

Congress of the United States
Washington, DC 20515

July 22, 2008

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Dear Secretary Leavitt:

Several among the signatories of this letter wrote to you on December 14, 2007 requesting immediate action and assistance in clarifying the scope of the regulation concerning "physician administered drugs" under the Medicaid rebate program. Your office has issued no clarification of this rule since our last letter. All of the signatories on this letter reiterate the need for your immediate action on this issue and request an across the board delay until March 31, 2009 from further implementation. Our concerns are outlined below.

CMS is Misinterpreting the Hospital Clinic Exemption from the Rebate Program

CMS is misinterpreting the clear language and intent of § 1927(j) of the Social Security Act which exempts hospital outpatient clinics from the Medicaid Drug Rebate Program for drugs billed at the hospital's "purchasing cost as determined under the State plan." The plain language of the federal statute states clearly that a drug billed by a hospital clinic is exempt from rebate if the reimbursement for the "purchasing cost" is set under the state plan. CMS is not authorized by law to substitute "purchasing cost" with "actual acquisition cost" as the exemption clearly reserves that function for the states.

CMS is erroneously equating "purchasing cost as determined under the State Plan" with actual acquisition cost (AAC). They are not the same thing. The term "purchasing cost" was structured by the Congress to include all of the costs of purchasing a drug, and not just the acquisition cost of the drug. When Congress enacted section 1927(j)(2) in 1990, the phrase "purchasing costs" was not defined in federal statute or regulation. The term "actual acquisition cost," by contrast, has been part of federal law since 1968. Thus, in choosing to use the phrase "purchasing costs," Congress intended to include all of the costs associated with purchasing a drug, not just the acquisition cost of the drug. This would include such costs as wholesaler fees, the labor costs attributable to placing orders and other in-house purchasing activities, maintenance costs such as the cost of refrigeration and storage, and the costs of transporting the drug from the warehousing facility to the hospital, all of which cost more than the AAC of the drug purchased.

CMS' substitution of "actual acquisition cost" for "purchasing costs as defined by the State Plan" contravenes the intended purpose under § 1927(j) of which inherently recognizes that hospital outpatient clinics and managed care organizations (MCOs) already receive significant private rebates or discounts from manufacturers because they utilize formularies to negotiate deep discounts and share those discounts with states. Given that states are already benefitting indirectly from manufacturer discounts negotiated privately by MCOs and hospitals, there is no need for manufacturers to pay additional rebates to states directly. Identifying which MCO and hospital outpatient drugs are exempt from rebates and how much these drugs should be billed and reimbursed in order to reduce Medicaid expenditures is a matter governed by state coverage and reimbursement rules for outpatient drugs. How states structure coverage and reimbursement of MCO and hospital outpatient drugs varies from state to state because they involve balancing a variety of competing interests, including lowering drug costs, improving patient access and

supporting provider participation in Medicaid. In drafting § 1927(j), Congress recognized that states are in a better position than the federal government in identifying and weighing these various factors.

Congress did not change the § 1927(j) exemption for hospital clinics when it enacted § 6002 of the DRA requiring NDC collection for physician administered drugs. Prior to the enactment of § 6002, CMS viewed hospital physician administered drugs as subject to rebates only if the drug is used in the outpatient pharmacy and the hospital bills Medicaid for reimbursement for dispensing the outpatient drug. Because physician administered drugs are typically not used in a hospital outpatient pharmacy, hospital physician administered drugs have historically been exempted from the rebate program. The shift in CMS policy is unjustified absent an action by Congress to amend section 1927(j)(2).

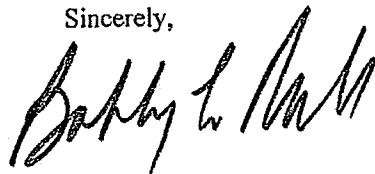
CMS Should Further Delay Implementation of Rule

We are very concerned that CMS failed to complete cost analyses necessary to comply with the legal prerequisites for valid rulemaking under the Regulatory Flexibility Act and the Paperwork Reduction Act of 1995. Medicaid agencies have reported to CMS that it has "significantly underestimated the burden of this provision on States." Recognizing the massive confusion among states and hospitals, CMS granted numerous waivers over the past six months. At this time, many states and hospitals are simply unprepared to comply with CMS' requirement of NDC reporting for hospital outpatient drugs when most of those waivers expired on July 1, 2008. There remains widespread confusion among State Medicaid agencies and hospitals in how to comply with the new rule.

