



## Safety Net Hospitals for Pharmaceutical Access

---

December 24, 2008

Ms. Alberta J. Dwivedi  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1404-FC  
Mail Stop C4-01-26  
P.O. Box 8013  
Baltimore, MD 21244-1850

**Re: Final Regulation CMS-1401-FC - Response to Questions Posed Regarding the Potential Influence of Federal 340B Discounts on the Calculation of Medicare Payment Rates for Separately Payable Drugs**

Dear Ms. Dwivedi:

Safety Net Hospitals for Pharmaceutical Access (SNHPA) represents close to 500 disproportionate share hospitals throughout the country that qualify for federal drug discounts under the 340B program due to the large volume of services they provide to Medicare, Medicaid and indigent patients. We are writing in response to the request by the Centers for Medicare and Medicaid Services (CMS), in the above-referenced final CMS Regulation 1401-FC, for information regarding the impact of outpatient prescription drug discounts under the federal 340B program on the calculation of Medicare Part B payment rates for separately payable drugs. We also wish to voice support for suggestions previously offered by non-340B hospital stakeholders to address issues raised in the preamble to the regulation. We agree with those stakeholders that any Medicare Part B reimbursement solution contemplated by CMS should take some form other than a reimbursement schedule for 340B hospitals that is different than the reimbursement schedule for non-340B hospitals.

In particular, we support the proposal previously presented in comments filed with CMS and presented to the Ambulatory Payment Classification Advisory Panel in August 2008 that the cost of outpatient drugs dispensed or administered by qualified 340B covered entity hospital departments or sites should be excluded from hospital-reported data used in setting the average sales price (ASP)-based Medicare reimbursement for separately payable drugs. We support this proposal – offered by the Association of Community Cancer Centers (ACCC), the American Society of Health-System Pharmacists (ASHP), BIO, Johnson & Johnson, and others – because the Medicare statute requires that 340B drug prices be excluded from ASP calculations. We believe that this recommended exclusion would be consistent with Medicare Improvement, Prescription Drug and Modernization Act of 2003 (MMA) provisions governing the calculation of ASP<sup>1</sup> and the Congressional intent behind those

---

<sup>1</sup> § 1847A(c)(2)(A) of the Medicare Improvement, Prescription Drug and Modernization Act of 2003.

provisions. It is our understanding that these stakeholders have suggested that the appropriate ASP-based reimbursement for separately payable drugs should be at least equal to the reimbursement set for drugs administered in physicians' offices, and we agree with that conclusion.

As previously mentioned, SNHPA represents the majority of the disproportionate share hospitals that qualify for the 340B program by virtue of providing large volumes of indigent care. These hospitals either are owned by state or local governments or have a contractual relationship with state or local governments to provide care to low-income populations. They include large inner-city public hospitals, academic medical centers, rural hospitals, high-Medicaid urban hospitals, and other safety net institutions.

While 340B hospitals only represent a small portion of the total number of hospitals in the country, they are responsible for a significant amount of the uncompensated hospital care provided. Uncompensated care costs constitute at least 20 percent of the annual expenses of safety net hospitals as opposed to only five percent of expenses for all other hospitals, according to the National Association of Public Hospitals and Health Systems (NAPH). NAPH also found in 2006 that its member hospitals' share of uncompensated care costs borne by hospitals nationwide was 20 percent. SNHPA, which represents the majority of the hospitals participating in the 340B program, represents not only the public hospitals included in the NAPH membership, but also several hundred other public and private nonprofit disproportionate share hospitals. Thus, SNHPA members' share of total uncompensated care costs borne by hospitals nationwide would be significantly higher than 20 percent.

This is the first opportunity we have had to offer input into CMS's apparently lengthy consideration of this issue, even though the discussion in the regulations' preamble indicates the agency has had "several meetings with interested stakeholders over the past year regarding the drug costs of hospitals that participate in the Federal 340B program."<sup>2</sup> We have not been participants in those meetings. In addition, we understand that officials at the Health Resources and Services Administration (HRSA) have been consulted only perfunctorily on the issues raised in the preamble, and that there have thus far been no in-depth discussions of these issues with the federal agency charged with administering the 340B program. SNHPA has assigned a high organizational priority to this issue, given our mission of representing the interests of 340B hospitals, and we stand ready to offer any assistance CMS needs in understanding the 340B program and its inter-relationship with hospital outpatient operations.

