## SEC. 7101. EXPANDED PARTICIPATION IN 340B PROGRAM. (a) EXPANSION OF COVERED ENTITIES RECEIVING DISCOUNTED Prices Section 240P(a)(4) of the Public Health Service Act (42)

PRICES.—Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4)) is amended by adding at the end the following:

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"(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph

(L)(i).

"(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent."

[See additional amendments to section 340B of PHSA made by

section 2302 of HCERA, p. 954]

- (b) EXTENSION OF DISCOUNT TO INPATIENT DRUGS.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended—
  - (1) in paragraphs (2), (5), (7), and (9) of subsection (a), by striking "outpatient" each place it appears [But see amendments made by section 2302(1) of HCERA on p. 954]; and

(2) in subsection (b)—

- (A) by striking "OTHER DEFINITION" and all that follows through "In this section" and inserting the following: "OTHER DEFINITIONS.—
- "(1) IN GENERAL.—In this section"; and
- (B) by adding at the end the following new paragraph: "(2) COVERED DRUG.—In this section, the term 'covered drug'—

"(A) means a covered outpatient drug (as defined in

section 1927(k)(2) of the Social Security Act); and

"(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section."

(c) Prohibition on Group Purchasing Arrangements.—Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is amended—[But see amendments made by section 2302(1) of

HCERA on p. 954]

[(1)] in paragraph (4)(L)—]

[(A) in clause (i), by adding "and" at the end;]

[(B) in clause (ii), by striking "; and" and inserting a period; and]

[(C) by striking clause (iii); and]

[(2) in paragraph (5), as amended by subsection (b)—]

[(A) by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E); respectively; and

(B) by inserting after subparagraph (B), the fol-

lowing:]

["(C) Prohibition on group purchasing arrange-

MENTS.—]

["(i) IN GENERAL.—A hospital described in subparagraph (L), (M), (N), or (O) of paragraph (4) shall not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except as permitted or provided for pursuant to clauses (ii) or (iii).]

["(ii) INPATIENT DRUGS.—Clause (i) shall not apply

to drugs purchased for inpatient use.]

["(iii) Exceptions.—The Secretary shall establish

reasonable exceptions to clause (i)—]

["(I) with respect to a covered outpatient drug that is unavailable to be purchased through the program under this section due to a drug shortage problem, manufacturer noncompliance, or any other circumstance beyond the hospital's control;]

["(II) to facilitate generic substitution when a generic covered outpatient drug is available at a

lower price; or]

["(III) to reduce in other ways the administrative burdens of managing both inventories of drugs subject to this section and inventories of drugs that are not subject to this section, so long as the exceptions do not create a duplicate discount problem in violation of subparagraph (A) or a diversion problem in violation of subparagraph (B)

["(iv) Purchasing arrangements for inpatient described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section shall have multiple options for purchasing covered drugs for inpatients, including by utilizing a group purchasing organization or other group purchasing arrangement, establishing and utilizing its own group purchasing program, purchasing directly from a manufacturer, and any other purchasing arrangements that the Secretary determines is appropriate to ensure access to drug discount pricing under this section for inpatient drugs taking into account the particular needs of small and rural hospitals.".]

[(d) MEDICAID CREDITS ON INPATIENT DRUGS.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by striking subsection (c) and inserting the following: [Section 2502(f)(1)(B) of PPACA strikes subsection (c) of section 340B of PHSA, as in effect on the date of PPACA, and redesignates subsection (d) of section

340B of PHSA, as in effect on such date, as subsection (c). This subsection strikes and replaces the redesignated version of subsection (c). Section 2302(a)(2) of HCERA strikes the version of subsection (c) inserted by this subsection.

["(c) MEDICAID CREDIT.—Not later than 90 days after the date of filing of the hospital's most recently filed Medicare cost report, the hospital shall issue a credit as determined by the Secretary to the State Medicaid program for inpatient covered drugs provided to Medicaid recipients.". (e) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by this section and section 7102 shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010.

(2) Effectiveness.—The amendments made by this section and section 7102 shall be effective and shall be taken into account in determining whether a manufacturer is deemed to meet the requirements of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), notwithstanding any other provision of law.