

Suspend the Rules And Pass the Bill, H.R. 5773, with Amendments

(The amendments strike all after the enacting clause and insert a new text and a new title)

115TH CONGRESS
2^D SESSION

H. R. 5773

To amend title XVIII of the Social Security Act to require Medicare prescription drug plans to establish drug management programs for at-risk beneficiaries, require electronic prior authorization for covered part D drugs, and to provide for other program integrity measures under parts C and D of the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

MAY 11, 2018

Mr. ROSKAM (for himself, Ms. SEWELL of Alabama, Mr. KNIGHT, and Ms. SINEMA) 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 title XVIII of the Social Security Act to require Medicare prescription drug plans to establish drug management programs for at-risk beneficiaries, require electronic prior authorization for covered part D drugs, and to provide for other program integrity measures under parts C and D of the Medicare 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.**

2 This Act may be cited as the “Preventing Addiction
3 for Susceptible Seniors Act of 2018” or the “PASS Act
4 of 2018”.

5 **SEC. 2. ELECTRONIC PRIOR AUTHORIZATION FOR COV-
6 ERED PART D DRUGS.**

7 (a) **INCLUSION IN ELECTRONIC PRESCRIPTION PRO-
8 GRAM.**—Section 1860D–4(e)(2) of the Social Security Act
9 (42 U.S.C. 1395w–104(e)(2)) is amended by adding at the
10 end the following new subparagraph:

11 “(E) **ELECTRONIC PRIOR AUTHORIZA-
12 TION.**—

13 “(i) **IN GENERAL.**—Not later than
14 January 1, 2021, the program shall pro-
15 vide for the secure electronic transmission
16 of—

17 “(I) a prior authorization request
18 from the prescribing health care pro-
19 fessional for coverage of a covered
20 part D drug for a part D eligible indi-
21 vidual enrolled in a part D plan (as
22 defined in section 1860D–23(a)(5)) to
23 the PDP sponsor or Medicare Advan-
24 tage organization offering such plan;
25 and

1 “(II) a response, in accordance
2 with this subparagraph, from such
3 PDP sponsor or Medicare Advantage
4 organization, respectively, to such pro-
5 fessional.

6 “(ii) ELECTRONIC TRANSMISSION.—

7 “(I) EXCLUSIONS.—For purposes
8 of this subparagraph, a facsimile, a
9 proprietary payer portal that does not
10 meet standards specified by the Sec-
11 retary, or an electronic form shall not
12 be treated as an electronic trans-
13 mission described in clause (i).

14 “(II) STANDARDS.—In order to
15 be treated, for purposes of this sub-
16 paragraph, as an electronic trans-
17 mission described in clause (i), such
18 transmission shall comply with tech-
19 nical standards adopted by the Sec-
20 retary in consultation with the Na-
21 tional Council for Prescription Drug
22 Programs, other standard setting or-
23 ganizations determined appropriate by
24 the Secretary, and stakeholders in-
25 cluding PDP sponsors, Medicare Ad-

1 vantage organizations, health care
2 professionals, and health information
3 technology software vendors.

4 “(III) APPLICATION.—Notwith-
5 standing any other provision of law,
6 for purposes of this subparagraph, the
7 Secretary may require the use of such
8 standards adopted under subclause
9 (II) in lieu of any other applicable
10 standards for an electronic trans-
11 mission described in clause (i) for a
12 covered part D drug for a part D eli-
13 gible individual.”.

14 (b) SENSE OF CONGRESS REGARDING ELECTRONIC
15 PRIOR AUTHORIZATION.—It is the sense of the Congress
16 that—

17 (1) there should be increased use of electronic
18 prior authorizations for coverage of covered part D
19 drugs for part D eligible individuals enrolled in pre-
20 scription drug plans under part D of title XVIII of
21 the Social Security Act and MA–PD plans under
22 part C of such title to reduce access delays by re-
23 solving coverage issues before prescriptions for such
24 drugs are transmitted; and

1 (2) greater priority should be placed on increas-
2 ing the adoption of use of such electronic prior au-
3 thorizations among prescribers of such drugs, phar-
4 macies, PDP sponsors, and Medicare Advantage or-
5 ganizations.

6 **SEC. 3. PROGRAM INTEGRITY TRANSPARENCY MEASURES**
7 **UNDER MEDICARE PARTS C AND D.**

8 (a) IN GENERAL.—Section 1859 of the Social Secu-
9 rity Act (42 U.S.C. 1395w–28) is amended by adding at
10 the end the following new subsection:

11 “(i) PROGRAM INTEGRITY TRANSPARENCY MEAS-
12 URES.—

13 “(1) PROGRAM INTEGRITY PORTAL.—

14 “(A) IN GENERAL.—Not later than two
15 years after the date of the enactment of this
16 subsection, the Secretary shall, after consulta-
17 tion with stakeholders, establish a secure Inter-
18 net website portal (or other successor tech-
19 nology) that would allow a secure path for com-
20 munication between the Secretary, MA plans
21 under this part, prescription drug plans under
22 part D, and an eligible entity with a contract
23 under section 1893 (such as a Medicare drug
24 integrity contractor or an entity responsible for
25 carrying out program integrity activities under

1 this part and part D) for the purpose of ena-
2 bling through such portal (or other successor
3 technology)—

4 “(i) the referral by such plans of sub-
5 stantiated fraud, waste, and abuse for ini-
6 tiating or assisting investigations con-
7 ducted by the eligible entity; and

8 “(ii) data sharing among such MA
9 plans, prescription drug plans, and the
10 Secretary.

