		(Original Signature of Member)
18TH CONGRESS	 <b>D</b>	

118TH CONGRESS 1ST SESSION

## H.R.

To amend titles XVIII and XIX of the Social Security Act and title 10, United States Code, to provide no-cost coverage for the preventive distribution of opioid overdose reversal drugs.

## IN THE HOUSE OF REPRESENTATIVES

Ms.	Pettersen	introduced	the	following	bill;	which	was	referred	to	the
	Comn	nittee on								

## A BILL

To amend titles XVIII and XIX of the Social Security Act and title 10, United States Code, to provide no-cost coverage for the preventive distribution of opioid overdose reversal drugs.

- 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 "Hospitals As Naloxone
- 5 Distribution Sites Act" or the "HANDS Act".
- 6 SEC. 2. FINDINGS.
- 7 Congress finds the following:

1	(1) Opioid use disorder is a treatable brain dis-
2	ease from which people can recover.
3	(2) Individuals living with opioid use disorder,
4	those who use opioids for chronic pain, and those
5	who use illicit substances that may be contaminated
6	with fentanyl or other illicit additives are at high
7	risk for fatal overdose.
8	(3) Individuals at-risk of overdose are fre-
9	quently cared for in emergency departments and
10	hospitals, making these locations ideal places to
11	screen and intervene. In addition, medical providers
12	have the knowledge and ability to provide medically
13	accurate information, but also treat the disease of
14	addiction once a person is ready for treatment.
15	(4) Overdose deaths are preventable with life-
16	saving opioid overdose reversal medications like
17	naloxone. Two-thirds of fatal overdoses have a wit-
18	ness, who can intervene and prevent overdose death
19	if they have access to opioid antagonists.
20	(5) Just as individuals with life-threatening al-
21	lergies should carry an EpiPen, individuals and close
22	contacts of those with opioid use disorder should
23	carry an opioid overdose reversal medication.
24	(6) While over the counter (OTC) access to re-
25	versal agents may increase their availability to cer-

1	tain populations, the hurdles to access these medica-
2	tions for many of the most at-risk patients will still
3	remain. These hurdles include out of pocket costs,
4	transportation or access to pharmacies or other
5	areas carrying OTC naloxone, stigma by pharmacy
6	staff, addiction-related compromised executive func-
7	tion, and more. Therefore, hospitals are uniquely po-
8	sitioned as a point of distribution to best serve those
9	who would most benefit.
10	(7) It is the intent of Congress to increase ac-
11	cess for all individuals with opioid use disorder, and
12	other risk factors, to opioid overdose reversal medi-
13	cation so that if they experience an overdose, they
14	will have a second chance. As long as there is
15	breath, there is hope for recovery.
16	SEC. 3. NO-COST COVERAGE OF PREVENTIVE OPIOID OVER-
17	DOSE REVERSAL DRUGS.
18	(a) Coverage Under Medicare.—
19	(1) Coverage.—Section 1861(s)(2) of the So-
20	cial Security Act (42 U.S.C. 1395x(s)(2)) is amend-
21	$\operatorname{ed}$ —
22	(A) in subparagraph (JJ), by adding
23	"and" after the semicolon at the end; and
24	(B) by adding at the end the following new

1	"(KK) a preventive opioid overdose rever-
2	sal drug (as defined in subsection (nnn)) fur-
3	nished on or after January 1, 2024;".
4	(2) Preventive opioid overdose reversal
5	DRUG DEFINED.—Section 1861 of the Social Secu-
6	rity Act (42 U.S.C. 1395x) is amended by adding at
7	the end the following new subsection:
8	"(nnn) Preventive Opioid Overdose Reversal
9	DRUG.—The term 'preventive opioid overdose reversal
10	drug' means an opioid overdose reversal drug that is fur-
11	nished by a physician, nurse practitioner, physician assist-
12	ant, or other attending clinical personnel (as determined
13	by the Secretary by regulation) to an individual who is
14	an inpatient of a hospital, critical access hospital, or rural
15	emergency hospital, or is a patient of the emergency de-
16	partment of such a hospital or an ambulatory surgical cen-
17	ter, but only if—
18	"(1) such physician, nurse practitioner, physi-
19	cian assistant, or attending clinical professional de-
20	termines that such individual is at risk for an opioid
21	overdose; and
22	"(2) such drug is furnished at the time such in-
23	dividual is discharged from the hospital or leaves the
24	emergency department or ambulatory surgical cen-

1	ter, as the case may be, together with instructions
2	for the administration of such drug.".
3	(3) Prohibition of cost sharing.—Section
4	1833 of the Social Security Act (42 U.S.C. 1395l)
5	is amended—
6	(A) in subsection (a)(1)—
7	(i) in subparagraph (S)(i), by striking
8	"subparagraph (EE)," and inserting "sub-
9	paragraphs (EE) and (II),";
10	(ii) in subparagraph (GG), by striking
11	"and" at the end; and
12	(iii) by inserting ", and (II) with re-
13	spect to a preventive opioid overdose rever-
14	sal drug (as defined in section 1861(nnn))
15	furnished on or after January 1, 2024, the
16	amounts paid shall be 100 percent of the
17	lesser of the actual charges for such drug
18	or the amount determined under section
19	1842(o)" before the semicolon at the end;
20	and
21	(B) in subsection (b)—
22	(i) by striking ", and (13)" and in-
23	serting "(13)"; and
24	(ii) by striking "section 1861(n)"
25	and inserting "section 1861(n), and (14)

