

THE 340B COALITION

March 5, 2004

Mr. Dennis Smith
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2175-IFC
Room 445-G, Hubert H. Humphrey Bldg.
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Comments on Interim Final Regulation Revising Pharmaceutical
Manufacturer Recordkeeping and Reporting Rule
REFERENCE FILE CODE CMS-2175-IFC

Dear Administrator Smith:

On January 6, 2004, the Centers for Medicare and Medicaid Services ("CMS") issued an Interim Final Rule modifying a previously issued final rule (see 68 Fed. Reg. 51912, August 29, 2003) that had established a three-year recordkeeping requirement for drug manufacturers under the Medicaid drug rebate program. This interim final rule removed the three-year recordkeeping requirements and replaced them with ten-year requirements on a temporary basis, while soliciting comments on the new, ten-year recordkeeping rule. See 69 Fed. Reg. 508. The 340B Coalition is submitting these comments in response to the January 6 Federal Register Notice.

The 340B Coalition is an organization of sixteen national advocacy groups whose members are comprised of "safety net" health care providers and programs that devote a significant portion of their health care services to indigent patients. In an effort to assist these providers and programs with their indigent care missions, Congress gave them access to deeply discounted drugs by creating the federal "340B program" – an outpatient drug discount program established under Section 340B of the Public Health Service Act, 42 U.S.C. 256b. Further background and explanation concerning the 340B program, as well as its interrelationship with the Medicaid drug rebate program, was provided in the Coalition's previous comments on the subject dated October 24, 2003. A copy of those comments is enclosed for your convenience. To summarize, the outpatient drug discounts that manufacturers are required to give to entities qualifying under the 340B program are calculated according to a formula that is directly tied to the calculation of Medicaid drug rebate amounts and to the manufacturers' figures for Average Manufacturer Price (AMP) and "best price." Consequently, 340B participants, like the Medicaid program, are adversely affected by inflated or inaccurate calculations or statements of AMP and best price.

AIDS Action; AIDS Alliance for Children, Youth and Families; Communities Advocating Emergency AIDS Relief Coalition; The Hemophilia Alliance, Inc.; Human Rights Campaign; National Healthcare for the Homeless Council; The National Alliance of State and Territorial AIDS Directors; The National Association of Community Health Centers; The National Association of People with AIDS; The National Association of Public Hospitals & Health Systems; The National Coalition For The Homeless; The National Family Planning & Reproductive Health Association; The National Hemophilia Foundation; The Public Hospital Pharmacy Coalition; San Francisco AIDS Foundation

The 340B Coalition applauds the modification of the August 29, 2003 rule to substitute a longer required recordkeeping period than three years for drug manufacturers. The ten-year recordkeeping requirement in the present Interim Final Rule is a significant improvement over the original rule, and will provide a more effective safeguard against improper or fraudulent drug price inflation and abuse of both the Medicaid rebate program and the 340B program. At the same time, however, the Coalition observes that more than one recent investigation into drug pricing fraud and abuse has involved activities and records spanning at least a decade, and ten years is hardly an "outside limit" on how far back in time it may be necessary to delve in order to fully investigate and obtain evidence of drug pricing errors, improprieties or fraud. The 340B Coalition therefore believes that an even longer period of record retention should be required of drug manufacturers. For purposes of the 340B program, records dating back to the inception of the program in 1992 may well be relevant to inquiries or investigations into possible overcharges to participating providers, and the 340B Coalition would endorse a further revision of the rule to require manufacturers to retain records of pricing and purchase data from that time onward.

