

[DISCUSSION DRAFT]

115TH CONGRESS
2^D SESSION

H. R. _____

To amend title XVIII of the Social Security Act to encourage the use of non-opioid analgesics for the management of post-surgical pain under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend title XVIII of the Social Security Act to encourage the use of non-opioid analgesics for the management of post-surgical pain under the Medicare program, and for other purposes.

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 “Postoperative Opioid
5 Prevention Act of 2018”.

6 **SEC. 2. FINDINGS; PURPOSES.**

7 (a) FINDINGS.—Congress finds the following:

1 (1) The surgical setting is contributing to the
2 opioid crisis by exposing millions of patients, includ-
3 ing Medicare beneficiaries, annually to excess risk
4 and potential addiction from opioids postoperatively.

5 (2) As many as 6.5 percent of patients who are
6 prescribed opioids to manage postoperative pain be-
7 come persistent opioid users. Of these patients, up
8 to 670,000 will develop opioid use disorder or be-
9 come addicted.

10 (3) Postoperative prescriptions put over a bil-
11 lion left-over opioids into American medicine cabi-
12 nets each year, creating a source of diversion and
13 abuse.

14 (4) In 2012, more than 255 million opioid pre-
15 scriptions were written in the United States. The
16 surgical process accounted for 36.5 percent of those
17 prescriptions.

18 (5) Recent studies show that more than two-
19 thirds of patients reported having unused opioids
20 after surgery.

21 (6) Most people who misuse opioids report ob-
22 taining them from family or friends who have excess
23 pills.

24 (7) Opioid related adverse events, such as res-
25 piratory depression, ileus, delirium, and constipation

1 add \$17 billion to \$29 billion annually to hospital
2 costs in the United States.

3 (9) Abuse and addiction cost the United States
4 as much as \$78.5 billion each year.

5 (10) An economic analysis released in February
6 2018 estimated that the economic and quantifiable
7 societal harms of opioid overdoses and deaths—

8 (A) exceeded \$95 billion dollars in 2016;
9 and

10 (B) will cost an additional \$500 billion be-
11 tween 2016 and 2020 if current conditions per-
12 sist.

13 (11) A Council of Economic Advisors report
14 from November 2017 estimates the costs of opioid
15 misuse at \$504 billion, of which \$431.7 billion is re-
16 lated to the unnecessary deaths of United States
17 citizens.

18 (b) PURPOSES.—The purposes of this Act are the fol-
19 lowing:

20 (1) To give patients greater access to innovative
21 non-opioid alternatives for postoperative pain man-
22 agement by removing the bundled cost conflict under
23 the Medicare program that creates incentives to use
24 inexpensive opioids in the postoperative setting.

1 (2) To change current prescribing practices in
2 the United States to reduce the overreliance on
3 opioids to manage postoperative pain and reduce the
4 number of left over pills.

5 (3) To encourage increased research and devel-
6 opment into non-opioid alternatives for pain man-
7 agement so clinicians have more and better options.

8 **SEC. 3. MEDICARE INCENTIVES FOR USE OF NON-OPIOID**
9 **ANALGESICS IN HOSPITAL OUTPATIENT DE-**
10 **PARTMENTS AND AMBULATORY SURGICAL**
11 **CENTERS.**

12 (a) HOSPITAL OUTPATIENT DEPARTMENTS.—Sec-
13 tion 1833(t) of the Social Security Act (42 U.S.C.
14 1395l(t)) is amended—

15 (1) in paragraph (2)(E), by striking “under
16 paragraph (6)” and inserting “under paragraphs (6)
17 and (22)”;

18 (2) in paragraph (5)(A)(i)(II), by striking
19 “under paragraph (6)” and inserting “under para-
20 graphs (6) and (22)”;

21 (3) by adding at the end the following new
22 paragraph:

23 “(22) TRANSITIONAL PASS-THROUGH FOR NON-
24 OPIOID ANALGESICS FOR POST-SURGICAL PAIN.—

1 “(A) IN GENERAL.—The Secretary shall
2 provide for an additional payment under this
3 paragraph for eligible non-opioid analgesics (as
4 defined in subparagraph (B)) that are provided
5 as part of a covered OPD service (or group of
6 services).

7 “(B) ELIGIBLE NON-OPIOID ANALGESIC
8 DEFINED.—In this paragraph, the term ‘eligible
9 non-opioid analgesic’ means a covered out-
10 patient drug (as defined in section
11 1927(k)(2))—

12 “(i) that is an analgesic that is not an
13 opioid;

14 “(ii) that demonstrated superiority to
15 a comparator in a clinical trial considered
16 by the Food and Drug Administration; and

17 “(iii) for which payment as [an out-
18 patient hospital service]/[a covered OPD
19 service] under this part was not being
20 made as of December 31, 2018.

21 “(C) ESTABLISHMENT OF SEPARATE AM-
22 BULATORY PAYMENT CLASSIFICATION
23 GROUPS.—The Secretary shall establish a sepa-
24 rate ambulatory payment classification group

1 for each drug or biological for which payment
2 may be made under this paragraph.

3 “(D) 5-YEAR PERIOD OF PAYMENT.—The
4 payment under this paragraph with respect to
5 a drug or biological shall begin on the later of
6 the date of enactment of this paragraph or the
7 date the drug or biological is first used as part
8 of a covered OPD service for which payment is
9 made under this part and shall end on the date
10 that is 5 years after that date.

11 “(E) AMOUNT OF ADDITIONAL PAY-
12 MENT.—The amount of the payment under this
13 paragraph with respect to a drug or biological
14 provided as part of a covered OPD service is
15 the amount by which the amount determined
16 under section 1842(o) (or, in the case of a drug
17 or biological that is covered under a competitive
18 acquisition contract under section 1847B, the
19 amount that would have been determined under
20 section 1842(o) if the drug or biological were
21 not covered under such a contract) for the drug
22 or biological exceeds the portion of the other-
23 wise applicable medicare OPD fee schedule that
24 the Secretary determines is associated with
25 drugs or biologicals that are opioid analgesics

1 which may have otherwise been provided as part
2 of the covered OPD service.

3 “(F) LIMITATION OF APPLICATION OF
4 FUNCTIONAL EQUIVALENCE STANDARD.—The
5 Secretary may not publish regulations that
6 apply a functional equivalence standard to a
7 drug or biological under this paragraph.

8 “(G) IMPLEMENTATION.—

9 “(i) AUTHORIZATION OF IMPLEMEN-
10 TATION OTHER THAN THROUGH REGULA-
11 TIONS.—The Secretary may implement the
12 provisions of this paragraph by program
13 memorandum or otherwise.

14 “(ii) DEADLINE.—The Secretary shall
15 implement this paragraph in a manner
16 that payments are made for under this
17 paragraph on and after January 1, 2019.”.

18 (b) AMBULATORY SURGICAL CENTERS.—Section
19 1833(i)(7)(B) of the Social Security Act (42 U.S.C.
20 1395l(i)(7)(B)) is amended by inserting “and paragraph
21 (22)” after “paragraph (17)”.