### **340B Program Was Intended to Help Safety Net Providers Stretch Scarce Resources**

The Federal 340B drug discount program was enacted to lower pharmaceutical costs for safety net providers who rely largely on government funding to provide health care services. Congress believed that, by reducing the cost of pharmaceuticals used by their patients, safety net providers would be able to stretch limited resources in providing a broader range of services to a greater number of the uninsured and other vulnerable patient populations. Any move by CMS to reduce Medicare hospital outpatient prospective payment system (HOPPS) drug reimbursement to 340B

---

<sup>2</sup> 73 Fed. Reg. 68502, 68655 (November 18, 2008).

hospitals because they are able to access lower-cost drugs would directly undermine the purposes of the 340B program by reducing funding for those other services.

The genesis of the 340B program arose out of the decision by Congress, in 1990, to create the Medicaid rebate program to lower the cost of pharmaceuticals reimbursed by state Medicaid agencies. As you know, the Medicaid rebate program requires drug companies to enter into a rebate agreement with the Department of Health and Human Services (HHS) as a precondition for coverage of their drugs under Medicaid. The rebate agreement specifies that, for each brand name outpatient drug covered under the Medicaid plan, the manufacturer of the drug must pay a rebate to Medicaid based in part on the manufacturer's "best price" for that drug.

After initial passage of the Medicaid rebate law, many pharmaceutical companies had a disincentive to continue giving deep discounts previously provided on drugs to safety net providers because they would have had to pay larger rebates to Medicaid if they gave deeper discounts in the non-Medicaid market (establishing even lower "best prices"). When manufacturers began eliminating discounts previously provided, increased government spending on drugs purchased by the federal- and state-supported safety net providers offset the Medicaid savings achieved through the rebate program. To correct this situation, Congress, in November 1992, enacted legislation providing for discounted drugs to the Veterans Administration, Public Health Service, Indian Health Service, Department of Defense, and Public Health Service covered entities.<sup>3</sup>

Section 340B of the Public Health Service Act (created under Section 602 of the Veterans Health Care Act of 1992) requires pharmaceutical manufacturers participating in the Medicaid program to enter into a second agreement with the Secretary, called a pharmaceutical pricing agreement (PPA). Under a PPA, a manufacturer agrees to provide front-end discounts on covered outpatient drugs to a dozen statutorily specified government-supported facilities, called "covered entities," that serve the nation's most vulnerable patient populations. Disproportionate share hospitals are among the entities entitled to these discounts. As noted above, Congressional intent in enacting the 340B statute was to enable covered entities to use these drug discounts to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."<sup>4</sup> Pharmaceutical prices available under Section 340B are significantly lower than both retail and wholesale prices.

### **Responses to Questions Posed in the Regulations' Preamble**

Having offered this important background information, SNHPA provides the following answers to the questions posed by CMS in Final Regulation CMS-1404-FC.

---

<sup>3</sup> Pub. L. 102-585 (1992).

<sup>4</sup> H.R.Rep. 102-384, 102d Cong., pt. 2, at 12 (2d Sess. 1992).

**(1) Do all hospital outpatient departments of a participating provider furnish drugs purchased under the 340B pricing program or only a subset of departments?**

Once a hospital joins the 340B program, HRSA expects that the hospital will purchase 100 percent of its covered outpatient drugs through the program. This all or nothing approach is intended to facilitate compliance with a program prohibition against hospitals using outpatient drugs purchased through group purchasing organizations (GPOs) for 340B patients, and to avoid having manufacturers pay duplicate 340B discounts on Medicaid drugs for which rebates are collected. An important outgrowth of these compliance concerns is the Office of Pharmacy Affairs (OPA's) prohibition against the practice of "cherry picking" – purchasing some covered outpatient drugs through the 340B program and others through a GPO. There are, however, several important exceptions to this expectation that hospitals will convert 100 percent of their outpatient drug purchases to the 340B program.

First, not every hospital outpatient department or site is eligible to purchase and use 340B drugs. Only those that are reflected on a reimbursable line of a filed Medicare cost report may participate. Until the costs of the disproportionate share site appear on a filed report, the hospital may not furnish 340B-purchased drugs at that site.

