



United States Senate

WASHINGTON, DC 20510-0905

May 26, 2009

Dr. Mary Wakefield
Administrator
Health Resources & Services Administration
Parklawn Building, 14-05
5600 Fishers Lane
Rockville, MD 20857

Dear Administrator Wakefield:

We write in reference to guidelines proposed by the Health Resources and Services Administration (HRSA) on January 12, 2007 that would create a new definition of "patient" under the Public Health Service Act Section 340B Drug Discount Program. We would like to respectfully urge that the rule be revised substantially before being finalized.

As you know, eligible hospitals are prohibited from administering or dispensing drugs discounted under the 340B program to anyone other than their patients. By restricting the definition of "patient" under the 340B program, we are concerned that the proposed guidelines would place a new administrative burden on hospitals and physicians. Hospitals could have to overhaul their purchasing and dispensing systems, inventory management programs, and other core practices designed to comply with current guidelines. Furthermore, pharmacists could have to perform research to ascertain the status of each patient's medical records, the relationship between the prescriber and the covered entity, and the services that give rise to the prescription.

These administrative requirements could undermine the ability of hospitals and physicians to serve the indigent populations the 340B program is meant to support. Moreover, we are concerned that the restrictive definition could exclude outright many individuals currently eligible for 340B discounts. Populations at risk of losing access to discounted medications include: discharged patients whose prescriptions for outpatient drugs were written while they were inpatients and are crucial to their post-hospitalization care; patients receiving hospital services in health departments, nursing homes, and home health agencies; patients treated in hospital-based indigent care and pediatric clinics; and patients treated by hospital contract providers in order to improve access or address hospital over-capacity problems.

We understand the importance of ensuring that medications purchased under the 340B program are provided to eligible patients as intended under the law. However, we urge you to revise your proposed rule so it does not impose an undue administrative burden on providers, and that it does not unintentionally exclude deserving populations.

Sincerely,

Handwritten signature of Bill Nelson in black ink, written over a horizontal line.

Handwritten signature in black ink, written over a horizontal line.

Norm Feig

Whitney

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Care MacCall

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