



**Shedding Light on Medicaid Billing Requirements:  
A Survey of State Policies Addressing  
the Drug Billing Practices  
of 340B Hospitals**

**by  
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## Background

When Congress established the 340B drug discount program in 1992, it recognized that, when a 340B hospital or clinic dispenses a covered outpatient drug to a Medicaid patient, the manufacturer is at risk of giving two discounts on the same drug – an up-front 340B discount to the covered entity at the time of purchase, and a post-sale rebate to the Medicaid program after Medicaid pays the covered entity for the drug and submits a rebate request to the manufacturer. This type of double price reduction is often referred to as a “duplicate discount.” To protect manufacturers from the duplicate discount problem, Congress included a provision in the law prohibiting covered entities, on the one hand, from seeking a 340B discount and state Medicaid agencies, on the other, from requesting a manufacturer rebate on the same drug.<sup>1</sup> Congress directed the Secretary of Health and Human Services to develop a mechanism to implement this provision within 12 months of the program’s effective date.<sup>2</sup>

Pressed to meet the statutory deadline set by Congress, the Health Resources and Services Administration (HRSA) issued in June 1993 a Federal Register notice that essentially created a two-step process for avoiding duplicate discounts.<sup>3</sup> The first part of HRSA’s duplicate discount mechanism directed state Medicaid agencies to forego Medicaid rebates on drugs that covered entities purchase through the 340B program. The second part required covered entities to pass their 340B discounts to Medicaid, by billing at actual acquisition cost (AAC), in order to compensate states for the loss of rebates on 340B drugs. In March 2000, HRSA retreated from the second requirement and advised covered entities to follow state billing and reimbursement guidance while the agency reevaluated the AAC billing standard.<sup>4</sup> HRSA also clarified in March 2000 the right of covered entities to purchase their Medicaid drugs outside the 340B program, often referred to as the Medicaid carve-out option, as an alternative way to protect manufacturers from duplicate discounts.<sup>5</sup>

In light of the above history, 340B hospitals and other covered entities have adopted two Medicaid billing practices that, although seemingly based on HRSA guidance, are now attracting scrutiny from federal and state enforcement authorities. The first practice is that, consistent with HRSA’s March 2000 Federal Register notice, many hospitals follow state law, rather than HRSA’s June 1993 guidance, in determining how to bill Medicaid for 340B drugs. This often means that they are not billing Medicaid at AAC, especially for physician-administered drugs. With respect to the second billing practice, hospitals generally do not alter how they bill Medicaid at all if there is no duplicate discount situation in which the state has communicated its intent to seek rebates on drugs purchased through the 340B program. Some Medicaid regulators take issue with one or both of these practices and assert that 340B providers are required to bill their discounted drugs at AAC, regardless of what state law requires and whether a duplicate discount situation exists. This is because the regulators believe that the federal AAC billing standard was established to save money for the Medicaid program. 340B providers, by contrast,

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<sup>1</sup> 42 U.S.C. § 256b(a)(5)(A) (2006), attached at Tab A.

<sup>2</sup> *Id.* at § 256b(a)(5)(A)(ii).

<sup>3</sup> Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34,058 (June 23, 1993), attached at Tab B.

<sup>4</sup> Notice Regarding the Section 340B Drug Pricing Program – Program Guidance Clarification, 65 Fed. Reg. 13,983, 13,984 (March 15, 2000), attached at Tab C.

<sup>5</sup> *Id.*

embrace the view that the AAC billing standard evolved out of federal efforts to solve the duplicate discount problem.

How Medicaid should be billed for 340B drugs is more than an academic question. For some covered entities, the stakes are high. Medicaid auditors in at least three states – Arkansas, Florida and New York – have investigated the Medicaid billing practices of numerous covered entities and, in some cases, demanded recoupment if the providers failed to bill at AAC.<sup>6</sup> Allegations of billing Medicaid above AAC was central to a federal whistleblower suit brought against a group of family planning clinics in the Los Angeles area, raising concerns that federal or state investigators may intervene in the case on behalf of the plaintiff.<sup>7</sup>

Safety Net Hospitals for Pharmaceutical Access (SNHPA) is alarmed by news of the family planning lawsuit and the growing number of Medicaid investigations of covered entities because the allegations underlying such legal actions conflict with SNHPA's understanding of the relevant law. Moreover, it is SNHPA's impression that many states have allowed 340B providers to deviate from AAC billing on a regular basis, even with respect to drugs for which a duplicate discount problem exists. This may occur, for example, if the state utilizes a billing system that does not accommodate AAC billing, if billing at AAC would not affect reimbursement to the covered entity or if the state is concerned that AAC billing is too onerous. If SNHPA's impression is correct, then both current and future enforcement activities premised on the inviolability of the AAC billing standard may be misguided. For these reasons, SNHPA decided to survey its members in an effort to identify states that have given covered entities flexibility in how they bill Medicaid for 340B drugs.