In addition, the 340B Coalition is concerned that modification of the earlier final rule at 42 CFR 447.534 to extend the length of recordkeeping requirements in subsection (h) of the rule, but to leave unchanged the three year reporting provision at subsection (i), may have some unanticipated negative consequences. We note that the standard Medicaid Rebate Agreement requires adjustments to be made to Medicaid rebate payments if information indicates that either Medicaid Utilization Information, AMP, or best price were greater or less than previously specified -- but that the Agreement itself does not set any time limitations on the period during which such adjustments are allowed. The current three-year reporting rule may be read to suggest that a manufacturer has no obligation to report to CMS data indicating inaccurate Medicaid Utilization Information or AMP or best price figures, if that information comes to the manufacturer's attention after the 12 quarter reporting period defined by the Rule. The provision might further be read to imply that in such circumstances there is no need for the manufacturer to adjust Medicaid rebate payments or reimburse 340B overcharges that may have resulted from the use of data or pricing figures discovered to be inaccurate after the 12 quarter period.

There is no question that it is preferable for manufacturers to be encouraged or required to report price changes to CMS as soon as possible, and thus the limitation of time for such reporting to no more than 12 quarters after the quarter in which the original data was due to CMS serves a generally beneficial purpose. However, the 340B Coalition believes that Section 447.534 should be further amended to clarify that there is an exception to this rule where, after the 12 quarter period defined by the Rule, new information relevant to pricing comes to light indicating that Medicaid rebates were underpaid or 340B entities were overcharged. The Federal Register Notice of August 29 noted that the Medicaid Rebate Agreement requires manufacturers to comply with determinations by CMS, the Office of the Inspector General, or another authorized government agency that adjustments or revisions to drug prices are necessary, irrespective of the quarter. See 68 Fed. Reg. 51914. The final rule at 42 CFR 447.553

should clarify, similarly, that a manufacturer is responsible for reporting and implementing drug price revisions, irrespective of the quarter, where the use of inaccurate data or drug pricing figures have resulted in a net overcharge for drugs purchased under any government program.

Finally, the 340B Coalition wishes to reiterate the point that the Medicaid Rebate Program and the 340B drug discount program are closely interrelated, particularly with respect to the common impact on both programs of any erroneous or improper inflation of drug manufacturers' calculations of AMP or best price. Accordingly, we believe there should be much better communication and coordination than there has been in the past between the federal entities responsible for administrating these programs, i.e., between CMS and the Health Resources and Services Administration (HRSA). We urge the Administrator and the Secretary to take whatever steps are necessary to assure improved coordination between these HHS agencies in the future, including through the establishment of a joint CMS/HRSA "Working Group" for purposes of overseeing the 340B and Medicaid drug rebate programs.

The 340B Coalition is appreciative of this opportunity to comment upon the Interim Final Rule promulgated on January 6, 2004. Please direct any questions you or your staff may have concerning these comments to Bill von Oehsen, Ted Slafsky, or Edith Marshall at 202-466-6550.

Sincerely,



Ted Slafsky
Executive Director
Public Hospital Pharmacy Coalition
(on behalf of 340B Coalition)

Enclosure

THE 340B COALITION

October 24, 2003

2003 OCT 27 PM 2:19

Mr. Tom Scully
Administrator
Centers for Medicare & Medicaid Services
Room 445-G, Hubert H. Humphrey Bldg.
200 Independence Avenue, SW
Washington, D.C. 20201

(File Code CMS 2175-FC)

**Re: Comments for Time Limitations on Price Recalculations and
Recordkeeping Requirements under the Medicaid Rebate Program**

Dear Administrator Scully:

On August 29, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule with comment period in which it established new policies pertaining to recordkeeping and reporting requirements for pharmaceutical manufacturers under the Medicaid drug rebate program. 68 Fed. Reg. 51912. The 340B Coalition is submitting these comments in response to your August 29 rule.

The 340B Coalition is an organization whose membership is comprised of thousands of health care safety net providers and programs nationally. One of the primary missions of our members is to provide health care services to the indigent patient populations within their communities, including ensuring that these patients have access to affordable pharmaceuticals. Because a significant portion of the health care services provided by our members is devoted to indigent patients, they are able to participate in the drug pricing program under Section 340B (42 U.S.C. §256b) of the Public Health Service Act (referred to herein as "340B" or "the 340B program").

