H. R. 4685

To amend titles XVIII and XIX of the Social Security Act to assure uninterrupted access to necessary medicines under the Medicare prescription drug program.

IN THE HOUSE OF REPRESENTATIVES

February 1, 2006

Mr. Dingell (for himself, Mr. Rangel, Mr. Spratt, Mr. Waxman, Mr. Brown of Ohio, Mr. Stark, Ms. Pelosi, Mr. Markey, Mrs. Capps, Mr. Boucher, Ms. Schakowsky, Ms. Degette, Mr. Pallone, Ms. Solis, Ms. Baldwin, Mr. Gene Green of Texas, Mr. Gordon, Mr. Allen, Mr. Inslee, Mr. Cleaver, Ms. Slaughter, Mr. Emanuel, Mr. Neal of Massachusetts, Mr. Delahunt, Mr. Doggett, Mr. Conyers, Ms. Matsui, Mr. Berman, Mr. Larson of Connecticut, Mr. Cardin, Mr. McNulty, Mr. Holden, Mr. Owens, Ms. Herseth, and Mrs. McCarthy) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend titles XVIII and XIX of the Social Security Act to assure uninterrupted access to necessary medicines under the Medicare prescription drug program.

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

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

- 2 (a) SHORT TITLE.—This Act may be cited as the
- 3 "Medicare Prescription Drug Emergency Guarantee Act
- 4 of 2006".
- 5 (b) Table of Contents of table of contents of
- 6 this Act is as follows:
 - Sec. 1. Short title; table of contents
 - Sec. 2. Protections to provide for uninterrupted access to medicines
 - Sec. 3. Required application of intermediate sanctions to protect against fraud and abuse
 - Sec. 4. Changes of enrollment in prescription drug plans and MA-PD plans allowed twice during year
 - Sec. 5. Prohibiting additional restrictions or limitations on coverage during year
 - Sec. 6. MedPAC study on appropriate enrollment of dual eligible individuals
 - Sec. 7. Prohibition on conditioning Medicaid eligibility on enrollment in Medicare part D coverage or other creditable coverage
 - Sec. 8. Reimbursement of third parties for 2006 transition costs

7 SEC. 2. PROTECTIONS TO PROVIDE FOR UNINTERRUPTED

- 8 ACCESS TO MEDICINES.
- 9 (a) Minimum Standard Transition Coverage.—
- 10 (1) IN GENERAL.—Section 1860D-4(b) of the
- 11 Social Security Act (42 U.S.C. 1395w–104(b)) is
- amended by adding at the end the following new
- paragraph:
- 14 "(4) Uninterrupted access to medi-
- 15 CINES.—
- 16 "(A) MINIMUM STANDARD TRANSITION
- 17 COVERAGE.—A PDP sponsor offering a pre-
- scription drug plan under this part or an MA-
- 19 PD plan under part C shall provide minimum

standard transition coverage in accordance with subparagraph (B).

"(B) REQUIREMENTS.—The minimum standard transition coverage under this subparagraph, with respect to a part D eligible individual who is enrolled in a prescription drug plan (or an individual who is presumed to be such an individual pursuant to subparagraph (F)) who presents a prescription for a drug at a pharmacy, is the following:

"(i) Guaranteed initial supply, regardless of coverage limitations or restrictions.—In the case that the PDP sponsor of such plan uses a formulary that does not cover the drug or otherwise imposes a restriction on the coverage of the drug (such as through the application of a preferred status, usage restriction, step therapy, prior authorization or a quantity limits) and during the period in which such individual has been enrolled in such plan the individual has not previously sought coverage under the plan for such drug the plan shall provide for the following:

1	"(I) Minimum supply of pre-
2	SCRIPTION DRUG.—The plan must
3	provide for coverage for at least a 60-
4	day supply (or a 90-day supply in the
5	case of an individual who is a resident
6	of a long-term care facility) of the
7	drug, or, if less, a supply of the drug
8	that is the full amount of the pre-
9	scription.