### **Methodology**

To learn more about state activities relating to the 340B AAC billing standard, SNHPA sent each of its member hospitals a six-question survey.<sup>8</sup> The first question asked for contact information, although members were informed that they could participate anonymously. The second question asked whether the respondent's state permitted deviation from AAC billing at any time between 1992 (the effective date of the 340B program) and the present, regardless of whether the state now requires AAC billing. SNHPA instructed members to answer NO if the only deviation from AAC billing was to allow hospitals to implement the Medicaid carve-out option. For those who answered YES to question two, participants were asked to identify their state in response to question three. Question four asked if the state Medicaid agency permitted, or at least did not object to, covered entities billing 340B drugs in a manner other than AAC prior to March 2000, the date of HRSA's notice clarifying and retreating from the AAC billing standard. Hospitals had the option of answering YES, NO or I DON'T RECALL.

Question five was probably the most challenging question to answer because it required the respondent to review a list of statements and select the ones that the hospital considered to be

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<sup>6</sup> *Medicaid Billing Practices at 340B Pharmacies Scrutinized*, Fed. Drug Discount & Compliance Monitor (Safety Net Hosp. for Pharm. Access, Wash., D.C.), Oct. 2008, at 1.

<sup>7</sup> *Id.*

<sup>8</sup> Safety Net Hosp. for Pharm. Access, SNHPA Medicaid Billing Survey, attached at Tab D.

true. Survey respondents were allowed to check off one or more of the following statements if they agreed with the statement.

- The state issued a formal regulation or guideline specifically allowing or directing 340B providers to bill some or all of their 340B drugs at a rate other than AAC.
- Our hospital found out through informal communications with the state that it did not have to bill all or some of its 340B drugs at AAC.
- It was (and/or still is) simply not possible to bill the state at AAC.
- We learned that billing at AAC is not required in our state from a third party (e.g. other hospitals, our state hospital association, a consultant, an attorney, SNHPA, etc.)
- The Office of Pharmacy Affairs was (and/or still is) aware of how our state permits non-AAC billing
- The Centers for Medicare & Medicaid Services was (and/or still is) aware of how our state permits non-AAC-billing.
- We advised the state that our hospital was not billing all or some of its outpatient drugs at AAC and the state did not object.
- We don't really know what the state's position was or is with respect to billing in a manner that is different from AAC billing, but the state has not objected (as far as we know) to the way our hospital does its 340B billing.
- Other (please describe)

The final question in the survey asked whether SNHPA could follow up directly with members to clarify their answers when necessary. Most hospitals responded affirmatively to this question and SNHPA availed itself of this opportunity when members submitted confusing or contradictory answers.

## **Results**

SNHPA received 88 responses to its survey, representing a response rate of about 18 percent. Question one asked for the respondent's contact information. Fifteen members responded anonymously. Many of the respondents were from the same state, so survey responses provided relevant information for only 27 states in total. The states associated with the anonymous responses are unknown.

Question two asked if the hospital's state Medicaid program permitted deviation from AAC billing for 340B drugs at any time from the inception of the 340B program to the present. The identity of the state was requested in question three. Approximately 45 percent of the respondents answered that they were allowed to deviate from AAC bill and 55 percent said they were not allowed. States that reportedly allowed non-AAC billing include: Arizona, Georgia, Maine, Maryland, Minnesota, New Jersey, Ohio, Oregon, Texas and West Virginia. States that required AAC billing include: Idaho, Iowa, Kansas, Rhode Island and South Dakota. Five of the anonymous responses indicated that they could deviate from AAC billing and the other ten said they could not.

Interestingly, hospitals in twelve different states gave conflicting answers. Whereas one or more respondents indicated that AAC billing has always been required in their state, others reported

that non-AAC billing has been permitted. The relevant states are: Arkansas, California, Florida, Kentucky, Louisiana, Massachusetts, Michigan, Missouri, New York, North Carolina, Pennsylvania and Washington. Some of the hospitals offered written comments in their survey responses addressing this matter. A comparison of comments from hospitals located in these twelve states provides a good illustration of the confusion that exists among them. In North Carolina, for example, a respondent stated: "I believe our state Medicaid agency has communicated repeatedly that they expect to be billed at AAC for physician-administered drugs." But a different North Carolina hospital commented that "the state has never required AAC billing in clinics...so we have always billed the state our usual and customary charges for clinic-administered drugs and continue to do so today." In Kentucky, two hospitals reported that their Medicaid agency did not object to them billing at rates other than AAC, but a third indicated that the state not only objected but demanded to be paid back the value of the hospital's 340B discounts.

Turning to question four, hospitals were asked the same question about deviating from AAC billing, but the question was limited to the time period prior to HRSA's March 2000 guidance when it essentially withdrew the AAC billing rule established in June 1993. Although one would predict that more states would have required hospitals to bill at AAC during this period, SNHPA's survey revealed that less than 15 percent of the hospitals were required to do so. Nearly 65 percent indicated that non-AAC billing was permitted and the rest replied that they did not enroll in the 340B program until after March 2000.