I. Background on the 340B Program

Congress created the 340B program in 1992, and it is administered by the Pharmacy Affairs Branch ("PAB") within the Health Resources and Services Administration ("HRSA"). The 340B program requires manufacturers of outpatient drugs that are paid for by State Medicaid programs to enter into an agreement with the Secretary of Health and Human Services ("HHS") to provide discounts on covered drugs to "covered entities."

Under these agreements, pharmaceutical manufacturers may not sell covered outpatient drugs (taking into account discounts or rebates) for more than the “average manufacturer price” (“AMP”) that is charged to Medicaid for the drug in the preceding calendar quarter. This price is then further reduced by a “rebate percentage” specified by statute. *See* 42 U.S.C. §256b(a)(1). The rebate percentage is an amount, expressed as a percentage, that is equal to the average, total rebate that the manufacturer is required to provide State Medicaid programs for covered outpatient drugs provided to Medicaid recipients, pursuant to 42 U.S.C. §1396r-8, which is then divided by the AMP for that drug during the relevant quarter. 42 U.S.C. §256b(a)(2)(A).

For most outpatient drugs, the 340B discount is simply the AMP reduced by a rebate percentage that is equivalent to the Medicaid rebate amount. By law, 340B covered entities receive a minimum discount of 15.1 percent for name-brand prescription drugs and 11 percent for generic and over-the-counter drugs. Covered entities are also entitled to an additional discount if the price of the drug in question has increased faster than the rate of inflation. Covered entities can also negotiate for discounts that are lower than the maximum allowable statutory prices.

In addition, the 340B program exempts prices that covered entities pay for covered outpatient drugs from “best price” formula used to calculate Medicaid rebates. Legislation passed earlier this year by the United States House of Representatives and the United States Senate (H.R.1 and S.1) contains language clarifying that this exemption is also applicable to inpatient drug prices paid by 340B hospitals. The “best price” policy was created by Congress in 1990 to ensure that State Medicaid programs would not be reimbursing pharmaceutical manufacturers at a higher rate than other non-government purchasers pay for those same drugs. This policy is achieved by manufacturers paying rebates to State Medicaid programs based upon the difference between a drug’s AMP and “best price” (with a minimum rebate of 15.1 percent of AMP).

II. Interrelationship Between 340B and Medicaid Rebate Programs

The drug discount framework of the 340B program is directly linked to the discount framework of the Medicaid drug rebate program, as 340B discounts are based upon the same pricing data and variables that are used to calculate Medicaid rebate amounts. Due to the interrelationships of these two programs, the 340B Coalition believes that more attention and collaboration should occur between their respective administering agencies, HRSA and CMS, in order to achieve their underlying policy objectives. In this regard, since the rule announces CMS’s intention to continue work on finalizing the complete drug rebate regulation for the Medicaid drug rebate program, the 340B Coalition urges CMS to work with HRSA to form a ‘Working Group’ between the two agencies to clarify a number of complex issues that have arisen over the years between the 340B program and the Medicaid drug rebate program. One of these complex issues is the manufacturer recordkeeping requirement addressed in CMS’s August 29 notice.

A. Coordination Problems Between CMS and HRSA

For some time, the 340B Coalition has advocated for the creation of a CMS/HRSA 'Working Group.' The concept was first proposed to CMS and HRSA on August 7, 2002 and reinforced in subsequent correspondence on September 23, 2003. We believe that such a 'Working Group' could coordinate current and future efforts to recover overcharges by pharmaceutical manufacturers who do not give their "best price" to the Medicaid and 340B programs as required by federal law. Additionally, the 'Working Group' could clarify the roles of the respective agencies in evaluating the eligibility of disproportionate share hospitals seeking to enroll in the 340B program, especially in circumstances where hospitals dispute Medicaid disproportionate share adjustment data that HRSA receives each quarter from CMS. The 'Working Group' could also seek to clarify billing procedures for certain outpatient drugs, as further discussed below.