"(II)" Information on FOR-MULARY, PRESCRIPTION DRUG PLANS, AND APPEAL RIGHTS.—The plan must provide the individual with a standard notice developed by the Secretary that informs the individual about the limitations and restrictions of the coverage of the drug, that describes the rights of the individual with respect to requesting a determination under subsection (g)(2) or an appeal of such a determination under subsection (h), that describes any ability of the individual to change the election of such plan under section 1860D-1(b)(1)(B), and that informs the individual about

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1	sources of information on prescription
2	drug plans to make such a change in
3	plans.
4	"(III) Refills during pending
5	APPEAL.—In the case of such an indi-
6	vidual who brings an appeal under
7	subsection (h), with respect to the
8	prescription drug involved, an addi-
9	tional supply of the drug (for the
10	amount of days provided to the indi-
11	vidual under subclause (I)) during the
12	period ending on the date on which a
13	final determination is made on the ap-
14	peal.
15	"(ii) Guaranteed supply when un-
16	ABLE TO VERIFY PLAN ENROLLMENT.—In
17	the case that the pharmacy is unable to lo-
18	cate or verify the individual's enrollment in
19	such plan through a reasonable effort:
20	"(I) MINIMUM SUPPLY OF PRE-
21	SCRIPTION DRUG.—The plan must
22	provide for coverage for at least a 60-
23	day supply (or a 90-day supply in the
24	case of an individual who is a resident
25	of a long-term care facility) of the

1	drug, or, if less, a supply of the drug
2	that is the full amount of the pre-
3	scription.
4	"(II) REFILLS.—The plan must
5	provide an additional 60-day supply
6	(or a 90-day supply in the case of an
7	individual who is a resident of a long-
8	term care facility) of the drug, or if
9	less, a supply of the drug that is the
10	full amount of the prescription, if the
11	pharmacy continues to be unable to
12	locate the individual's enrollment
13	through such reasonable efforts when
14	a prescription is presented on or after
15	the date that a prescription refill is
16	appropriate.
17	"(C) Reimbursements.—
18	"(i) Reimbursements to Phar-
19	MACIES.—
20	"(I) In general.—If a phar-
21	macy provides prescription drugs for
22	which the minimum standard transi-
23	tion coverage is required under sub-
24	paragraph (B), the Secretary shall re-
25	imburse the pharmacy for the costs

1 incurred in providing the prescription 2 drugs, including acquisition costs, dis-3 pensing costs, and other overhead costs. The Secretary shall provide prompt payment (consistent with the 6 provisions of section 1842(c)(2)) of 7 such reimbursements from the Medi-8 care Prescription Drug Account under 9 section 1860D–16 of the Social Secu-10 rity Act (42 U.S.C. 1395w-116). 11 Such reimbursements shall be deemed 12 to be payments from such Account 13 under subsection (b) of such section. 14 "(II) SANCTIONS FOR FRAUDU-15 LENT CLAIMS.—In the case of a phar-16 macy that knowingly provides to the 17 Secretary false information in connec-18 tion with a claim for reimbursement 19 under subclause (I), the Secretary 20 may impose a civil money penalty in 21 an amount not to exceed \$10,000 for 22 each such claim. The provisions of

section 1128A (other than subsections

(a) and (b) and the second sentence of

subsection (f)) shall apply to a civil

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money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(ii) Recovery from Plans of Pharmacy reimbursements.—The Secretary shall establish a process for recovering the reimbursements made to pharmacies under clause (i) from prescription drug plans and MA-PD plans if the Secretary determines that such plans should have incurred such costs. Amounts recovered pursuant to the preceding sentence shall be deposited in the Medicare Prescription Drug Account.

"(iii) APPLICATION OF INTERMEDIATE SANCTIONS.—In the case of a failure of a prescription drug plan under this part or an MA-PD plan under part C to provide for the minimum coverage required under subparagraph (B), the failure shall be treated as a failure to provide medically necessary items and services under section 1857(g)(1)(A), as applied by section 1860D-12(b)(3)(E), and the Secretary