Question five was the last substantive question in the survey because question six simply asked if the respondent could be contacted for follow-up issues. In question five, hospitals were presented a list of eight statements regarding AAC billing and were asked to identify the ones with which they agreed. The results are summarized in the chart below:

Question 5 Statements	Percent of Respondents who Agreed with Statement
It was (and/or still is) simply not possible to bill the state at AAC.	36.5%
We don't really know what the state's position was or is with respect to billing in a manner that is different from AAC billing, but the state has not objected (as far as we know) to the way our hospital does its 340B billing.	31.7%
Our hospital found out through informal communications with the state that it did not have to bill all or some of its 340B drugs at AAC.	29.2%
We learned that billing at AAC is not required in our state from a third party (e.g. other hospitals, our state hospital association, a consultant, an attorney, SNHPA, etc.)	21.9%

We advised the state that our hospital was not billing all or some of its outpatient drugs at AAC and the state did not object.	14.6%
The Office of Pharmacy Affairs was (and/or still is) aware of how our state permits non-AAC billing.	9.7%
The state issued a formal regulation or guideline specifically allowing or directing 340B providers to bill some or all of their 340B drugs at a rate other than AAC.	9.7%
The Centers for Medicare & Medicaid Services was (and/or still is) aware of how our state permits non-AAC-billing.	4.8%
Other	19.5%

It is clear from the above chart that, according to the hospital respondents, few states provided clear guidance about billing at non-AAC rates. Most hospitals acquired the relevant information through informal or indirect means or by noting the lack of objection by the state when engaging in non-AAC billing.

### **Discussion**

The above results suggest that, over the 17-year history of the 340B program, few state Medicaid agencies have provided clear and consistent guidance to disproportionate share hospitals about billing their 340B drugs at AAC. According to the survey, more states have allowed non-AAC billing than not. In some cases, permission to deviate from AAC billing was specifically communicated by the state. But in most cases, hospitals acquired such information indirectly or based on inference when the state did not object to the hospital billing at rates other than AAC. Perhaps most striking about the results is the large number of states for which hospitals gave conflicting answers to the survey. Some hospitals reported that deviation from AAC billing was permitted and others reported the opposite. The results, taken as a whole, provide strong evidence that there is confusion within the 340B hospital community about whether their 340B-discounted drugs should be billed to Medicaid at AAC or not.

The results also appear to undermine the position of those Medicaid enforcement authorities who insist that the AAC billing standard is a federal requirement with which all covered entities must comply. If this position were correct, ten or more states have been operating in violation of federal law and almost half of the hospitals have been out of compliance. A more plausible explanation, in SNHPA's view, is that federal law does not actually mandate AAC billing of 340B drugs. This alternative understanding appears especially compelling for 340B drugs billed to Medicaid after March 2000 when HRSA issued its clarification of the AAC billing standard. In the clarification, HRSA announced that it was revisiting its AAC billing directive and that

covered entities should instead follow state reimbursement guidelines for applicable billing limits. It is difficult to understand how a covered entity could be successfully charged with overbilling the Medicaid program by not abiding by the AAC billing standard after publication of HRSA's clarification.

And even for the period prior to March 2000, SNHPA believes there are serious weaknesses in the position that covered entities were obligated under federal law to bill Medicaid at AAC. SNHPA's position is that the AAC billing standard articulated by HRSA in June 1993 was an informal agency interpretation that states were free to apply or ignore. It is SNHPA's impression that many states developed different billing and reimbursement policies for 340B drugs during the early years of the program and that virtually all of these policies allowed non-AAC billing. In many cases, 340B drugs were billed and reimbursed the same way as non-340B drugs. SNHPA's survey bears out this point because, according to the results, fewer hospitals (less than 15 percent) were directed by their states to bill at AAC prior to March 2000 compared to the number of hospitals (about 55 percent) billing at AAC for the periods both before and after March 2000. Utilization of the AAC billing standard by states has apparently grown over time, notwithstanding HRSA's withdrawal of the requirement at the federal level in March 2000.

As previously mentioned, disproportionate share hospitals and other 340B providers generally bill Medicaid for 340B drugs at non-AAC rates in two situations – when non-AAC billing is required or contemplated under state reimbursement guidance or when no duplicate discount problem exists. These billing practices have triggered Medicaid audits and, in the case of the Los Angeles family planning clinics, a whistleblower lawsuit. Notwithstanding, the results of SNHPA's survey suggest that deviation from AAC billing is widespread, and often with the knowledge and/or approval of the state. One can therefore draw two very different conclusions from the survey data. Either a very large number of covered entities are at risk of being subject to Medicaid recoupment actions, or the enforcement actions taken to date are out of line with proper federal and state implementation of the AAC billing restriction. SNHPA believes that anyone who takes the time to research carefully the laws and policies relevant to the 340B AAC billing standard will invariably reach the second conclusion.

