

March 11, 2010

Ms. Charlene Frizzera  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Mail Stop C5-11-24  
7500 Security Boulevard  
Baltimore, MD 21244

Dr. Mary Wakefield, R.N., PhD.  
Administrator  
Health Resources and Services Administration  
Department of Health and Human Services  
5600 Fishers Lane  
Room 14-05 Parklawn Building  
Rockville, MD 20857

Dear Acting Administrator Frizzera and Dr. Wakefield:

The undersigned members of the 340B Coalition understand that the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) are working together to create a policy guidance that would clarify the two agencies' positions on Medicaid billing by covered entities participating in the federal 340B drug discount program. We are writing to express our support for this effort and to request that any policy guidance produced by HRSA and CMS focus on minimizing practices that might result in a drug manufacturer paying a duplicate discount, rather than the promulgation of a policy that would require or could be interpreted to require that 340B covered entities pass through their 340B discounts to state Medicaid programs. We also hope that the guidance will encourage states to negotiate with providers to develop shared savings arrangements.

The organizations participating in the 340B Coalition represent thousands of safety net providers and programs participating in the Public Health Service 340B drug discount program. The Coalition was created to allow its member provider groups to address 340B issues of common concern. The 340B Coalition members sending this letter includes those representing disproportionate share hospitals and children's hospitals, federally qualified health centers, hemophilia treatment centers, and family planning clinics.

### **Requiring Covered Entities to Pass All of Their Discounts to Medicaid Undermines the Purpose of the 340B Program**

The 340B drug discount program was enacted to lower pharmaceutical costs for safety net providers that rely largely on government funding to provide health care services. The program's legislative history shows that it was established by Congress to enable covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."<sup>1</sup> Mandating that 340B covered entities pass on all of their discounts directly to the Medicaid program undermines the purposes of the 340B program by depriving the covered entities of the savings they need and rely on to underwrite the costs of other safety net health care services.

---

<sup>1</sup> H.R.Rep. 102-384, 102d Cong., pt. 2, at 12 (2d Sess. 1992).

There is no federal statutory mandate that covered entities bill Medicaid at actual acquisition cost (AAC). If 340B covered entities are only permitted to bill Medicaid agencies at AAC without any additional markup, the purposes of the 340B program – to help stretch scarce resources to provide medical services to the uninsured and under-insured – will be thwarted. No 340B entity can support a large Medicaid patient base relying only on reimbursement for product at AAC plus the meager Medicaid dispensing fee that most states offer. The role of pharmaceuticals in meeting the health care needs of individuals, especially those suffering from one or more chronic conditions, has grown significantly over the past two decades. It is no exaggeration to say that access to affordable medications and appropriate clinical care can make a critical difference in patient outcomes and, in some cases, can mean the difference between life and death.

How 340B drugs should be billed and reimbursed is a matter of state policy, not federal law. Any arrangement that doesn't result in a manufacturer having to pay a duplicate discount should be allowed. If there is no threat of a duplicate discount, covered entities should not be required to pass on their discounts to the state – otherwise, the purpose of the 340B program will be undercut.

The initial suggestion in a 1993 HRSA guidance that covered entities should bill at AAC was designed by CMS and HRSA as the best way to ensure that states received the financial benefit (the Medicaid rebate) that they presumably lose in allowing covered entities to utilize the 340B discounted drugs.<sup>2</sup> However, many states found after the 1993 guidance was issued that their automated reimbursement systems and covered entities' automated billing systems could not accommodate AAC billing. They complained to HRSA that mandated AAC billing created hardships both for the state Medicaid programs and the covered entity providers. Over the ensuing years, a process was developed by which 340B providers could “carve out” their Medicaid drugs from 340B purchases. Under this process, drugs not purchased through the 340B program could be billed at the normal Medicaid estimated acquisition cost – usually a discount off of average wholesale price (AWP). The covered entity has to first notify HRSA of its intent to carve out so that HRSA can alert the affected Medicaid program(s) that it can charge manufacturers for Medicaid rebates on those drugs when dispensed by that entity. Many states and providers choose the 340B carve out as it allows safety net providers to receive a fair payment for drugs for their Medicaid patients without the possibility of a duplicate discount since the provider is not using 340B drugs. States and safety net providers need the flexibility offered by the carve-out.

