[DISCUSSION DRAFT]

115TH CONGRESS  
2D 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

Mr. ______ 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Postoperative Opioid Prevention Act of 2018”.

SEC. 2. FINDINGS; PURPOSES.

(a) FINDINGS.—Congress finds the following:
(1) The surgical setting is contributing to the opioid crisis by exposing millions of patients, including Medicare beneficiaries, annually to excess risk and potential addiction from opioids postoperatively.

(2) As many as 6.5 percent of patients who are prescribed opioids to manage postoperative pain become persistent opioid users. Of these patients, up to 670,000 will develop opioid use disorder or become addicted.

(3) Postoperative prescriptions put over a billion left-over opioids into American medicine cabinets each year, creating a source of diversion and abuse.

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

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

(6) Most people who misuse opioids report obtaining them from family or friends who have excess pills.

(7) Opioid related adverse events, such as respiratory depression, ileus, delirium, and constipation
add $17 billion to $29 billion annually to hospital costs in the United States.

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

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

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

(B) will cost an additional $500 billion between 2016 and 2020 if current conditions persist.

(11) A Council of Economic Advisors report from November 2017 estimates the costs of opioid misuse at $504 billion, of which $431.7 billion is related to the unnecessary deaths of United States citizens.

(b) PURPOSES.—The purposes of this Act are the following:

(1) To give patients greater access to innovative non-opioid alternatives for postoperative pain management by removing the bundled cost conflict under the Medicare program that creates incentives to use inexpensive opioids in the postoperative setting.
(2) To change current prescribing practices in the United States to reduce the overreliance on opioids to manage postoperative pain and reduce the number of left over pills.

(3) To encourage increased research and development into non-opioid alternatives for pain management so clinicians have more and better options.

SEC. 3. MEDICARE INCENTIVES FOR USE OF NON-OPIOID ANALGESICS IN HOSPITAL OUTPATIENT DEPARTMENTS AND AMBULATORY SURGICAL CENTERS.

(a) HOSPITAL OUTPATIENT DEPARTMENTS.—Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) is amended—

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

(2) in paragraph (5)(A)(i)(II), by striking “under paragraph (6)” and inserting “under paragraphs (6) and (22)”; and

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

“(22) TRANSITIONAL PASS-THROUGH FOR NON-OPIOID ANALGESICS FOR POST-SURGICAL PAIN.—
“(A) IN GENERAL.—The Secretary shall provide for an additional payment under this paragraph for eligible non-opioid analgesics (as defined in subparagraph (B)) that are provided as part of a covered OPD service (or group of services).

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

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

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

“(iii) for which payment as [an outpatient hospital service] [a covered OPD service] under this part was not being made as of December 31, 2018.

“(C) ESTABLISHMENT OF SEPARATE AMBULATORY PAYMENT CLASSIFICATION GROUPS.—The Secretary shall establish a separate ambulatory payment classification group
for each drug or biological for which payment may be made under this paragraph.

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

“(E) AMOUNT OF ADDITIONAL PAYMENT. — The amount of the payment under this paragraph with respect to a drug or biological provided as part of a covered OPD service is the amount by which the amount determined under section 1842(o) (or, in the case of a drug or biological that is covered under a competitive acquisition contract under section 1847B, the amount that would have been determined under section 1842(o) if the drug or biological were not covered under such a contract) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with drugs or biologicals that are opioid analgesics.
which may have otherwise been provided as part of the covered OPD service.

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

“(G) IMPLEMENTATION.—

“(i) AUTHORIZATION OF IMPLEMENTATION OTHER THAN THROUGH REGULATIONS.—The Secretary may implement the provisions of this paragraph by program memorandum or otherwise.

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

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