1	shall impose intermediate sanctions under
2	such section 1857(g).
3	"(D) Cost-sharing.—The cost-sharing
4	for a prescription filled pursuant to subpara-
5	graph (B) for an individual shall be in accord-
6	ance with the prescription drug plan in which
7	the individual attests to be enrolled and the
8	class of individual (such as subsidy-eligible indi-
9	viduals) to which the individual so attests.
10	"(E) Refunds to individuals with in-
11	APPROPRIATE CHARGES.—If the Secretary de-
12	termines, in accordance with a method deter-
13	mined by the Secretary, that an individual was
14	inappropriately charged for a prescription drug
15	dispensed to such individual under this part or
16	part C, the Secretary shall—
17	"(i) reduce payments to the sponsor
18	of the prescription drug plan under section
19	1860D-15 or to the organization offering
20	the MA-PD plan under section 1853 that
21	inappropriately charged the individual by
22	an amount equal to the amount the indi-
23	vidual was inappropriately charged; and
24	"(ii) refund such amount to the indi-
25	vidual within 30 days of the date of the de-

1	termination that the individual was inap-
2	propriately charged.
3	"(F) Presumptive eligibility.—
4	"(i) Subsidy-eligible individ-
5	UALS.—For purposes of this paragraph, an
6	individual shall be presumed to be a dual
7	eligible individual or subsidy-eligible indi-
8	vidual if the individual self attests to being
9	such an individual, respectively.
10	"(ii) Plan enrollment.—For pur-
11	poses of this paragraph, an individual shall
12	be presumed to be enrolled in a prescrip-
13	tion drug plan under this part or an MA-
14	PD plan under part C if the individual self
15	attests to being enrolled under such plan.
16	"(iii) Individual liable for costs
17	OF FALSE ATTESTATION.—
18	"(I) IN GENERAL.—If the Sec-
19	retary, as the result of verification ac-
20	tivities conducted by the Secretary,
21	determines after a fair hearing that
22	an individual has knowingly made a
23	false self-attestation described in
24	clause (i) or (ii) or in subparagraph
25	(D), the Secretary may, subject to

1	subclause (II), seek recovery from the
2	individual for the full amount of the
3	cost of benefits provided to the indi-
4	vidual under this paragraph as a re-
5	sult of such self attestation.
6	"(II) Exception.—The Sec-
7	retary shall at its discretion not seek
8	recovery under subclause (I) if the
9	Secretary determines that it would not
10	be cost-effective to do so.
11	"(III) REIMBURSEMENTS TO
12	FEDERAL GOVERNMENT.—Any
13	amounts recovered by the Secretary in
14	accordance with this clause shall be
15	returned to the prescription drug plan
16	or MA-PD plan if the Secretary has
17	previously recovered payment from
18	such plan.
19	"(iv) Requirements for self at-
20	TESTATION.—The Secretary shall promul-
21	gate requirements for self attestations
22	under this subparagraph, but the failure of
23	the Secretary to promulgate such require-
24	ments shall not preclude the applications

1	of the previous provisions of this subpara
2	graph.".
3	(2) Effective date.—The amendment made
4	by paragraph (1) shall take effect on the date of the
5	enactment of this Act, but shall apply to prescription
6	drugs dispensed on and after January 1, 2006.
7	(b) Notice for Change in Formulary and
8	OTHER RESTRICTIONS OR LIMITATIONS ON COVERAGE.—
9	(1) IN GENERAL.—Section 1860D-4(a) of such
10	Act (42 U.S.C. 1395w-104(a)) is amended by add
11	ing at the end the following new paragraph:
12	"(5) Annual notice of changes in for
13	MULARY AND OTHER RESTRICTIONS OR LIMITATIONS
14	ON COVERAGE.—Each PDP sponsor offering a pre-
15	scription drug plan (and each MA organization of
16	fering an MA-PD plan) shall furnish to each en
17	rollee at the time of each annual coordinated election
18	period (referred to in section 1860D–1(b)(1)(B)(iii)
19	for a plan year a notice of any changes in the for
20	mulary or other restrictions or limitations on cov
21	erage of a covered part D drug under the plan that
22	will take effect for the plan year.".
23	(2) Effective date.—The amendment made