Further, the rule unnecessarily imposes enormous financial burdens on all hospitals and will be particularly devastating to safety-net hospital clinics serving high percentages of indigent and underinsured patients. CMS maintains that hospitals participating in the 340B program may only be exempt from the reporting requirement under existing law if they bill the Medicaid program at the hospital's actual acquisition cost, which could essentially nullify any 340B discount. These hospitals rely heavily on savings achieved through participation in the 340B drug discount program to enable them to continue to provide sophisticated and expensive drug treatments needed to treat ailments such as cancer and autoimmune deficiencies and prevent post-transplant organ rejection in these traditionally underserved populations. Further, the rule will greatly diminish the ability of children's hospitals to take advantage of recent legislative policy changes allowing their participation in the 340B federal drug discount program

We request that you direct CMS to immediately delay further implementation of the rule as applicable to hospital outpatient clinics until March 31, 2009 and clarify its interpretation of the physician administered drug regulation in a manner that does not defy the intent of § 1927(j). We look forward to your prompt reply to this request.

Sincerely,



Bobby L. Rush
Member of Congress



Jo Ann Emerson
Member of Congress



Diana DeGette
Member of Congress

Paul Buchanan

Member of Congress

Sam Am

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Bob Kline

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Shelley Moore Capito

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Harold D. B. Lofgren

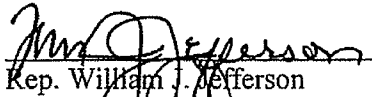
Member of Congress

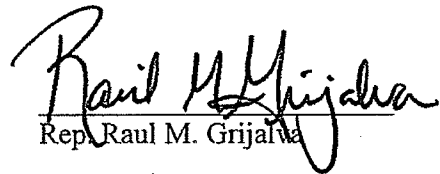
Walter B. Jones

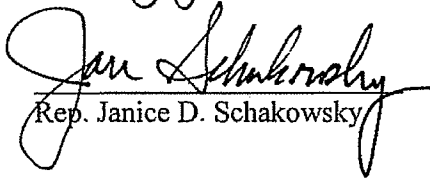
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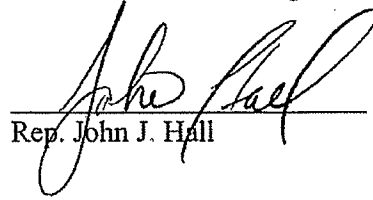
Tom Bonner

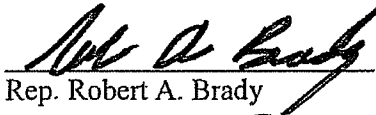
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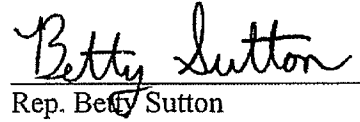

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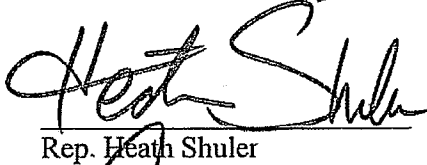

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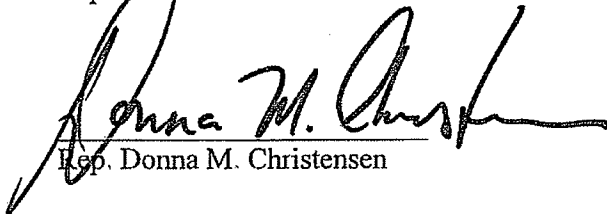

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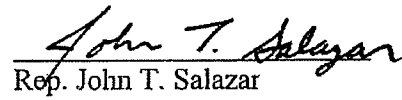

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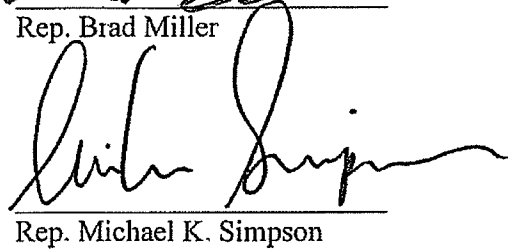

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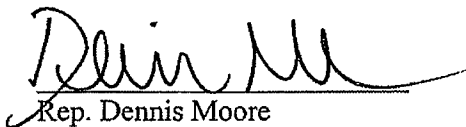

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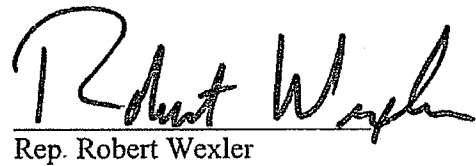

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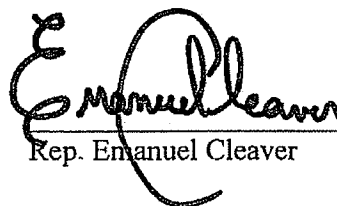

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