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(Original Signature of Member)

108TH CONGRESS
2ND SESSION

H. R. _____

To amend the Public Health Service Act to revise and expand the section 340B program to improve the provision of discounts on drug purchases for certain safety net providers.

IN THE HOUSE OF REPRESENTATIVES

Mr. RUSH introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to revise and expand the section 340B program to improve the provision of discounts on drug purchases for certain safety net providers.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “340B Program Revi-
5 sion and Expansion Act of 2004”.



1 **SEC. 2. IMPROVEMENTS TO SECTION 340B PROGRAM.**

2 (a) EXPANSION OF COVERED ENTITIES RECEIVING
3 DISCOUNTED PRICES.—Subsection (a)(4) of section 340B
4 of the Public Health Service Act (42 U.S.C. 256b) is
5 amended by adding at the end the following subpara-
6 graphs:

7 “(M) An entity receiving funds under title
8 V of the Social Security Act (relating to mater-
9 nal and child health) for the provision of health
10 services.

11 “(N) An entity receiving funds under sub-
12 part I of part B of title XIX of this Act (relat-
13 ing to comprehensive mental health services) for
14 the provision of community mental health serv-
15 ices.

16 “(O) An entity receiving funds under sub-
17 part II of such part B (relating to the preven-
18 tion and treatment of substance abuse) for the
19 provision of treatment services for substance
20 abuse.”.

21 (b) EXTENSION OF DISCOUNTS TO INPATIENT
22 DRUGS.—Subsection (b) of such section is amended by in-
23 serting before the period at the end the following: “, except
24 that the terms ‘covered outpatient drug’ and ‘covered
25 drug’ include a drug provided in an inpatient setting”.



1 (c) ELIMINATION OF GROUP PURCHASING PROHIBI-
2 TION FOR CERTAIN HOSPITALS.—Subsection (a)(4)(L) of
3 such section is amended—

4 (1) by adding “and” at the end of clause (i);

5 (2) by striking “; and” at the end of clause (ii)
6 and inserting a period; and

7 (3) by striking clause (iii).

8 (d) PERMITTING USE OF MULTIPLE CONTRACT
9 PHARMACIES.—Such section is amended by adding at the
10 end the following new subsection:

11 “(e) PERMITTING USE OF MULTIPLE CONTRACT
12 PHARMACIES.—Nothing in this section shall be construed
13 as prohibiting a covered entity from entering into con-
14 tracts with more than one pharmacy for the provision of
15 covered drugs, including such a contract that supplements
16 the use of an in-house pharmacy arrangement or as re-
17 quiring the approval of the Secretary for entering into
18 such a contract.”.

19 (e) IMPROVEMENTS IN PROGRAM ADMINISTRA-
20 TION.—Such section is further amended by adding at the
21 end the following new subsection:

22 “(f) IMPROVEMENTS IN PROGRAM ADMINISTRA-
23 TION.—

24 “(1) IN GENERAL.—The Secretary shall pro-
25 vide, from funds appropriated under paragraph (2),



1 for improvements in the integrity and administration
2 of the program under this section in order to pre-
3 vent abuse and misuse of discounted prices made
4 available under this section. Such improvements
5 shall include the following:

6 “(A) The development of a system to verify
7 the accuracy of information regarding covered
8 entities that is listed on the website of the De-
9 partment of Health and Human Services relat-
10 ing to this section.

11 “(B) The establishment of a third-party
12 auditing system by which covered entities and
13 manufacturers are regularly audited to ensure
14 compliance with the requirements of this sec-
15 tion.

16 “(C) The conduct of such audits under
17 subsection (a)(5)(C) that supplement the audits
18 conducted under subparagraph (B) as the Sec-
19 retary finds appropriate and the implementa-
20 tion of dispute resolution guidelines and other
21 compliance programs.

22 “(D) The development of more detailed
23 guidance regarding the definition of section
24 340B patients and describing options for billing
25 under the medicaid program under title XIX of



1 the Social Security Act in order to avoid dupli-
2 cative discounts.

3 “(E) The issuance of advisory opinions
4 within defined time periods in response to ques-
5 tions from manufacturers or covered entities re-
6 garding the application of the requirements of
7 this section in specific factual circumstances.

8 “(F) Insofar as the Secretary deems it fea-
9 sible, providing access through the website of
10 the Department of Health and Human Services
11 on the prices for covered drugs made available
12 under this section, but only in a manner (such
13 as through the use of password protection) that
14 limits such access to covered entities.

15 “(2) AUTHORIZATION OF APPROPRIATIONS.—
16 There are authorized to be appropriated for fiscal
17 year 2005 and each succeeding fiscal year such sums
18 as may be necessary to carry out paragraph (1).”.