by paragraph (1) shall apply to annual coordinated

- election periods beginning after the date of the enactment of this Act.
- 3 (c) Standardized Forms and Procedures for
- 4 RECONSIDERATIONS AND APPEALS.—
- 5 (1) IN GENERAL.—Section 1860D-4 of such
- 6 Act (42 U.S.C. 1395w–104) is amended by adding
- 7 at the end the following new subsection:
- 8 "(1) STANDARDIZED FORMS AND PROCEDURES FOR
- 9 RECONSIDERATIONS AND APPEALS.—
- "(1) STANDARD ENROLLEE NOTICE.—The Secretary shall develop a standard notice to be distributed by a prescription drug plan (or an MA-PD plan) to an enrollee when a covered part D drug prescribed for the enrollee is not covered, or the coverage of such drug is otherwise restricted, by the
- 17 "(2) Standardized process for reconsid-18 ERATIONS AND APPEALS.—The Secretary shall re-19 quire prescription drug plans and MA-PD plans to 20 follow the same standardized process for reconsider-21 ations and redeterminations under subsections (g) 22 and (h). Such process shall require that determina-23 tions regarding medical necessity are based on pro-24 fessional medical judgement, the medical condition

plan.

- of the enrollee, the treating physician's recommendation, and other medical evidence.".
- 3 (2) Effective date.—The Secretary of
- 4 Health and Human Services shall provide for the
- 5 standard notice and the standardized process, and
- 6 the application of such notice and process, under the
- 7 amendment made by paragraph (1) by not later
- 8 than January 1, 2007.
- 9 SEC. 3. REQUIRED APPLICATION OF INTERMEDIATE SANC-
- 10 TIONS TO PROTECT AGAINST FRAUD AND
- ABUSE.
- 12 (a) IN GENERAL.—Section 1860D-12(b)(3)(E) of
- 13 the Social Security Act (42 U.S.C. 1395w–112(b)(3)(E))
- 14 is amended by inserting "and the reference to may pro-
- 15 vide' in section 1857(g)(1) is deemed a reference to 'shall
- 16 provide'" after "this part".
- 17 (b) Application to MA-PD Plans.—Section
- 18 1857(g)(1) of such Act (42 U.S.C. 1395w-27(g)(1)) is
- 19 amended by inserting "(or in the case of an MA-PD plan
- 20 or a prescription drug plan under part D, the Secretary
- 21 shall provide)" after "may provide".

1	SEC. 4. CHANGES OF ENROLLMENT IN PRESCRIPTION
2	DRUG PLANS AND MA-PD PLANS ALLOWED
3	TWICE DURING YEAR.
4	(a) Additional Election Permitted Once Each
5	YEAR OUTSIDE OF ANNUAL COORDINATED ELECTION
6	Period.—Section 1851(e)(4) of the Social Security Act
7	(42 U.S.C. 1395w–21(e)(4)) is amended by inserting
8	"once every year, and in addition," after "make a new
9	election under this section".
10	(b) Effective Date.—The amendment made by
11	subsection (a) shall take effect as of the date of the enact-
12	ment of this Act.
13	SEC. 5. PROHIBITING ADDITIONAL RESTRICTIONS OR LIMI-
14	TATIONS ON COVERAGE DURING YEAR.
14 15	tations on coverage during year. (a) In General.—Section 1860D-4(b)(4) of the So-
15 16	(a) In General.—Section 1860D–4(b)(4) of the So-
15 16 17	(a) In General.—Section 1860D–4(b)(4) of the Social Security Act (42 U.S.C. 1395w–104(b)(4)) is amend-
15 16 17	(a) IN GENERAL.—Section 1860D–4(b)(4) of the Social Security Act (42 U.S.C. 1395w–104(b)(4)) is amended by inserting after subparagraph (F) the following new
15 16 17 18	(a) IN GENERAL.—Section 1860D–4(b)(4) of the Social Security Act (42 U.S.C. 1395w–104(b)(4)) is amended by inserting after subparagraph (F) the following new subparagraph:
15 16 17 18 19	(a) In General.—Section 1860D–4(b)(4) of the Social Security Act (42 U.S.C. 1395w–104(b)(4)) is amended by inserting after subparagraph (F) the following new subparagraph: "(G) Prohibiting additional restrictions of the Social Security Act (42 U.S.C. 1395w–104(b)(4)) is amended by inserting after subparagraph (F) the following new subparagraph:
15 16 17 18 19 20	(a) In General.—Section 1860D–4(b)(4) of the Social Security Act (42 U.S.C. 1395w–104(b)(4)) is amended by inserting after subparagraph (F) the following new subparagraph: "(G) Prohibiting additional restrictions or limitations on coverage during
15 16 17 18 19 20 21	(a) In General.—Section 1860D–4(b)(4) of the Social Security Act (42 U.S.C. 1395w–104(b)(4)) is amended by inserting after subparagraph (F) the following new subparagraph: "(G) Prohibiting additional restrictions or limitations on coverage during year.—A prescription drug plan and an MA—
15 16 17 18 19 20 21 22	(a) In General.—Section 1860D–4(b)(4) of the Social Security Act (42 U.S.C. 1395w–104(b)(4)) is amended by inserting after subparagraph (F) the following new subparagraph: "(G) Prohibiting additional restrictions or limitations on coverage during year.—A prescription drug plan and an MAPD plan may only impose a restriction or limitations.
15 16 17 18 19 20 21 22 23	(a) In General.—Section 1860D–4(b)(4) of the Social Security Act (42 U.S.C. 1395w–104(b)(4)) is amended by inserting after subparagraph (F) the following new subparagraph: "(G) Prohibiting additional restrictions or limitation on the coverage of a covered part D drug