In a 2000 OPA final guidance outlining the carve-out procedures, HRSA acknowledged that not all Medicaid programs were requiring covered entities to bill at AAC. In addition to Medicaid carve-outs, a number of states over the years had worked out other arrangements with covered entities to “share” the savings arising from the purchase of Medicaid drugs through the 340B program. It told covered entities that it was reviewing its 1993 guidance on the issue and recommended that covered entities “refer to their respective Medicaid State agency drug reimbursement guidelines for applicable billing limits.”<sup>3</sup> Accordingly, the concept of a federal AAC billing requirement

---

<sup>2</sup> Proposed Notice Regarding Section 602 of the Veterans Health Care Act of 1992: Duplicate Discounts and Rebates on Drug Purchases, 58 *Fed. Reg.* 27293-27294 (May 7, 1993); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992: Duplicate Discounts and Rebates on Drug Purchases, 58 *Fed. Reg.* 34058- 34059 (June 13, 1993).

<sup>3</sup> Final Notice Regarding the 340B Drug Pricing Program – Program Guidance Clarification, 65 *Fed. Reg.* 13983-13984 (March 15, 2000).

applicable to 340B drugs was abandoned by HRSA, with covered entities being allowed to follow state guidance in this area instead.

### **States Should Seek Shared Savings Arrangements with Covered Entities**

State Medicaid shared savings arrangements with 340B providers take various forms, outlined in the attached document, including: (1) enhanced dispensing fees; (2) modest add-ons to, or mark-ups of, product cost; and (3) fees for providing both product at acquisition cost *plus* care management or disease management services to targeted high-cost Medicaid populations. The basic concept underlying the shared savings approach is that, because 340B prices are on average 20 to 25 percent below Medicaid net payments (including rebates) for covered outpatient drugs, states can structure a 340B reimbursement program under which both the state and 340B providers benefit from the spread. In each of these circumstances, both the state and the covered entity benefits from the discounts provided under the 340B program.

The ACC issue has recently been elevated in importance due to new legislation and practices in some states. For example, California has just enacted and implemented a law requiring covered entities to bill at AAC and at the same time prohibiting the Medicaid carve-out. Recent experience with this California law illustrates the adverse consequences of mandating AAC billing. In that state, a 190-bed children's hospital has chosen not to enroll in the 340B program despite being newly eligible under recent changes to the program. The hospital made that decision because it has a high Medicaid patient mix, and any savings it might have achieved by serving non-Medicaid patients would not offset the losses it will incur under Medi-Cal. As a result, that hospital had to forfeit access to low-cost prescription drugs, and the AAC billing rule did not generate any savings for the state. Other California children's hospitals are weighing their options. Since September 1, when children's hospitals were first permitted to enroll in 340B, no California children's facility has joined the program. Rather than capitalizing on a potential win-win arrangement between children's hospitals and Medi-Cal, the new law has resulted in a lose-lose situation for the parties.

In contrast, MaineCare issued a transmittal to its 340B hospitals on December 2009 stating that the existing Medicaid prospective payment and settlement approach was deemed to constitute billing at AAC for 340B hospitals. Under that approach, included in the MaineCare state plan, Maine hospitals bill for outpatient drugs at usual and customary, but reimbursement is settled annually at a percentage of the costs reflected on the hospitals' filed Medicare cost reports, with hospitals required to repay the state the difference between the costs initially billed and the final settled costs. The Maine Care settlement process results in the state and 340B hospitals sharing the savings associated with the hospitals' purchase of drugs through the 340B program. An additional benefit is that this approach does not require the Maine hospitals to change their billing systems or bill manually.