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If you have any questions, please contact SNHPA's President and General Counsel William von Oehsen at (202) 872-6765 or [william.vonoehsen@snhpa.org](mailto:william.vonoehsen@snhpa.org).

**TAB A**

Effective:[See Text Amendments]

United States Code Annotated Currentness

Title 42. The Public Health and Welfare

Chapter 6A. Public Health Service (Refs & Annos)

Subchapter II. General Powers and Duties

▣ Part D. Primary Health Care

▣ Subpart VII. Drug Pricing Agreements

→ § 256b. Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C.A. § 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

(2) Rebate percentage defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to--

(i) the average total rebate required under section 1927(c) of the Social Security Act [42 U.S.C.A. § 1396r-8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act [42 U.S.C.A. § 1396r-8(c)] is based on the applicable percentage provided under section 1927(c)(4) of such Act [42 U.S.C.A. § 1396r-8(c)(4)].

(ii) Definition

The term “over the counter drug” means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State Medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act [42 U.S.C.A. § 1396 et seq.].

(4) Covered entity defined

In this section, the term “covered entity” means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act [42 U.S.C.A. § 1396d(l)(2)(B)]).

(B) An entity receiving a grant under section 256a of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II of part C of subchapter XXIV of this chapter (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV of this chapter.

(F) A black lung clinic receiving funds under section 937(a) of this title.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C.A. § 701(a)(2)].

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C.A. § 1651 et seq.].

(J) Any entity receiving assistance under subchapter XXIV of this chapter (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 U.S.C.A. § 1395ww(d)(1)(B)]) that--

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C.A. § 1395 et seq.] or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act [42 U.S.C.A. § 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 U.S.C.A. § 1395ww(d)(5)(F)(i)(II)]; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act [42 U.S.C.A. § 1396 et seq.] for medical assistance described in section 1905(a)(12) of such Act [42 U.S.C.A. § 1396d(a)(12)] with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act [42 U.S.C.A. § 1396r-8].

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act [42 U.S.C.A. § 1396r-8(a)(5)(C)] shall apply.

(B) Prohibiting resale of drugs

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in sub-

paragraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act [42 U.S.C.A. § 1396a(a)(5)] of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions

In this section, the terms “average manufacturer price”, “covered outpatient drug”, and “manufacturer” have the meaning given such terms in section 1927(k) of the Social Security Act [42 U.S.C.A. § 1396r-8(k)].

(c) References to Social Security Act

Any reference in this section to a provision of the Social Security Act [42 U.S.C.A. § 301 et seq.] shall be deemed to be a reference to the provision as in effect on November 4, 1992.

(d) Compliance with requirements

A manufacturer is deemed to meet the requirements of subsection (a) of this section if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after November 4, 1992), as applied by the Secretary, and would have entered into an agreement under this section (as such section was in effect at such time), but for a legislative change in this section (or the application of this section) after November 4, 1992.

CREDIT(S)

(July 1, 1944, c. 373, Title III, § 340B, as added Nov. 4, 1992, Pub.L. 102-585, Title VI, § 602(a), 106 Stat. 4967, and amended June 10, 1993, Pub.L. 103-43, Title XX, § 2008(i)(1)(A), 107 Stat. 212.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1992 Acts. Senate Report No. 102-401, see 1992 U.S. Code Cong. and Adm. News, p. 4113.

1993 Acts. Senate Report No. 103-2 and House Conference Report No. 103-100, see 1993 U.S. Code Cong. and Adm. News, p. 196.

References in Text

The Social Security Act, referred to in subsecs. (a)(1),(3), (4)(L)(i), (5)(A)(i) and (c), is Act Aug. 14, 1935, c. 531, 49 Stat. 620, as amended, which is classified generally to chapter 7 (section 301 et seq.) of this title. Titles XVIII and XIX of such Act are classified generally to subchapters XVIII (section 1395 et seq.) and XIX (section 1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 256a of this title, referred to in subsec. (a)(4)(B), was repealed by Pub.L. 104-299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

Subpart II of part C of subchapter XXIV of this chapter, referred to in subsec. (a)(4)(D), was redesignated subpart I of part C of subchapter XXIV of this chapter by Pub.L. 106-345, Title III, § 301(b)(1), Oct. 20, 2000, 114 Stat. 1345, and is classified to section 300ff0951 et seq. of this title.

The Native Hawaiian Health Care Act of 1988, referred to in subsec. (a)(4)(H), is Pub.L. 100-579, Oct. 31, 1988, 102 Stat. 2916, and Pub.L. 100-690, Title II, Subtitle D, §§ 2301 to 2312, Nov. 18, 1988, 102 Stat. 4222 to 4230, formerly classified to chapter 122 (section 11701 et seq.) of this title prior to its omission in the general revision of that chapter by Pub.L. 102-396, Title IX, § 9168, Oct. 6, 1992, 106 Stat. 1948. For complete classification of this Act to the Code, see Tables.