We believe the formation of a CMS/HRSA 'Working Group' will significantly benefit the 340B community and State Medicaid programs by helping to eliminate inconsistent guidance and by facilitating cooperation between the agencies as they fulfill their overlapping administrative functions in carrying out the policies of the 340B and Medicaid rebate programs.

B. Inconsistent Billing Policies

An important example of the need for greater collaboration between CMS and HRSA involves how 340B covered entities bill State Medicaid agencies for 'clinic-administered' drugs (i.e., drugs that are administered by physicians and nurses rather than dispensed by an outpatient pharmacy), specifically, whether these drugs must be billed at acquisition cost plus a dispensing fee. Despite the fact that CMS has issued no formal guidance on this issue, it has informed one of our member associations that represents disproportionate share hospitals (the Public Hospital Pharmacy Coalition) that 'clinic administered' drugs should be billed at acquisition cost plus a dispensing fee. This position is inconsistent with the agency charged with administering the 340B program, HRSA, which has taken the position that 340B covered entities should refer to their "respective Medicaid State agency drug reimbursement guidelines" in determining proper billing procedures. 65 Fed. Reg. 13, 984 (March 15, 2000). In most states, Medicaid billing guidelines contemplate reimbursement above acquisition cost. Consequently, the inconsistencies between CMS and HRSA on this important issue have created a considerable amount of confusion among 340B providers and State Medicaid agencies. We believe that an active working group between the two agencies would serve to provide much-needed clarity regarding the policies associated with this and other billing requirements.

III. The Three-Year Timeline For Records

The 340B Coalition believes that CMS's final rule requiring that pharmaceutical manufacturers maintain their pricing data for only three years is a regrettable policy choice that will impose negative financial burdens on 340B providers. In this regard, we respectfully and strongly disagree with CMS when it says that this final rule will have "no impact" upon providers such as our members.

A. Adverse Impact on "Best Price" Recoveries

As noted above, 340B discounts are formulated based upon the rebate amounts that pharmaceutical manufacturers must extend to State Medicaid agencies pursuant to the Medicaid drug rebate program. In order for the intended policy outcomes of both programs to be achieved – especially with respect to calculating rebate amounts owed to State Medicaid programs and 340B discounts owed to covered entities in light of manufacturer "best price" requirements – a thorough examination of records maintained by pharmaceutical manufacturers containing their pricing information may be necessary depending upon the circumstances at hand.

The interplay between the Medicaid drug rebate and 340B programs was specifically noted by HHS's Office of Inspector General ("OIG") earlier this year when it issued guidance to the pharmaceutical industry relating to establishing internal compliance plans. 68 Fed. Reg. 23,731 (May 5, 2003). OIG also advised manufacturers to "retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements." *Id.* at 23,734. Presumably this would apply to 340B program requirements as well.

Our concern with establishing a three-year recordkeeping requirement is exemplified by the recent Medicaid settlements with Bayer and GlaxoSmithKline. Some of the drug pricing irregularities in these settlements date back to the first quarter of 1996 – over six years ago. Had this rule's three-year recordkeeping limitation for manufacturers been in place, however, it could have effectively limited (if not altogether prevented) the efforts of federal investigators from securing the crucial evidence – namely, the pricing data maintained by these respective companies – that ultimately permitted the government to bring these cases to a successful settlement. Significantly, 340B providers will receive approximately \$12 million under the Bayer and GlaxoSmithKline settlement agreements.