Second, after a new hospital or DSH site is officially enrolled into the 340B program, it may take a while before the purchase of outpatient drugs used at those sites is shifted to the 340B program. The prohibition against cherry-picking may pose a hardship for newly enrolled hospitals or hospital outpatient departments due to the difficulties of instantaneously converting all of their outpatient purchases to the program on the first day of participation. To address this hardship, HRSA permits a hospital or department to phase in implementation. A newly-enrolled hospital may decide to implement the program initially in only one clinic or small group of clinics until it can determine how best to maintain the appropriate tracking systems to avoid diversion or another program violation. In fact, it is not unusual for hospitals to never use 340B drugs in settings where the hospital has been unable to establish an effective tracking system and the hospital wants to take a conservative approach to complying with the prohibition against diversion, i.e., using 340B drugs for non-340B patients. This is especially common in mixed-use settings like surgery departments where both inpatients and outpatients are treated.

Third, even for a hospital that does not take advantage of HRSA's phase-in policy, agency rules governing item-by-item stock replacement of 340B drugs as an alternative to preventing diversion through the maintenance of two separate inventories do not trigger until the existing non-340B product in stock is dispensed and a 340B replacement product needed. Until the first charge is generated by a hospital's charge-master that qualifies for 340B coverage, outpatient drugs will not be purchased through the 340B program.

Fourth, HRSA guidelines allow covered entities to purchase outpatient drugs dispensed or administered to Medicaid patients outside the 340B program. In general, 340B pharmacies must bill their state Medicaid agencies at actual acquisition cost. However, HRSA allows covered entities to "carve out" their Medicaid drugs from the 340B program in order to avoid this billing restriction. Carved out drugs may be billed at normal Medicaid reimbursement rates, but must be purchased outside the 340B program.

Fifth, many covered outpatient drugs are not available at 340B prices because manufacturers often do not comply with program price reduction requirements. Please see our response to the next question for additional information on this concern.

For all of the above reasons, not all hospital outpatient departments furnish 340B drugs to eligible patients and, even within a 340B-participating department, not all outpatient drugs can be purchased through 340B. The lack of 340B prices for some drugs, the transition by new hospitals or new hospital outpatient departments to 340B status, and the flaws and shortcomings of hospital billing systems mean that 100 percent utilization of 340B-priced outpatient drugs is a goal that is often difficult to achieve.

**(2) Are all drugs available to participating hospitals under the 340B program?**

No, the 340B law only requires manufacturers to provide 340B discounts on “covered outpatient drugs” as defined under the Medicaid statute, and the Medicaid law excludes vaccines, non-prescription over-the-counter drugs, and most durable medical devices from this definition.

Further, drugs produced by manufacturers not participating in the 340B program – that is, drugs produced by manufacturers not participating in Medicaid – are not available at 340B discounts. Manufacturers that choose not to participate in the 340B and Medicaid drug rebate programs are not required to offer 340B discounts to covered entities. Even with respect to drugs sold by 340B-participating manufacturers, certain categories of drugs – intravenous immunoglobulins (IVIGs), contrast media, and radiopharmaceuticals – have historically been virtually unavailable at 340B prices, as have individual drugs such as the heart medication Integrilin and the anticoagulant Angiomax.

It often happens that participating manufacturers will fail to make some drugs available at 340B prices because they misunderstand how the program works. Recently, manufacturers have told our hospitals that 340B prices are not available on drugs discontinued but still on the market, or drugs that have gone generic or over-the-counter. OPA officials have advised us that both of these assumptions are incorrect. Similarly, some manufacturers have limited 340B pricing to certain package sizes or strengths of a product, even though they are supposed to offer discounts on all covered outpatient drugs they manufacture.

Finally, manufacturers are permitted by law to ration some scarce products to the 340B community so that there remains an adequate supply for other purchasers in the marketplace. This is the reason that manufacturers give for being unable to provide IVIG therapies at 340B prices.

**(3) Are hospital drugs provided to inpatients purchased by hospitals at 340B program prices if the hospital is a participating provider?**

The 340B program is limited to outpatient pharmaceuticals, and hospitals have to pay on average 25 percent or more for inpatient pharmaceuticals that, in many cases, may be the same drug products administered or dispensed in the outpatient venue. Some generic manufacturers and a

very small number of trade name manufacturers may provide discounts to disproportionate share hospitals for inpatient drugs, but this limited number of discounts is provided outside the parameters of the 340B program. These inpatient discounts are far less deep than those afforded for outpatient drugs under 340B.