The Indian Health Care Improvement Act, referred to in subsec. (a)(4)(I), is Pub.L. 94-437, Sept. 30, 1976, 90 Stat. 1400, as amended, which is classified to chapter 18 (section 1601 et seq.) of Title 25, Indians. Title V of that Act is classified to subchapter IV (section 1651 et seq.) of chapter 18 of Title 25. For complete classification of this Act to the Code, see section 1 of Pub.L. 94-437, set out as a Short Title note under section 1601 of Title 25 and Tables.

Section 247b(j)(2) of this title, referred to in subsec. (a)(4)(K), was repealed and section 247b(j)(1)(B) was redesignated section 247b(j)(2) by Pub.L. 103-183, Title III, § 301(b)(1)(A), (C), Dec. 14, 1993, 107 Stat. 2235.

#### Codifications

Another section 340B of act July 1, 1944, was renumbered section 340C and is classified to section 256c of this title. Another section 340B of act July 1, 1944, was renumbered section 340C and is classified to 42 U.S.C.A. § 256c

As in effect immediately after November 4, 1992, referred to in subsec. (d), in the original read “as in effect immediately after the enactment of the Veterans Health Care Act of 1992”, which has been translated as meaning immediately after the date of the enactment of Pub.L. 102-585, Nov. 4, 1992, 106 Stat. 4943, known as the Veterans Health Care Act of 1992, as the probable intent of Congress. Pub.L. 102-585 was approved Nov. 4, 1992.

#### Amendments

1993 Amendments. Pub.L. 103-43, § 2008(i)(1)(A), amended section 602(a) of Pub.L. 102-585 to correct a technical error in the directory language of section 602(a) of Pub.L. 102-585 which, in enacting this section, had failed to indicate with sufficient specificity exactly where in this part this section was to be set out.

#### Effective and Applicability Provisions

1993 Acts. Amendment by Pub.L. 103-43 effective June 10, 1993, see section 2101 of Pub.L. 103-43, set out as a note under section 201 of this title.

#### Study of Treatment of Certain Clinics as Covered Entities Eligible for Prescription Drug Discounts

Section 602(b) of Pub.L. 102-585 provided that:

**“(1) Study.**--The Secretary of Health and Human Services shall conduct a study of the feasibility and desirability of including entities described in paragraph (3) as covered entities eligible for limitations on the prices of covered out-

patient drugs under section 340B(a) of the Public Health Service Act (as added by subsection (a)) [subsec. (a) of this section].

“(2) **Report.**--Not later than 1 year after the date of the enactment of this Act [Nov. 4, 1992], the Secretary shall submit a report to Congress on the study conducted under paragraph (1), and shall include in the report--

“(A) a description of the entities that are the subject of the study;

“(B) an analysis of the extent to which such entities procure prescription drugs; and

“(C) an analysis of the impact of the inclusion of such entities as covered entities under section 340B(a) of the Public Health Service Act [subsec. (a) of this section] on the quality of care provided to and the health status of the patients of such entities.

“(3) **Entities described.**--An entity described in this paragraph is an entity--

“(A) receiving funds from a State for the provision of mental health or substance abuse treatment services under subparts I or II of part B of title XIX of the Public Health Service Act [42 U.S.C.A. §§ 300x et seq. or 300x-21 et seq., respectively] or under title V of such Act [42 U.S.C.A. § 290aa et seq.]; or

“(B) receiving funds from a State under title V of the Social Security Act [42 U.S.C.A. § 701 et seq.] for the provision of maternal and child health services that are furnished on an outpatient basis (other than an entity described in section 340B(a)(4)(G) of the Public Health Service Act [subsec. (a)(4)(G) of this section]).”


## NOTES OF DECISIONS

Class actions 3

Eligibility 1

Persons entitled to maintain action 2

### 1. Eligibility

Injury suffered by university medical center when Department of Health and Human Services (HHS) determined, based on allegedly erroneous calculation of its disproportionate share adjustment percentage, that center was ineligible to participate in drug pricing agreement program under Public Health Services Act (PHSA), was not redressable, and center thus lacked standing to challenge calculation, where center also participated in group drug purchasing agreements, making it automatically unable to qualify as covered entity which could participate in pricing agreement program; because center was ineligible regardless of proper calculation, court intervention could not provide tangible benefit. University Medical Center of Southern Nevada v. Shalala, D.D.C.1998, 5 F.Supp.2d 4, affirmed on other grounds 173 F.3d 438, 335 U.S.App.D.C. 322. United States 82(1)