\* \* \* \* \*

In conclusion, the undersigned members of the 340B Coalition hope that you will agree that it is critical that you clarify for the states that the AAC billing rule does not further the purposes of the 340B program, and in fact, may cripple it. The benefits of sharing savings from the 340B program among providers, their patients, and state Medicaid programs far outweigh any benefits derived from the ACC billing rates. We urge CMS and HRSA to clarify to state Medicaid programs as soon as

possible that federal law does not require that 340B covered entities bill at AAC and can be harmful to state Medicaid programs and the 340B program and providers, while highlighting that there are a number of available pathways to sharing 340B savings in ways that benefit providers, the states, and – most importantly – Medicaid patients. We ask that CMS and HRSA promote these shared savings approaches.

Thank you for your attention to this critical issue. If you have any questions regarding this letter, please feel free to contact William von Oehsen, President and General Counsel of the Safety Net Hospitals for Pharmaceutical Access (SNHPA) at 202-872-6765 or [william.vonoehsen@snhpa.org](mailto:william.vonoehsen@snhpa.org) or Roger Schwarz, Vice President and Legal Counsel of the National Association of Community Health Centers (NACHC) at [rschwarz@nachc.com](mailto:rschwarz@nachc.com) or 202-296-0158.

Sincerely,

Safety Net Hospitals for Pharmaceutical Access (SNHPA)  
National Association of Community Health Centers (NACHC)  
Planned Parenthood Federation of America (PPFA)  
Hemophilia Alliance

## STATE 340B MEDICAID BILLING BEST PRACTICES

State Medicaid program shared savings arrangements with 340B providers take various forms, including: (1) enhanced dispensing fees, (2) modest add-ons to, or mark-ups of, product cost, and (3) fees for providing both product at acquisition cost *plus* care management or disease management services to targeted high-cost Medicaid populations. The basic concept underlying the shared savings approach is that, because 340B prices are on average 20 to 25 percent below Medicaid net payments (including rebates) for covered outpatient drugs, states can structure a 340B reimbursement program under which both the state and 340B providers benefit from the spread.

1. **Enhanced Dispensing Fee Model** – Under an enhanced dispensing fee arrangement, the state agrees to pay 340B providers a dispensing fee significantly higher than the normal Medicaid dispensing fee, while paying for product at actual acquisition cost. States paying enhanced dispensing fees include: Florida -- \$7.50; West Virginia -- \$8.25; Massachusetts -- \$10; and Louisiana -- \$10.10; Vermont (FQHC Network pilot) -- \$14.25. Alaska has developed a variation of this model under which the Medicaid program pays a “freight charge” in addition to the normal Medicaid dispensing fee and actual acquisition cost for the product. States such as Kansas and Massachusetts set a separate dispensing fee for clotting factor that is based on units of product. In Kansas, that dispensing fee is 12 ½ cents per unit dose; in Massachusetts it is 9 cents per unit.
2. **Modest Markup Model** – States like Connecticut and Minnesota pay for 340B drugs at rates above the drugs’ actual acquisition cost, but less than non-340B post-rebate reimbursement rates. Connecticut statutes provide for payment to 340B providers at the Federal Supply Schedule (FSS) reimbursement rate, which on average exceeds 340B rates by 3 to 5 percent. Minnesota pays a discount off of average wholesale price (AWP) that is deeper than its standard AWP-based discount for non-340B pharmacies. Maine has negotiated agreements with 340B hospital providers under which the hospitals bill the state something other than actual acquisition cost – often usual and customary – but are subsequently paid in a prospective payment-like settlement at something other than the cost billed.
3. **Targeted Disease Management Model** – A number of states, such as Utah and Arizona, utilizing § 1915(b) freedom of choice waivers, steer targeted high-cost Medicaid patient groups into care management/disease management programs operated by 340B providers. Because the state reduces its drug expenditures for each patient shifted from a non-340B pharmacy program, it can afford to reimburse its 340B partner facility for both the facility’s pharmaceutical costs and care management program, while retaining significant savings for itself. Both Utah and Arizona currently do this for hemophilia and other clotting factor diseases, but the Arizona Health Care Cost Containment System (AHCCCS) has just closed bidding on a contract to provide care for other chronic diseases such as asthma, arthritis, Hepatitis C, and AIDS/HIV. Utah is also talking with providers about a similar expansion of their specialty pharmacy programs. A similar arrangement exists between a Medicaid managed care plan and participating 340B providers in Pennsylvania. This model saves money for the plan which, in turn, generates savings for the state as a result of paying lower capitation rates.