**(4) What proportion of a participating hospital's total costs and charges for drugs reflect drugs purchased through the 340B program?**

The percentages vary from hospital to hospital. Although SNHPA does not track costs and charges associated with the 340B program, we have recently surveyed the payer mix for 340B drugs for about 70 SNHPA hospitals, and that survey provides us with some indication of what proportion of Medicare charges and costs are for drugs purchased through 340B.

According to the survey, spending on outpatient drugs constitutes on average 53.6 percent of all hospital drug expenditures. Of those outpatient drugs, about half are dispensed from the outpatient pharmacy, and about half are physician-administered. Thus, on average, between 26 and 27 percent of all hospital drug expenditures are for the kind of outpatient drugs that are reimbursed under HOPPS. SNHPA's survey found that the percentage of hospital outpatient drugs that are administered or dispensed by physicians and covered under the Medicare Part B program ranges among hospitals from 3 percent to 65 percent, but the average is approximately 30 percent. Applying this 30 percent average to the average spending on hospital physician-administered drugs, we estimate that an average of about 8 percent of all hospital drug expenditures are covered by Medicare Part B and would be eligible for 340B prices.

However, it should be remembered that many outpatient drugs with significant costs, particularly IVIG therapies and some costly cancer therapies, are generally not available at 340B prices and must be purchased at market prices. When that happens, SNHPA members say, outpatient drug costs for facilities dispensing or administering high quantities of those drugs may constitute as much as 70 percent of all hospital drug costs.

**(5) Do 340B hospitals receive other manufacturer discounts that impact their final drug costs?**

The 340B program sets a ceiling price for drugs, and manufacturers may offer drugs at sub-ceiling prices. In addition, many manufacturers have established free drug patient assistance programs (PAP) for uninsured and under-insured individuals. In some cases, the free drugs are donated to the PAP patient. In other instances, they are donated to the treating hospital. The latter category of PAP programs is known as an "institutional" PAP. There is evidence that some manufacturers may be phasing out or reducing their PAP programs.

In addition to 340B sub-ceiling and PAP-related discounts, 340B hospitals may receive discounts from wholesalers for high volume purchases and from GPOs for inpatient and other non-340B drug purchases.

Further, as part of the original 340B legislation, the government was required to establish a prime vendor program (PVP). The PVP serves its participants by negotiating 340B sub-ceiling pricing on pharmaceuticals, by establishing distribution solutions and networks that improve access to affordable medications, and by providing other value-added products and service. The PVP is a voluntary program, and provides the only legal means for 340B-eligible hospitals to conduct group purchasing and leverage their outpatient drug purchases to secure sub-ceiling discounts. A 340B hospital must register with OPA prior to participation in the PVP to access the program's sub-ceiling contract portfolio. Presently, OPA has subcontracted management of the PVP to the firm Apexus, which has contracts with 19 manufacturers or suppliers of brand name drugs and 18 manufacturers or suppliers of generic drugs. Apexus also contracts for discounts on vaccines and medical devices not covered under 340B.<sup>5</sup>

**(6) Do hospitals set different charges for drugs purchased through the 340B program than their charges for those same drugs purchased outside the program?**

The 340B program does not restrict how much is charged for a drug acquired at a 340B price. However, the Medicaid program does expect hospitals to set charges for 340B-priced outpatient drugs at actual acquisition cost or alternative state-specific rates designed to compensate states for the loss of rebates that they would otherwise have collected under the Medicaid rebate program. The reason why 340B pharmacies are subject to Medicaid billing restrictions, and why state Medicaid agencies forego collecting manufacturer rebates on 340B drugs, is to protect manufacturers from giving 340B discounts and Medicaid rebates on the same drugs. The Medicaid program controls charges through provider participation agreements, state plan amendments (SPAs), and provider manuals, and it should be noted that the charges billed by the hospital often do not relate at all to the reimbursement paid.

It also should be noted that because Medicare does not allow multiple levels of charges for the same services to different payers, hospital charge-masters generally do not permit hospitals to charge two different payers at two different levels. Hence, with the exception of Medicaid, 340B patients are not charged differently than other payers.

It also is important to note that 340B hospitals by definition provide services to a disproportionate share of low-income Americans.<sup>6</sup> Most have charity care policies that require them to accept nominal reimbursement or no reimbursement in providing pharmacy services for indigent or otherwise vulnerable patients. SNHPA has drafted a model charity care policy for its members, and most 340B hospitals have implemented a policy based on, or similar to, that model.

---

<sup>5</sup> Additional information about the Prime Vendor Program can be found at <https://www.340bpvp.com/public/>.