### 2. Persons entitled to maintain action

University medical center lacked standing to sue Department of Health and Human Services (HHS) on grounds that HHS acted arbitrarily and capriciously in failing to add center to list of hospitals eligible for outpatient drug discounts under Public Health Service Act (PHSA) before expiration of period in which eligible hospitals could obtain retroactive discounts from drug manufacturers, given absence of redressable injury; if claimed injury was merely HHS' alleged failure to add center to eligible hospital list in timely manner, no injury in fact existed, while loss of retroactive discounts, which were payable by nonparty manufacturers, was not redressable by judgment against HHS. University

Medical Center of Southern Nevada v. Shalala, C.A.D.C.1999, 173 F.3d 438, 335 U.S.App.D.C. 322. United States  
82(1)

3. Class actions

Class certification was not warranted in county's proposed class action seeking to recover overcharges from a dozen drug manufacturers for charges that exceeded price ceilings imposed by the Public Health Service Act and contractual agreements thereunder, given concern as to manageability of action related to vast number of drugs, public health care institutions, and prices involved. County of Santa Clara v. Astra USA, Inc., N.D.Cal.2009, 257 F.R.D. 207, reconsideration denied 2009 WL 1765811. Federal Civil Procedure 182.5

42 U.S.C.A. § 256b, 42 USCA § 256b

Current through P.L. 111-86 (excluding P.L. 111-84) approved 10-29-09

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**TAB B**

NOTICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992  
Duplicate Discounts and Rebates on Drug Purchases

Wednesday, June 23, 1993

\*34058 AGENCY: Public Health Service, HHS.

ACTION: Final notice.

SUMMARY: Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act, "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides discounts on covered outpatient drugs to eligible entities. Section 340B(a)(5)(A) provides that a drug purchase shall not be subject to both a discount under section 340B and a Medicaid rebate under section 1927 of the Social Security Act. The Department is directed to establish a mechanism to assure that covered entities comply with this prohibition. The purpose of this notice is to announce the final mechanism to prevent duplicate discounts and rebates.

The proposed mechanism was announced in the Federal Register at 58 FR 27293 on May 7, 1993. A comment period of 30 days was established to allow public comment on the proposed mechanism. Two comments were received. Both comments concerned issues involving implementation of the mechanism and did not raise substantive issues concerning the mechanism itself; therefore, we will address both comments in the Effective Date section. The mechanism, in its final form, is adopted as proposed.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R.Ph., Director, Office of Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, Room 7A-55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Phone: (301) 443-0004

DATES: The Department proposed to begin implementation of the mechanism on July 1, 1993, if the Public Health Service (PHS) could provide the State Medicaid agencies with the Medicaid \*34059 provider numbers for all covered entities. One comment addressed the necessity for a date by which PHS could, with certainty, provide the numbers to the States.

The Department has developed an implementation plan which involves providing covered entity Medicaid provider numbers to the State Medicaid agencies on a monthly basis for July, August, and September, 1993. From October, 1993, until June 30, 1994, the files will be updated on a quarterly basis. Thereafter, the files will be updated annually.

As outlined in the first notice, all State Medicaid drug utilization data for the third calendar quarter, due to manufacturers by November 30, 1993, would exclude rebates for discounted drugs sold to PHS covered entities. For claims paid by Medicaid prior to July 1, 1993, State agencies will bill manufacturers for rebates on all drugs paid by Medicaid.

SUPPLEMENTARY INFORMATION: The other comment dealt with entity participation in the PHS drug discount program prior to their exclusion from the Medicaid rebate program. Entities that utilize Medicaid billing systems that include pharmacy in their all-inclusive rates or do not submit Medicaid claims for covered outpatient drug reimbursement do not generate Medicaid rebates and have no need to participate in the mechanism to prevent duplicate discounts and rebates. These entities may request drug discounts retroactive to December 1, 1992, and may accept further drug discounts as soon as possible.

Those entities which bill Medicaid separately for covered outpatient drugs can only accept a discount on those drugs for which no claims for Medicaid reimbursement were sent to their respective State Medicaid agencies. They may accept the discounted price once their Medicaid provider numbers are received by the Drug Pricing Program, and the Program provides these numbers to the respective State Medicaid agencies.

Dated: June 16, 1993.

William A. Robinson,

Acting Administrator, Health Resources and Services Administration.

(FR Doc. 93-14767 Filed 6-22-93; 8:45 am)

BILLING CODE 4160-15-M

58 FR 34058-03, 1993 WL 218540 (F.R.)

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**TAB C**

NOTICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding the Section 340B Drug Pricing Program--Program Guidance  
Clarification

Wednesday, March 15, 2000

\*13983 AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act, "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible (covered) entities must sign a pharmaceutical pricing agreement with the Secretary of HHS in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to clarify section 340B program guidance related to the mechanism to prevent duplicate discounts (i.e., the generation of a \*13984 Medicaid rebate on a section 340B discounted drug). Any covered entity that purchases its non-Medicaid drugs through the 340B program but its Medicaid drugs through other avenues must provide the Office of Drug Pricing (ODP) notice of this type of dual purchasing activity. The ODP will place a notation "non-applicable" (N/A) by the covered entity name on the eligibility list so that any reimbursement requests for its Medicaid drugs will continue to generate manufacturer rebates. For appropriate Medicaid drug reimbursement procedures, the Health Resources and Services Administration (HRSA) refers the covered entity to its respective State Medicaid agency for guidance.

