

Congress of the United States
Washington, DC 20515

May 19, 2009

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

Dear Dr. Wakefield:

We are writing to express concern about guidelines proposed by the Bush Administration on January 12, 2007 that would create a new definition of "patient" under the Public Health Service Act Section 340B Drug Discount Program. While the previous administration did not finalize these guidelines, the language has not yet been formally withdrawn by HRSA.

As you know, eligible disproportionate share hospitals, community health centers, and other covered entities are prohibited from dispensing or administering drugs discounted under the 340B program to anyone other than their patients. By substantially restricting the definition of "patient" under the 340B program, the proposed guidelines would create a new administrative burden on hospitals and health care practitioners, and ultimately, would reduce access to affordable medications for vulnerable patients. Hospitals and health care centers would have to overhaul their purchasing and dispensing systems, inventory management programs, and other core practices designed to comply with the existing guidelines. Pharmacists would 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 unnecessary administrative requirements would undermine the ability of safety net providers to offer comprehensive care, including pharmacy services, to indigent populations the 340B program was created to support. Moreover, 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 recovery; patients receiving hospital services in health departments, nursing homes, and home health agencies; patients treated in indigent care and pediatric clinics; and patients treated by hospital contract providers in order to improve access or address hospital over capacity problems.

The proposed guidelines would also jeopardize the many innovative partnerships between 340B providers and state, county, and municipal governments. For example, several state and county corrections systems outsource health care services, including pharmacy

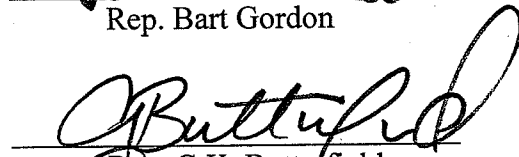
services, to 340B hospitals. The proposed patient definition guidance would eliminate access to 340B discounted drugs in these partnership arrangements which, in turn, would drive up health care costs for state, county, and municipal governments.

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 withdraw the guidelines issued by the previous administration and instead work with 340B providers to develop practical standards for determining patient eligibility in this vital program.

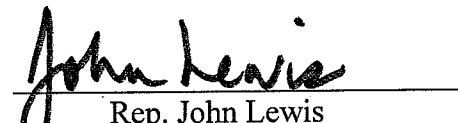
Sincerely,

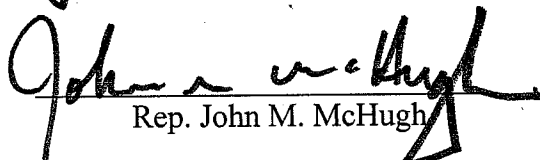

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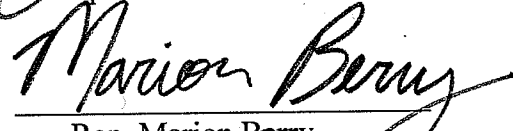

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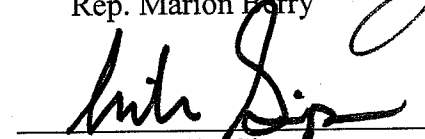

Rep. John M. McHugh

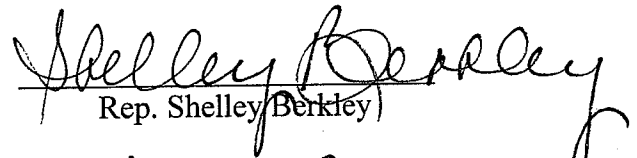

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Rep. Dennis Kucinich

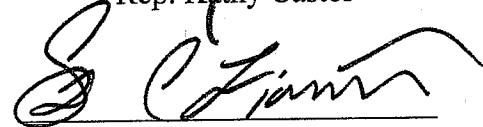

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