<sup>6</sup> To qualify for the 340B program, a hospital must have a Medicare disproportionate share (DSH) adjustment of 11.75 or greater and must be either a public hospital or a private non-profit with a contractual relationship with state or local government to serve the indigent.

**(7) What is the impact of 340B drug purchasing agreements on OPSS hospital claims data used to estimate drug costs?**

340B drug purchasing agreements do not change the way in which hospitals charge or estimate drug costs, and Medicare requires that all payers be charged the same.

SNHPA notes that Congress has determined that 340B prices should be excluded from computation of average sales price under the ASP-based reimbursement methodology for Medicare Part B drugs.<sup>7</sup> It would therefore provide consistent public policy if claims for outpatient drugs dispensed or administered by qualified 340B covered entity hospital departments or sites were also excluded from the claims data used by CMS to determine the cost-to-charge ratio applied in calculating reimbursement for drugs under HOPPS.

**(8) Should hospitals participating in the 340B program be paid for drugs under HOPPS at adjusted rates because they have different average hospital acquisition costs for drugs and biologicals from non-participating hospitals?**

No. As noted above, disproportionate share hospitals that qualify for the 340B program provide a high level of uncompensated and charity care and are expected by federal, state, and local governments to absorb those unpaid costs. The 340B program was intended to provide low-cost drugs to covered entities so that they could stretch scarce resources and expand health care services further to the uninsured and other vulnerable populations. Using 340B program discounts to offset Medicare program costs would contravene the Congressional purposes behind creating the 340B program.

**(9) Should CMS use its statutory equitable adjustment authority to adjust HOPPS payments for separately payable drugs based on their participation or non-participation in the 340B program?**

As noted above, using 340B discounts to subsidize costs under the Medicare program would undermine Congressional intent behind the 340B program. The 340B law was structured to support the general charitable-based mission of hospitals and other safety net providers that serve large numbers of indigent patients. The legislative intent behind 340B was to enable safety net providers to stretch scarce resources as far as possible, reaching more eligible patients and providing more comprehensive services. As a result of this program, safety net pharmacies have been able to remain open and improve services to vulnerable patient populations. For example, 340B providers often voluntarily use their 340B discounts to reduce or waive patient co-pays for Part D drugs according to need. Using 340B discounts to underwrite the costs of hospital outpatient charges to the Medicare program would significantly impact the ability of 340B hospitals to continue to serve the safety net population in the many ways they are currently served.

---

<sup>7</sup> § 1847A(c)(2)(A) of the Medicare Improvement, Prescription Drug and Modernization Act of 2003.

**(10) Is there additional information that we would like CMS to understand in considering the impact of 340B pricing under the HOPPS rule for potential rulemaking in the future?**

Yes, we would emphasize again the importance of the legislative history behind the 340B program, and Congressional intent to provide covered entities with low-cost pharmaceuticals so that they are better able to utilize their scarce resources to provide a wider array of services to the safety net population. Any changes to Medicare hospital outpatient reimbursement methodology that would lower hospital outpatient reimbursement to 340B hospitals for separately payable drugs because those hospitals are able to obtain outpatient drugs at 340B prices would, in essence, transfer the savings from the 340B program to the Medicare program. If 340B savings are to be used to subsidize outpatient drug costs under Medicare, rather than provide funding for the safety net services the program was intended to subsidize, disproportionate share hospitals could find themselves unable to continue meet the wide range of health care needs of their disadvantaged patients.

**Conclusion**

SNHPA has appreciated this first opportunity to provide the information about the 340B program requested by CMS. As CMS continues to review this issue, we ask that it keep in mind the purposes of the 340B program and not thwart those purposes by using the savings from 340B-priced drugs to subsidize the costs of another government program. Specifically, we ask that CMS not set a separate Part B reimbursement schedule for separately payable drugs dispensed or administered by 340B hospitals. Instead, we join other stakeholders in urging that hospital outpatient drug claims data from 340B qualified hospital sites and departments not be used in calculating cost-to-charge ratios applied in setting reimbursement for HOPPS drugs.


We also urge HRSA's involvement in the review of these comments and any deliberations and decision-making over how to account for 340B pricing within the HOPPS payment system.

Thank you for the opportunity to offer these thoughts.

Sincerely,



William von Oehsen  
President and General Counsel



Stuart Yael Gordon  
Director, Legal and Regulatory Affairs