- 1 only at the beginning of a plan year, except in
- 2 the case that the Commissioner of Food and
- 3 Drugs issues a clinical warning during a year
- 4 that imposes such a restriction or limitation on
- 5 the drug.".
- 6 (b) Effective Date.—The amendment made by
- 7 subsection (a) shall take effect on the date of the enact-
- 8 ment of this Act and shall apply to the removal of a drug
- 9 or a change in the status of such drug on and after such
- 10 date.

11 SEC. 6. MEDPAC STUDY ON APPROPRIATE ENROLLMENT

- 12 **OF DUAL ELIGIBLE INDIVIDUALS.**
- 13 (a) Study.—The Medicare Payment Advisory Com-
- 14 mission shall conduct a study to determine the extent to
- 15 which full-benefit dual eligible individuals (as defined in
- 16 section 1935(c)(6) of the Social Security Act (42 U.S.C.
- 17 1396u5(c)(6)) were enrolled (by assignment or otherwise)
- 18 in the most appropriate prescription drug plans under
- 19 part D of title XVIII of such Act for such individuals.
- 20 (b) Report.—The Commission shall submit a report
- 21 to Congress on the study under subsection (a) not later
- 22 than February 1, 2007.

1	SEC. 7. PROHIBITION ON CONDITIONING MEDICAID ELIGI-
2	BILITY ON ENROLLMENT IN MEDICARE PART
3	D COVERAGE OR OTHER CREDITABLE COV-
4	ERAGE.
5	(a) In General.—Section 1935 of the Social Secu-
6	rity Act (42 U.S.C. 1396v) is amended by adding at the
7	end the following new subsection:
8	"(f) Prohibition on Conditioning Medicaid Eli-
9	GIBILITY ON ENROLLMENT IN MEDICARE PART D COV-
10	ERAGE OR OTHER CREDITABLE COVERAGE.—
11	"(1) In general.—A State shall not condition
12	eligibility for medical assistance under the State
13	plan for a part D eligible individual (as defined in
14	section $1860D-1(a)(3)(A)$) who is enrolled in cred-
15	itable prescription drug coverage described in any of
16	subparagraphs (C) through (H) of section 1860D-
17	13(b)(4) on the individual's enrollment in a prescrip-
18	tion drug plan under part D of title XVIII or an
19	MA-PD plan under part C of such title.
20	"(2) Coordination of Benefits with Part
21	D FOR OTHER INDIVIDUALS.—Nothing in this sub-
22	section shall be construed as prohibiting a State
23	from coordinating medical assistance under the
24	State plan with benefits under part D of title XVIII
25	for individuals not described in paragraph (1).".

- 1 (b) Treatment of State Plan Amendments, Re-
- 2 DETERMINATION OF ELIGIBILITY.—In the case of a State
- 3 that, as of the date of the enactment of this Act, has an
- 4 approved amendment to its State plan under title XIX of
- 5 the Social Security Act with a provision that conflicts with
- 6 section 1935(f) of such Act (as added by subsection (a)),
- 7 such provision is, as of such date of enactment, null and
- 8 void. The State shall redetermine any applications for
- 9 medical assistance that have been denied solely on the
- 10 basis of such a State plan amendment not later than De-
- 11 cember 31, 2006. Such redetermination shall be effective
- 12 as of the date of the individual's application for medical
- 13 assistance.