FOR FURTHER INFORMATION CONTACT: Captain Robert Staley, Office of Drug Pricing, Bureau of Primary Health Care, Health Resources and Services Administration, 10th Floor, East-West Towers, 4350 East-West Highway, Bethesda, MD 20814; Phone (800) 628-6297; Fax (301) 594-4982.

SUPPLEMENTARY INFORMATION: Section 340B(a)(5)(A) required HHS to develop a mechanism to prevent a section 340B drug discount and a Medicaid rebate on the same drug (i.e., prevention of double discounting). HRSA, together with the Medicaid Rebate Program, Health Care Financing Administration, developed a process to prevent this potential double price reduction and published the final notice of this mechanism on June 23, 1993, at 58 FR 34058. The mechanism, which focuses only on 340B covered outpatient drugs, requires a covered entity that bills Medicaid on a cost basis (e.g., community health

centers using fee for service and not all inclusive rates) to submit to ODP its Pharmacy Medicaid Number (i.e., the number used to bill Medicaid for the drugs). This information is placed by the name of the covered entity on the master electronic eligibility list. Using this Medicaid number, the State Medicaid agency creates a separate provider file for claims from that covered entity. This computer file then excludes data from this provider file when generating the rebate bills to the manufacturers. In this way, the mechanism prevents double discounting.

An entity which utilizes a Medicaid billing system that includes pharmacy in an all-inclusive rate or does not submit Medicaid claims for covered outpatient drugs would not generate Medicaid rebates. Consequently, these entities do not have to provide their pharmacy numbers (58 FR 34059). However, such entities were instructed to provide ODP with notice of such purchasing practices so that this information could be provided to participating manufacturers and appropriate State Medicaid agencies (59 FR 25112, May 13, 1994).

It has come to our attention that there may be some confusion concerning the appropriate reporting procedures for an entity not participating in the 340B Program for its Medicaid drugs (i.e., purchasing its non-Medicaid drugs through the 340B Program and its Medicaid drugs outside the Program). Because drugs purchased outside of the 340B Program are not considered covered 340B outpatient drugs, an entity that only purchases non-Medicaid drugs through the 340B Program would not request Medicaid reimbursement for its covered outpatient drugs (i.e., non-Medicaid drugs discounted through the 340B program). Consequently, the covered entity would not provide ODP its Medicaid Pharmacy number. However, this entity still must notify ODP of this type of purchasing practice. ODP will place N/A by the name of the covered entity, signaling no Medicaid reimbursement requests on drugs purchased with discounts under section 340B. In this way, Medicaid rebates will continue to be generated on its Medicaid drugs purchased outside the 340B program.

Covered entities that have submitted Medicaid Pharmacy provider numbers now included in the covered entity database but are purchasing drugs for their Medicaid patients on the open market should contact ODP as soon as possible to request that their Medicaid Pharmacy numbers be replaced by N/A in the covered entity database. An entity that has purchased Medicaid drugs outside of the 340B Program but submitted its Medicaid provider number to ODP should attempt to preserve any documentation of such purchasing activity. The entity should contact its State Medicaid agency about these past drug purchases so that the agency can bill manufacturers for rebates that were excluded from past rebate claims.

On behalf of the Medicaid Drug Rebate Program, HRSA provided notice to covered entities regarding appropriate procedures for requesting Medicaid reimbursement for covered outpatient drugs (58 FR 27293 and 59 FR 25112 regarding "actual acquisition cost"). Currently, HRSA is reviewing that portion of the guidance and recommends that covered entities refer to their respective Medicaid State agency drug reimbursement guidelines for applicable billing limits.

Dated: March 9, 2000.

Claude Earl Fox,

65 FR 13983-02  
65 FR 13983-02, 2000 WL 275053 (F.R.)  
(Cite as: 65 FR 13983)

Page 3

Administrator.

[FR Doc. 00-6287 Filed 3-14-00; 8:45 am]

BILLING CODE 4160-15-P

65 FR 13983-02, 2000 WL 275053 (F.R.)

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**TAB D**


**SNHPA**
**Safety Net Hospitals for Pharmaceutical Access**

## SNHPA Medicaid Billing Survey

You may have read in the May issue of the *Monitor* that the HHS Office of the Inspector General (OIG) has launched a study on the Medicaid billing practices of 340B providers. SNHPA has already spoken with the OIG to educate the investigators about the hardships associated with billing Medicaid at actual acquisition cost (AAC) and the various situations in which compliance with AAC billing standards does or should not apply. We shared with the OIG SNHPA's longstanding position that, in the absence of a duplicate discount problem (when a drug is subject to both a 340B discount and a Medicaid rebate), a covered entity is relieved of its obligation to bill its 340B drugs at AAC. Therefore, while there are instances where billing at AAC is required, there are situations where states have not applied this standard. We also discussed the Medicaid carve-out option and other examples of how states have allowed covered entities to deviate from AAC billing.

