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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. _____

To amend title XVIII of the Social Security Act to combat the opioid crisis by promoting access to non-opioid treatments in the hospital outpatient setting.

IN THE HOUSE OF REPRESENTATIVES

Ms. SEWELL of Alabama introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title XVIII of the Social Security Act to combat the opioid crisis by promoting access to non-opioid treatments in the hospital outpatient setting.

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 “Non-Opioids Prevent
5 Addiction in the Nation Act” Act or the “NOPAIN Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) The United States is undergoing an epi-
2 demic of addiction and deaths caused by prescription
3 drug overdoses. According to the Centers for Disease
4 Control and Prevention (CDC), opioids are the main
5 driver of drug overdose deaths accounting for 47,600
6 overdose deaths in 2017. Every day, over 130 people
7 die in the United States from opioid overdoses.

8 (2) Additionally, the CDC estimates that the
9 economic costs associated with prescription opioid
10 misuse exceeds \$78 billion annually. These costs in-
11 clude those associated with healthcare, lost produc-
12 tivity, addiction treatment, and the criminal justice
13 system.

14 (3) Certain non-opioid treatments and services
15 can be successful in replacing, delaying, or reducing
16 the use of opioids to treat postsurgical pain.

17 (4) The Substance Use-Disorder Prevention
18 that Promotes Opioid Recovery and Treatment
19 (SUPPORT) for Patients and Communities Act was
20 enacted on October 24, 2018. This law requires that
21 CMS review payments under Medicare's Outpatient
22 Prospective Payment System (OPPS) and ASC Pay-
23 ment System "with a goal of ensuring there are not
24 financial incentives to use opioids instead of non-
25 opioid alternatives. Additionally, the bill requires

1 CMS to “consider the extent to which payment poli-
2 icy revisions (such as the creation of additional
3 groups of covered OPD services to classify sepa-
4 rately those procedures that utilize opioids and non-
5 opioid alternatives for pain management) would re-
6 duce payment incentives to use opioids instead of
7 non-opioid alternatives for pain management.”

8 (5) Pursuant to section 319 of the Public
9 Health Service Act, the Acting Secretary for the
10 U.S. Department of Health & Human Services de-
11 termined on October 26, 2017 that a public health
12 emergency exists as a result of the consequences of
13 the opioid crisis, and the Secretary renewed this de-
14 termination on October 16, 2019.

15 (6) The President’s Commission on Combating
16 Drug Addiction and the Opioid Crisis was estab-
17 lished on March 29, 2017. The Commission rec-
18 ommended that CMS examine payment policies for
19 certain drugs that function specifically as non-opioid
20 pain management treatments. According to the
21 Commission’s report, “. . .the current CMS pay-
22 ment policy for ‘supplies’ related to surgical proce-
23 dures creates unintended incentives to prescribe
24 opioid medications to patients for postsurgical pain
25 instead of administering non-opioid pain medica-

1 tions. Under current policies, CMS provides one all-
2 inclusive bundled payment to hospitals for all ‘sur-
3 gical supplies,’ which includes hospital administered
4 drug products intended to manage patients’ post-
5 surgical pain. This policy results in the hospitals re-
6 ceiving the same fixed fee from Medicare whether
7 the surgeon administers a non-opioid medication or
8 not.”

9 (7) The Pain Management Best Practices
10 Inter-Agency Task Force was authorized by section
11 101 of the Comprehensive Addiction and Recovery
12 Act of 2016. The Task Force consisted of federal
13 agency representatives as well as experts and rep-
14 resentatives from a broad group of invested stake-
15 holders and was convened to issue recommendations
16 for identifying and addressing gaps and inconsis-
17 tencies for managing acute pain. In the Task Force’s
18 Final Report on Best Practices: Updates, Gaps, In-
19 consistencies and Recommendations, the following
20 gap was identified: “Multimodal, non-opioid thera-
21 pies are underutilized in the perioperative, inflam-
22 matory, musculoskeletal, and neuropathic injury set-
23 tings.” The report also states that “Non-opioids
24 should be used as first-line therapy whenever clini-

1 cally appropriate in the inpatient and outpatient set-
2 tings.”

3 (8) Research shows that despite ongoing efforts
4 to end the opioid crisis, patients continue to receive
5 large quantities of opioids to treat postsurgical pain.
6 One 2018 study showed that 12 percent of patients
7 who had a soft tissue or orthopedic operation in the
8 year prior reported that they had become addicted
9 or dependent on opioids. Further research shows
10 that patients receiving an opioid prescription after
11 short-stay surgeries have a 44% increased risk of
12 opioid use.