14 SEC. 8. REIMBURSEMENT OF THIRD PARTIES FOR 2006

- 15 TRANSITION COSTS.
- 16 (a) Reimbursement.—
- 17 (1) IN GENERAL.—Notwithstanding section
- 18 1935(d) of the Social Security Act (42 U.S.C.
- 19 1396u-5(d) or any other provision of law, the Sec-
- 20 retary of Health and Human Services shall reim-
- burse covered third parties for 100 percent of the
- costs incurred by the covered third party during
- 23 2006 for covered part D drugs for part D eligible in-
- 24 dividuals who are enrolled in a prescription drug
- plan under part D of title XVIII of such Act (or an

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MA-PD plan under part C of such title) which the individual reasonably expected would have been covered under such part but were not because the individual was unable to access on a timely basis prescription drug benefits to which the individual was entitled under such part. Such payments shall be made from the Medicare Prescription Drug Account under section 1860D–16 of the Social Security Act (42 U.S.C. 1395w-116) and shall be deemed to be payments from such Account under subsection (b) of such section. The provisions of clauses (ii) through (iv) of subparagraph (F) of paragraph (4) of section 1860D-4(b) of the Social Security Act, as added by section 2(a), shall apply under this paragraph in the same manner as they apply under such paragraph (4).

(2) Sanctions for fraudulent claims.—
The provisions of subclause (II) of section 1860D–4(b)(4)(C)(i) of the Social Security Act, as added by section 2(a), shall apply to a covered third party with respect to a claim for reimbursement under paragraph (1) in the same manner that such provisions apply to a pharmacy in connection with a claim for reimbursement under subclause (I) of such section 1860D–4(b)(4)(C)(i).

- 20 1 (3) Retroactive application to beginning 2 OF 2006.—The costs incurred by a third party which 3 may be reimbursed under paragraph (1) shall include costs incurred during the period beginning on 5 January 1, 2006, and before the date of enactment 6 of this Act. 7 (b) Recovery of Costs From Plans by Sec-8 RETARY.—The Secretary of Health and Human Services shall establish a process for recovering the costs described 10 in subsection (a)(1) from prescription drug plans and
- 11 MA-PD plans if the Secretary determines that such plans 12 should have incurred such costs. Amounts recovered pur-
- 13 suant to the preceding sentence shall be deposited in the
- 14 Medicare Prescription Drug Account described in sub-
- 15 section (a)(1).
- 16 (c) Definitions.—For purposes of this section:
- 17 (1) COVERED PART D DRUG.—The term "cov-18 ered part D drug" has the meaning given such term 19 under section 1860D–2(e) of the Social Security Act 20 (42 U.S.C. 1395w–102(e)).
- 21 (2) COVERED THIRD PARTY.—The term "cov-22 ered third party" means any individual or party 23 (such as a State, charity, or family member of the 24 part D eligible individual involved) other than a 25 party that is obligated under part D of title XVIII

- of the Social Security Act to incur the costs involved. Such term shall not include a pharmaceutical company or an assistance program sponsored or assisted (in whole or in part) by such company.
- 5 (3) MA-PD PLAN.—The term "MA-PD plan" 6 has the meaning given such term under section 7 1860D-41(a)(14) of the Social Security Act (42 8 U.S.C. 1395w-151(a)(14)).
- 9 (4) PART D ELIGIBLE INDIVIDUAL.—The term
 10 "part D eligible individual" has the meaning given
 11 such term under section 1860D–1(a)(3)(A) of the
 12 Social Security Act (42 U.S.C. 1394w–
 13 101(a)(3)(A)).
 - (5) PRESCRIPTION DRUG PLAN.—The term "prescription drug plan" has the meaning given such term under section 1860D–1(a)(3)(C) of the Social Security Act (42 U.S.C. 1394w–101(a)(3)(C)).
- 19 (6) STATE.—The term "State" includes the 20 District of Columbia.

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