The same Monitor issue describes a pending enforcement action against a group of family planning clinics for failing to bill Medicaid at AAC for 340B drugs, even though the state Medicaid agency admits that the drugs in question are not subject to rebates under the Medicaid drug rebate program. Stories such as this highlight a disturbing reality that some government regulators have a different understanding of the purpose of the AAC billing rule than SNHPA and the broader 340B community. In particular, whereas 340B providers embrace the view that the AAC billing standard evolved out of federal efforts to solve the duplicate discount problem, others believe that AAC billing standards were established to save money for the Medicaid program. This alternative understanding of the purpose of AAC billing may be driving in large part the recent rise in state enforcement actions against covered entities for failing to bill at AAC.

SNHPA is alarmed by news of the family planning enforcement action and other investigations of covered entities because they conflict with both SNHPA's understanding of the relevant law and our impression that many states have allowed 340B providers to deviate from AAC billing on a regular basis, even with respect to drugs for which a duplicate discount problem exists. It is with respect to the second point where we could use your help. In particular, SNHPA is looking for examples of states that have given covered entities flexibility in how they bill Medicaid for 340B drugs. Our hope is that if we share this information with the OIG, we can use the report to educate both federal and state Medicaid officials about the non-binding nature of the AAC billing standard. This, in turn, may deter states from pursuing enforcement actions that could otherwise set a dangerous precedent for SNHPA members and the 340B provider community in general. Accordingly, we ask your help in answering a few short questions. If you want, you can respond to these questions anonymously. We ask that you complete this survey by **August 20**.

If you have any questions, please contact SNHPA's Director of Legal and Regulatory Affairs Stuart Gordon at [stuart.gordon@snhpa.org](mailto:stuart.gordon@snhpa.org) or 202-552-5851 or SNHPA's President and General Counsel Bill von Oehsen at [william.vonoehsen@snhpa.org](mailto:william.vonoehsen@snhpa.org) or 202-872-6765. <!--[if gte mso 9]-->

### 1. Contact Information

(Optional)

Contact Information:

Name:

Title:

Hospital:

City:

State:

E-Mail:

Phone:

**2. It is SNHPA's impression that some state Medicaid programs have specifically allowed, or at least not objected to, covered entities billing 340B drugs at rates different from their 340B actual acquisition cost (AAC). This may occur, for example, if the state utilizes a billing system that does not accommodate AAC billing, if billing at AAC would not affect reimbursement to the covered entity or if the state is concerned that AAC billing is too onerous. Are you aware of a state Medicaid agency that falls into this category?**

Please answer YES if the state permitted deviation from AAC billing at any time between 1992 (the effective date of the 340B program) and the present, even if AAC billing is currently required. Please also answer YES if the hospital's right to bill at rates other than AAC relates only to a subset of outpatient drugs purchased by the hospital through the 340B program (for example, infusion products, injectibles and other physician-administered drugs). Do not answer YES if the only deviation from AAC billing is if your hospital purchased its Medicaid drugs outside the 340B program (i.e. if your hospital implements the Medicaid carve-out option).

Yes No

3. If you answered NO to question (2), you do not have to answer any further questions. If you responded YES, please indicate the state.

4. Did the state Medicaid agency permit, or at least not object to, covered entities billing 340B drugs in a manner other than at AAC prior to March 2000?

Yes No I don't recall

5. With respect to the period of time in which deviation from AAC billing was allowed, please let us know which of the following statements is true (you can check more than one answer).

The state issued a formal regulation or guideline specifically allowing or directing 340B providers to bill some or all of their 340B drugs at a rate other than AAC.

Our hospital found out through informal communications with the state that it did not have to bill all or some of its 340B drugs at AAC.

It was (and/or still is) simply not possible to bill the state at AAC.

We learned that billing at AAC is not required in our state from a third party (e.g. other hospitals, our state hospital association, a consultant, an attorney, SNHPA, etc.)

The Office of Pharmacy Affairs was (and/or still is) aware of how our state permits non-AAC billing

The Centers for Medicare & Medicaid Services was (and/or still is) aware of how our state permits non-AAC-billing.

We advised the state that our hospital was not billing all or some of its outpatient drugs at AAC and the state did not object.

We don't really know what the state's position was or is with respect to billing in a manner that is different from AAC billing, but the state has not objected (as far as we know) to the way our hospital does its 340B billing.

Other (please describe)

6. Please indicate whether you are available for follow-up questions.

Yes No

Next

Cancel