11 “(B) REQUIRED USES OF PORTAL.—The
12 Secretary shall disseminate the following infor-
13 mation to MA plans under this part and pre-
14 scription drug plans under part D through the
15 secure Internet website portal (or other suc-
16 cessor technology) established under subpara-
17 graph (A):

18 “(i) Providers of services and sup-
19 pliers that have been referred pursuant to
20 subparagraph (A)(i) during the previous
21 12-month period.

22 “(ii) Providers of services and sup-
23 pliers who are the subject of an active ex-
24 clusion under section 1128 or who are sub-
25 ject to a suspension of payment under this

1 title pursuant to section 1862(o) or other-
2 wise.

3 “(iii) Providers of services and sup-
4 pliers who are the subject of an active rev-
5 ocaation of participation under this title, in-
6 cluding for not satisfying conditions of par-
7 ticipation.

8 “(iv) In the case of such a plan that
9 makes a referral under subparagraph
10 (A)(i) through the portal (or other suc-
11 cessor technology) with respect to activities
12 of substantiated fraud, waste, or abuse of
13 a provider of services or supplier, if such
14 provider or supplier has been the subject of
15 an administrative action under this title or
16 title XI with respect to similar activities, a
17 notification to such plan of such action so
18 taken.

19 “(C) RULEMAKING.—For purposes of this
20 paragraph, the Secretary shall, through rule-
21 making, specify what constitutes substantiated
22 fraud, waste, and abuse, using guidance such as
23 what is provided in the Medicare Program In-
24 tegrity Manual 4.7.1. In carrying out this sub-
25 section, a fraud hotline tip (as defined by the

1 Secretary) without further evidence shall not be
2 treated as sufficient evidence for substantiated
3 fraud, waste, or abuse

4 “(D) HIPAA COMPLIANT INFORMATION
5 ONLY.—For purposes of this subsection, com-
6 munications may only occur if the communica-
7 tions are permitted under the Federal regula-
8 tions (concerning the privacy of individually
9 identifiable health information) promulgated
10 under section 264(e) of the Health Insurance
11 Portability and Accountability Act of 1996.

12 “(2) QUARTERLY REPORTS.—Beginning two
13 years after the date of enactment of this subsection,
14 the Secretary shall make available to MA plans
15 under this part and prescription drug plans under
16 part D in a timely manner (but no less frequently
17 than quarterly) and using information submitted to
18 an entity described in paragraph (1) through the
19 portal (or other successor technology) described in
20 such paragraph or pursuant to section 1893, infor-
21 mation on fraud, waste, and abuse schemes and
22 trends in identifying suspicious activity. Information
23 included in each such report shall—

24 “(A) include administrative actions, perti-
25 nent information related to opioid overpre-

1 scribing, and other data determined appropriate
2 by the Secretary in consultation with stake-
3 holders; and

4 “(B) be anonymized information submitted
5 by plans without identifying the source of such
6 information.

7 “(3) CLARIFICATION.—Nothing in this sub-
8 section shall be construed as precluding or otherwise
9 affecting referrals described in subparagraph (A)
10 that may otherwise be made to law enforcement en-
11 tities or to the Secretary.”.

12 (b) CONTRACT REQUIREMENT TO COMMUNICATE
13 PLAN CORRECTIVE ACTIONS AGAINST OPIOID OVER-PRE-
14 SCRIBERS.—Section 1857(e) of the Social Security Act
15 (42 U.S.C. 1395w–27(e)) is amended by adding at the end
16 the following new paragraph:

17 “(5) COMMUNICATING PLAN CORRECTIVE AC-
18 TIONS AGAINST OPIOIDS OVER-PRESCRIBERS.—

19 “(A) IN GENERAL.—Beginning with plan
20 years beginning on or after January 1, 2021, a
21 contract under this section with an MA organi-
22 zation shall require the organization to submit
23 to the Secretary, through the process estab-
24 lished under subparagraph (B), information on
25 the investigations and other actions taken by

1 such plans related to providers of services who
2 prescribe a high volume of opioids.

3 “(B) PROCESS.—Not later than January
4 1, 2021, the Secretary shall, in consultation
5 with stakeholders, establish a process under
6 which MA plans and prescription drug plans
7 shall submit to the Secretary information de-
8 scribed in subparagraph (A).