1	such deductible shall not apply with re-
2	spect to a preventive opioid reversal drug
3	(as defined in section 1861(nnn)) fur-
4	nished on or after January 1, 2024."
5	(4) Prohibition of cost sharing for medi-
6	CARE ADVANTAGE PLANS.—Section 1852(a)(1)(B) of
7	the Social Security Act (42 U.S.C. 1395w-
8	22(a)(1)(B)) is amended—
9	(A) in clause (iv)—
10	(i) by redesignating subclause (VIII)
11	as subclause (IX); and
12	(ii) by inserting after subclause (VII)
13	the following new subclause:
14	"(VIII) A preventive opioid rever-
15	sal drug (as defined in section
16	1861(nnn))."; and
17	(B) in clause (v), by striking "and (VI)"
18	and inserting "(VI), and (VIII)".
19	(b) Coverage Under Medicaid.—
20	(1) Mandatory Coverage.—
21	(A) In general.—Section 1902(a)(10)(A)
22	of the Social Security Act (42 U.S.C.
23	1396a(a)(10)(A)) is amended by striking "and
24	(30)" and inserting "(30), and (31)".

1	(B) Alternative benefit plans.—Sec-
2	tion 1937(b) of the Social Security Act (42
3	U.S.C. 1396u-7(b)) is amended by adding at
4	the end the following new paragraph:
5	"(9) Preventive opioid overdose reversal
6	DRUGS.—Notwithstanding the previous provisions of
7	this section, a State may not provide for medical as-
8	sistance through enrollment of an individual with
9	benchmark coverage or benchmark-equivalent cov-
10	erage under this section unless, beginning on Janu-
11	ary 1, 2024, such coverage includes (and does not
12	impose any deduction, cost sharing, or similar
13	charge for) preventive opioid overdose reversal drugs
14	described in section 1861(nnn)).".
15	(2) Inclusion in medical assistance.—
16	(A) In general.—Section 1905(a) of the
17	Social Security Act (42 U.S.C. 1396d(a)) is
18	amended—
19	(i) in paragraph (30), by striking
20	"and" at the end;
21	(ii) by redesignating paragraph (31)
22	as paragraph (32); and
23	(iii) by inserting after paragraph (30)
24	the following new paragraph:

1	"(31) beginning January 1, 2024, preventive
2	opioid overdose reversal drugs described in section
3	1861(nnn); and".
4	(3) Application of Rebate Require-
5	MENTS.—Section 1927 of the Social Security Act
6	(42 U.S.C. 1396r-8) is amended—
7	(A) in subsection (d)(7), by adding at the
8	end the following new subparagraph:
9	"(F) Preventive opioid overdose reversal
10	drugs described in section 1861(nnn) that are
11	furnished as medical assistance in accordance
12	with section 1905(a)(31) and section
13	1902(a)(10)(A)."; and
14	(B) in subsection (k)(4)—
15	(i) by striking "If a State plan" and
16	inserting:
17	"(A) IN GENERAL.—If a State plan"; and
18	(ii) by adding at the end the following
19	new subparagraph:
20	"(B) Preventive opioid overdose re-
21	VERSAL DRUGS.—Beginning January 1, 2024,
22	in applying paragraph (2)(A) to a preventive
23	opioid overdose reversal drug described in sec-
24	tion 1861(nnn), such drug shall be deemed a

1	prescribed drug for purposes of section
2	1905(a)(12).".
3	(4) Prohibition of cost sharing.—
4	(A) IN GENERAL.—Section 1916 of the So-
5	cial Security Act (42 U.S.C. 1396o) is amend-
6	$\operatorname{ed}$ —
7	(i) in subsection (a)(2)—
8	(I) in subparagraph (I), by strik-
9	ing "or" at the end;
10	(II) in subparagraph (J), by
11	striking "; and" at the end and in-
12	serting ", or"; and
13	(III) by adding at the end the
14	following new subparagraph:
15	"(K) beginning January 1, 2024, preven-
16	tive opioid overdose reversal drugs described in
17	section 1861(nnn); and"; and
18	(ii) in subsection (b)(2)—
19	(I) in subparagraph (I), by strik-
20	ing "or" at the end;
21	(II) in subparagraph (J), by
22	striking "; and" at the end and in-
23	serting ", or"; and
24	(III) by adding at the end the
25	following new subparagraph:

1	"(K) beginning January 1, 2024, preven-
2	tive opioid overdose reversal drugs described in
3	section 1861(nnn); and".
4	(B) Application to alternative cost
5	Sharing.—Section 1916A(b)(3)(B) of the So-
6	cial Security Act (42 U.S.C. 1396o–1(b)(3)(B))
7	is amended by adding at the end the following
8	new clause:
9	"(xv) Beginning January 1, 2024,
10	preventive opioid overdose reversal drugs
11	described in section 1861(nnn).".
12	(c) Coverage Under TRICARE.—Section 1074g
13	of title 10, United States Code, is amended as follows:
14	(1) In subsection (a)(6), by adding at the end
15	the following new subparagraph:
16	"(D) Notwithstanding subparagraphs (A) through
17	(C), beginning on January 1, 2024, an eligible covered
18	beneficiary shall not be required to pay a cost-sharing
19	amount for a preventive opioid overdose reversal drug.".
20	(2) In subsection (i), by adding at the end the
21	following new paragraph:
22	"(5) The term 'preventive opioid overdose rever-
23	sal drug' has the meaning given such term in section
24	1861 of the Social Security Act (42 U.S.C.
25	1395x).".

## 1 SEC. 4. REGULATORY GUIDANCE.

2	Not later than 1 year after the date of the enactment
3	of this Act, the Commissioner of Food and Drugs shall
4	issue guidance for State boards of pharmacy, nursing, and
5	medicine with respect to—
6	(1) enhancing safe and effective hospital-based
7	dispensing and distribution of opioid overdose rever-
8	sal drugs; and
9	(2) eliminating barriers to such dispensing and
10	distribution.