For additional information on Medicaid Billing Best Practices, please contact SNHPA President and General Counsel, Bill von Oehsen, at 202-872-6765 or [william.vonoehsen@snhpa.org](mailto:william.vonoehsen@snhpa.org).

## STATUTORY & REGULATORY REFERENCES TO STATE MEDICAID BILLING BEST PRACTICES

### 1. Alaska

#### **7 Alaska Admin. Code 43.591**

If a facility is a covered entity and receives its drugs as described in 42 U.S.C. 256b, the facility may not charge Medicaid more than its **actual acquisition cost, a freight charge of five percent, and a dispensing fee** calculated under (g) of this section.

### 2. Arizona Health Care Cost Containment System

Under an RFP and a § 1915(b) [freedom of choice] waiver, Arizona Medicaid pays Phoenix Children's Hospital for hemophilia drugs, as well as dispensing, distribution, and care coordination. The provider is paid for product and care coordination services.

Under a similar RFP issued September 10, 2009 with bids to close November 9, (presumably also subject to a § 1915(b) waiver), Arizona Medicaid will pay a 340B provider to provide dispensing and distribution of specialty biologics and care coordination for a number of diseases, including: asthma, connective tissue disorders, arthritis, psoriasis, Crohn's Disease, Gaucher & Fabry Disease, growth hormone deficiency, Hepatitis C, HIV/AIDS, multiple sclerosis, organ transplants, and respiratory syncytial Virus (RSV). **Reimbursement is to be based on acquisition cost plus a fee designed to include the dispensing fee, costs for supplies to administer the medication and costs associated with the delivery of the medication to the patient or the prescribing clinician's office site.**

### 3. Connecticut

#### **Conn. Gen. Stat. § 17b-192**

(e) Each federally qualified health center participating in the program shall enroll in the federal Office of Pharmacy Affairs Section 340B drug discount program established pursuant to 42 USC 256b **to provide pharmacy services to recipients at Federal Supply Schedule costs.** Each such health center may establish an on-site pharmacy or contract with a commercial pharmacy to provide such pharmacy services.

#### **Conn. Gen. Stat. § 17b-280.**

(b) **The Department of Social Services may provide an enhanced dispensing fee** to a pharmacy enrolled in the federal Office of Pharmacy Affairs Section 340B drug discount program established pursuant to 42 USC 256b or a pharmacy under contract to provide services under said program.

#### 4. Florida

##### ***Florida Medicaid Prescribed Drugs Reimbursement Methodology***

Dispensing fee: \$7.50 for 340B drugs

##### **Florida 59G-4.251**

(2) For drugs purchased by qualified entities under Section 340B of the Public Health Service Act: Covered entities and Federally Qualified Health Centers or their contracted agents that fill Medicaid patient prescriptions with drugs purchased at prices authorized under Section 340B of the Public Health Service Act **must bill Medicaid for reimbursement at the actual acquisition cost plus a dispensing fee of \$7.50 for these drugs.**

#### 5. Kansas

##### **907 Kansas Administrative Regulations 3:205**

**Section 4. Hemophilia Treatment Reimbursement Via the 340B Drug Pricing Program.** The department shall reimburse for hemophilia treatment, including a factor product, provided by a CHDTC participating as a 340B drug pricing program entity:

- (1) Exclusively via the department's 340B drug pricing program;
- (2) Not via the department's pharmacy reimbursement provisions established in [907 KAR 1:018](#); and
- (3) **At the 340B drug pricing program ceiling price for the factor product pursuant to [42 U.S.C. 256b](#) plus a dispensing fee of twelve and one-half (12 1/2) cents per unit dose.**

#### 6. Louisiana

##### **Louisiana Administrative Code 50:XXIX §925**

**C. The dispensing fee for drugs obtained through the Public Health Service 340B Program will be \$ 10.10 per prescription.** This includes the provider fee assessed for each prescription filled in the state or shipped into the state.

