINESS OFFICE**: Please distribute to all appropriate health care facility personnel.

On December 16, 1996, the United States Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) released the following information to health care providers. On November 1, November 6, and November 26, 1996, the Parke-Davis division of Warner-Lambert Company voluntarily recalled eleven (11) lots of their *trivalent influenza virus vaccine* (*Fluogen*) because of decreased potency of the A/Nanchang/933/95 (H3N2) component of the vaccine. The recalled lots were:

00176P	00276P	00576P	00586P
00676P	00686P	00786P	00886P
00966P	00986P	1066P	

Doses from these lots were administered to approximately 5-7% of all those who received the 1996-97 influenza virus vaccine.

A study of elderly nursing home residents vaccinated with *Fluogen* from the recalled lots has shown that because of the reduced potency of the vaccine they received, they are at somewhat greater risk of acquiring serious influenza illness from the A/Nanchang influenza strain or developing a clinical complication if they become ill with influenza. Therefore, the CDC and the FDA have recommended that high risk individuals who received *Fluogen* from the lots recalled by Parke-Davis should be revaccinated with the remaining supplies of influenza vaccine. High risk individuals include all persons age 65 years of age and older but especially those with underlying chronic medical conditions such as cardiac or pulmonary disease.

Medicare covers medically necessary revaccination of beneficiaries with the influenza virus vaccine and, therefore, will make payment for revaccination of beneficiaries who received *Fluogen* from the recalled lots.

Information from the CDC indicates that the recalled lots were distributed throughout the United States. Therefore, the Health Care Financing Administration (HCFA) has instructed all Medicare contractors (intermediaries and carries) to inform physicians and other providers via the provider bulletin mechanism that **Medicare will pay for revaccination of beneficiaries who received** 

## Fluogen from the recalled lots.

Providers are not required to specially code or otherwise annotate claims for revaccination of the affected beneficiaries. These claims should be billed just the same as any influenza vaccinations; however, under some circumstances, Medicare contractors may develop these claims for medical necessity.

## ADDITIONAL MEDICARE BULLETINS REGARDING INFLUENZA VACCINE

Providers may obtain additional information regarding the coverage and billing of the influenza vaccine (or pneumococcal pneumonia vaccine) by referencing the following Medicare Part A Bulletins:

<u>Medicare Bulletin Number</u>	<u>Bulletin Date</u>	
General Medicare Bulletin G-247	November 26, 1996	
General Medicare Bulletin G-235	October 3, 1996	

You may obtain bulletin copies by calling the Medicare A Xpress (MAX) Line, which is a voice messaging service available 24 hours per day, 7 days per week, at 904/355-8263; or Contact the Medicare Part A Customer Service Department by calling (904)355-8899.