We recognize that CMS is making an exception to the three-year recordkeeping requirement for price data that is the subject of a government audit or investigation. We do not believe, however, that this adequately protects either the Medicaid program or 340B providers from situations where possible drug pricing improprieties are not discovered until after the three year recordkeeping period has expired and manufacturers have disposed of their pricing records. Other settlements between pharmaceutical manufacturers and the federal government for violations of the Medicaid drug rebate program have occurred, and the investigations precipitating some of them no doubt

involved an examination of pricing data maintained by pharmaceutical manufacturers that was both in excess of three years old and not the subject of an audit or investigation. Simply put, CMS's new recordkeeping rule will likely deprive 340B safety net providers from collecting millions of dollars of overpayments made to companies that overstate their "best price."

Accordingly, we are very concerned that this rule will in fact have a negative impact upon the 340B program and the ability of 340B covered entities to secure accurate rebate amounts and a pharmaceutical manufacturer's "best price" charged to the Medicaid program, both of which our members are entitled to under the Medicaid statute. The fact that CMS has indicated that providers will not be affected by this rule is a fairly clear indication that the agency has simply failed to consider how 340B providers would be affected by it. We therefore urge you to reconsider your position on this rule and not implement it at this time.

B. Inconsistency with Federal Fraud Statutes

In addition, it is difficult to see how CMS's recordkeeping rule will comport with other federal laws, such as the False Claims Act ("FCA"), that are used to combat fraud and abuse within federal health care programs such as the Medicaid drug rebate program. This rule will have the effect of creating an effective three-year time bar for discovering the pricing records associated with the Medicaid drug rebate program that are maintained by pharmaceutical manufacturers whose pricing practices may have been fraudulent or otherwise unscrupulous, so long as those records do not become the subject of an audit or investigation prior to the expiration of the three-year period.

The statute of limitations under the FCA is generally six years. 31 U.S.C. §3731(b)(1). This six year period "begins to run on the date the claim is made, or, if the claim is paid, on the date of payment." U.S. ex rel. Kreindler & Kreindler v. United Technologies Corp., 985 F.2d 1148, 1157 (2d Cir. 1993). For *qui tam* suits, the statute of limitations can be extended to no more than three years after the date when facts material to the right of actions are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than ten years on which the violation is committed. 31 U.S.C. §3731(b)(2). Consequently, we believe that the FCA's six-year statute of limitations will be undermined by this three-year recordkeeping requirement.

We also believe that this rule vitiates both the intent and spirit of the Health Care Fraud and Abuse Control Program ("HCFAC") that was established as part of the Health Insurance Portability and Accountability Act of 1996 ("HIPPA"). As you are aware, the HCFAC was created in order to bring together the collective resources and expertise of HHS and the Department of Justice in order to discover and prosecute fraud and abuse within federal health care programs.

HIPPA includes a provision to ensure that the OIG of HHS is authorized to exercise certain authorities enumerated within the Inspector General Act of 1978 in carrying out the underlying purpose of the HCFAC. 42 U.S.C. §1320a-7c(a)(4). Those authorities include the exercise of subpoena power in connection with “the production of all information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence necessary in the performance of the functions assigned by this Act...” 5 U.S.C. App. §6(a)(4). It is clear, however, that this rule would effectively limit the ability of the OIG from discovering crucial evidence should such discovery become necessary should the case require the need to discover and examine pricing data that is in excess of three years old and has not been the subject of an audit or prior investigation.

IV. Conclusion

For the reasons cited above, we respectfully request CMS to work with HRSA in establishing a joint CMS/HRSA ‘Working Group’ for purposes of administering and overseeing the 340B and Medicaid drug rebate programs. We believe that the formation of such a group should occur prior to CMS’s effort to finalize its pending Medicaid drug rebate regulations. We also respectfully request CMS to abandon its plan to establish a three-year recordkeeping requirement for the pricing records of pharmaceutical manufacturers participating in the Medicaid drug rebate program.

The 340B Coalition appreciates this opportunity to comment on CMS’s August 29th Federal Register notice. Any questions regarding these comments should be directed to Bill von Oehsen, Ted Slafsky or Justin Hunter at 202-466-6550.

Sincerely,


on behalf of
340B Coalition