13 (9) CMS has reiterated its position in rule-
14 making that it is appropriate to pay separately for
15 certain non-opioid pain management treatments that
16 function as surgical supplies in the ASC setting, it
17 is clear that direction from Congress is necessary to
18 modify Medicare’s outpatient policies with the goal
19 of encouraging access to non-opioid treatments and
20 services to address the opioid crisis.

21 **SEC. 3. ACCESS TO NON-OPIOID TREATMENTS FOR PAIN.**

22 (a) IN GENERAL.—Section 1833(t) of the Social Se-
23 curity Act (42 U.S.C. 1395l(t)) is amended—

24 (1) in paragraph (2)(E), by inserting “and sep-
25 arate payments for non-opioid treatments under

1 paragraph (16)(G),” after “payments under para-
2 graph (6)”; and

3 (2) in paragraph (16), by adding at the end the
4 following new subparagraph:

5 “(G) ACCESS TO NON-OPIOID TREATMENTS
6 FOR PAIN.—

7 “(i) IN GENERAL.—Notwithstanding
8 any other provision of this subsection, with
9 respect to a covered OPD service (or group
10 of services) furnished on or after January
11 1, 2020, and before January 1, 2025, the
12 Secretary shall not package, and shall
13 make a separate payment as specified in
14 clause (ii) for, a non-opioid treatment (as
15 defined in clause (iii)) furnished as part of
16 such service (or group of services).

17 “(ii) AMOUNT OF PAYMENT.—The
18 amount of the payment specified in this
19 clause is, with respect to a non-opioid
20 treatment that is—

21 “(I) a drug or biological product,
22 the amount of payment for such drug
23 or biological determined under section
24 1847A; or

1 “(II) a medical device, the
2 amount of the hospital’s charges for
3 the device, adjusted to cost.

4 “(iii) DEFINITION OF NON-OPIOID
5 TREATMENT.—A ‘non-opioid treatment’
6 means—

7 “(I) a drug or biological product
8 that is indicated to produce analgesia
9 without acting upon the body’s opioid
10 receptors; or

11 “(II) an implantable, reusable, or
12 disposable medical device cleared or
13 approved by the Administrator for
14 Food and Drugs for the intended use
15 of managing or treating pain;

16 that has demonstrated the ability to re-
17 place or reduce opioid consumption in a
18 clinical trial or through clinical data pub-
19 lished in a peer-reviewed journal, as deter-
20 mined by the Secretary.”.

21 (b) AMBULATORY SURGICAL CENTER PAYMENT SYS-
22 TEM.—Section 1833(i)(2)(D) of the Social Security Act
23 (42 U.S.C. 1395l(i)(2)(D)) is amended—

24 (1) by aligning the margins of clause (v) with
25 the margins of clause (iv);

1 (2) by redesignating clause (vi) as clause (vii);

2 and

3 (3) by inserting after clause (v) the following

4 new clause:

5 “(vi) In the case of surgical services
6 furnished on or after January 1, 2020, and
7 before January 1, 2025, the payment sys-
8 tem described in clause (i) shall provide for
9 a separate payment for a non-opioid treat-
10 ment (as defined in clause (iii) of sub-
11 section (t)(16)(G)) furnished as part of
12 such services in the amount specified in
13 clause (ii) of such subsection.”.

14 (c) EVALUATION OF THERAPEUTIC SERVICES FOR
15 PAIN MANAGEMENT.—

16 (1) REPORT TO CONGRESS.—Not later than 1
17 year after the date of the enactment of this Act, the
18 Secretary of Health and Human Services (in this
19 subsection referred to as the “Secretary”), acting
20 through the Administrator of the Centers for Medi-
21 care & Medicaid Services, shall submit to Congress
22 a report identifying—

23 (A) limitations, gaps, barriers to access, or
24 deficits in Medicare coverage or reimbursement
25 for restorative therapies, behavioral approaches,

1 and complementary and integrative health serv-
2 ices that are identified in the Pain Management
3 Best Practices Inter-Agency Task Force Report
4 and that have demonstrated the ability to re-
5 place or reduce opioid consumption; and

6 (B) recommendations to address the limi-
7 tations, gaps, barriers to access, or deficits
8 identified under subparagraph (A) to improve
9 Medicare coverage and reimbursement for such
10 therapies, approaches, and services.

11 (2) PUBLIC CONSULTATION.—In developing the
12 report described in paragraph (1), the Secretary
13 shall consult with relevant stakeholders as deter-
14 mined appropriate by the Secretary.

15 (3) EXCLUSIVE TREATMENT.—Any drug, bio-
16 logical product, or medical device that is a non-
17 opioid treatment (as defined in section
18 1833(t)(16)(G)(iii) of the Social Security Act, as
19 added by subsection (a)) shall not be considered a
20 therapeutic service for the purpose of the report de-
21 scribed in paragraph (1).