##### **Louisiana Administrative Code 50:XXIX §963**

**C. Dispensing Fees. The covered entity shall be paid a dispensing fee of \$ 10.10 for each prescription dispensed to a Medicaid patient.** With respect to contract pharmacy arrangements in which the contract pharmacy also serves as the covered entity's billing agent, the contract pharmacy shall be paid the \$ 10.10 dispensing fee on behalf of the covered entity.

**Louisiana Administrative Code 50:XXIX § 971**

A. Anti-hemophilia drugs purchased by a covered entity through the **340B** Program and dispensed to Medicaid recipients **shall be billed to Medicaid at actual acquisition cost plus 10 percent and the dispensing fee unless the covered entity has implemented the Medicaid carve-out option. If the covered entity has implemented the Medicaid carve-out option, such drugs shall be reimbursed at AWP minus 30 percent plus the dispensing fee or the billed charges, whichever is less.**

**7. MaineCare**

MaineCare Medical Director Dr. Rod Prior has informed hospitals verbally, during NDC related conference calls with Maine hospitals, that MaineCare considers hospitals to meet the requirement for billing at cost. Dr. Prior announced this most recently during a October 28, 2009 MaineCare conference call with providers. He stated that MaineCare considers hospitals to bill at cost because they pay based on a MaineCare formula that utilizes data from the hospitals' Medicare cost report, and they interpret that to meet the requirement of "bill at cost." In practice, hospitals bill at "usual and customary" and MaineCare pays what they determine is "cost" based upon their formula. Although Dr. Prior has made this statement several times on conference calls with hospitals and with other Medicaid officials present, the hospitals have never received written documentation of this practice.

**8. Massachusetts**

***Division of Health Care Policy and Financing – Prescribed Drugs***  
(114.3 Code of Massachusetts Regulations 31.7):

**31.07: Special Provisions**

(1) Payment for 340B Covered Entities.

(a) The payment for Drugs other than blood clotting factor, obtained through the 340B Program and dispensed by 340B Covered Entities is the **Actual Acquisition Cost plus a \$10.00 Dispensing Fee.**

(b) 340B Payment for Blood Clotting Factor

The payment for blood clotting factor obtained through the 340B program and dispensed by 340B covered entities is the **actual acquisition cost plus a dispensing fee of 9 cents per unit (IU/RCo/Fu/mcg). This rate includes supplies for standard infusion (e.g. Butterfly/ PIV access.)**

## 9. Utah

### **Utah Hemophilia Case Management/Disease Management Program**

Under a § 1915(b) freedom of choice waiver, the Utah Medicaid program contracts with a single 340B provider to provide home care and clotting factor for blood clotting disorders. Utah Medicaid is currently looking at expanding that program to other disease states.

The Utah partnership requires hemophilia patients to make at least one trip a year to the state's hemophiliac treatment center. Then throughout the year, nurses either employed by University of Utah or by a home health agency that is contracted with the hospital, make monthly visits to patients and provide them with drugs purchased with the 340B program needed for treatment.

While the state has benefitted from the savings associated with discounted drugs, the partnership has significantly improved the standard of care for patients participating in Utah's hemophiliac treatment program. Patient satisfaction surveys consistently indicate that at least 98% of those enrolled in the program approve of the care they are receiving. In addition, monthly visits have established productive relationships between health care professionals and patients that have led healthy life style changes that make treating hemophilia easier and less costly.

## 10. West Virginia

### ***West Virginia BMS Medicaid Pharmacy Provider User Guide Revision Date: 09-2009***

Dispensing fee requirements are:

\$2.50 Single Ingredient Brand Drug Dispensing Fee

\$5.30 Single Ingredient Generic Drug Dispensing Fee

\$6.30 Compound with Primary Ingredient Generic Drug Dispensing Fee

\$3.50 Compound with Primary Ingredient Brand Drug Dispensing Fee

**\$8.25 340B PHS Provider Dispensing fee**