9 “(C) REGULATIONS.—For purposes of this
10 paragraph, including as applied under section
11 1860D–12(b)(3)(D), the Secretary shall, pursu-
12 ant to rulemaking—

13 “(i) specify a definition for the term
14 ‘high volume of opioids’ and a method for
15 determining if a provider of services pre-
16 scribes such a high volume; and

17 “(ii) establish the process described in
18 subparagraph (B) and the types of infor-
19 mation that shall be submitted through
20 such process.”.

21 (c) REFERENCE UNDER PART D TO PROGRAM IN-
22 TEGRITY TRANSPARENCY MEASURES.—Section 1860D–4
23 of the Social Security Act (42 U.S.C. 1395w–104) is
24 amended by adding at the end the following new sub-
25 section:

1 “(m) PROGRAM INTEGRITY TRANSPARENCY MEAS-
2 URES.—For program integrity transparency measures ap-
3 plied with respect to prescription drug plan and MA plans,
4 see section 1859(i).”.

5 **SEC. 4. EXPANDING ELIGIBILITY FOR MEDICATION THER-**
6 **APY MANAGEMENT PROGRAMS UNDER PART**
7 **D.**

8 Section 1860D–4(c)(2)(A)(ii) of the Social Security
9 Act (42 U.S.C. 1395w–104(c)(2)(A)(ii)) is amended—

10 (1) by redesignating subclauses (I) through
11 (III) as items (aa) through (cc), respectively, and
12 adjusting the margins accordingly;

13 (2) by striking “are part D eligible individuals
14 who—” and inserting “are the following:

15 “(I) Part D eligible individuals
16 who—”; and

17 (3) by adding at the end the following new sub-
18 clause:

19 “(II) Beginning January 1,
20 2021, at-risk beneficiaries for pre-
21 scription drug abuse (as defined in
22 paragraph (5)(C)).”.

1 **SEC. 5. MEDICARE NOTIFICATIONS TO OUTLIER PRE-**
2 **SCRIBERS OF OPIOIDS.**

3 Section 1860D–4(c)(4) of the Social Security Act (42
4 U.S.C. 1395w–104(c)(4)) is amended by adding at the end
5 the following new subparagraph:

6 “(D) OUTLIER PRESCRIBER NOTIFICA-
7 TION.—

8 “(i) NOTIFICATION.—Beginning not
9 later than two years after the date of the
10 enactment of this subparagraph, the Sec-
11 retary shall, in the case of a prescriber
12 identified by the Secretary under clause
13 (ii) to be an outlier prescriber of opioids,
14 provide, subject to clause (iv), an annual
15 notification to such prescriber that such
16 prescriber has been so identified and that
17 includes resources on proper prescribing
18 methods and other information specified in
19 accordance with clause (iii).

20 “(ii) IDENTIFICATION OF OUTLIER
21 PRESCRIBERS OF OPIOIDS.—

22 “(I) IN GENERAL.—The Sec-
23 retary shall, subject to subclause (III),
24 using the valid prescriber National
25 Provider Identifiers included pursuant
26 to subparagraph (A) on claims for

1 covered part D drugs for part D eligi-
2 ble individuals enrolled in prescription
3 drug plans under this part or MA–PD
4 plans under part C and based on the
5 threshold established under subclause
6 (II), conduct an analysis to identify
7 prescribers that are outlier opioid pre-
8 scribers for a period specified by the
9 Secretary.

10 “(II) ESTABLISHMENT OF
11 THRESHOLD.—For purposes of sub-
12 clause (I) and subject to subclause
13 (III), the Secretary shall, after con-
14 sultation with stakeholders, establish
15 a threshold, based on prescriber spe-
16 cialty and geographic area, for identi-
17 fying whether a prescriber in a spe-
18 cialty and geographic area is an
19 outlier prescriber of opioids as com-
20 pared to other prescribers of opioids
21 within such specialty and area.

22 “(III) EXCLUSIONS.—The Sec-
23 retary may exclude the following indi-
24 viduals and prescribers from the anal-
25 ysis under this clause:

1 “(aa) Individuals receiving
2 hospice services.

3 “(bb) Individuals with a
4 cancer diagnosis.

5 “(cc) Prescribers who are
6 the subject of an investigation by
7 the Centers for Medicare & Med-
8 icaid Services or the Office of In-
9 spector General of the Depart-
10 ment of Health and Human
11 Services.

12 “(iii) CONTENTS OF NOTIFICATION.—
13 The Secretary shall, based on input from
14 stakeholders, specify the resources and
15 other information to be included in notifi-
16 cations provided under clause (i).

17 “(iv) MODIFICATIONS AND EXPAN-
18 SIONS.—

19 “(I) FREQUENCY.—Beginning 5
20 years after the date of the enactment
21 of this subparagraph, the Secretary
22 may change the frequency of the noti-
23 fications described in clause (i) based
24 on stakeholder input.

1 “(II) EXPANSION TO OTHER
2 PRESCRIPTIONS.—The Secretary may
3 expand notifications under this sub-
4 paragraph to include identifications
5 and notifications with respect to con-
6 current prescriptions of covered Part
7 D drugs used in combination with
8 opioids that are considered to have
9 adverse side effects when so used in
10 such combination, as determined by
11 the Secretary.

12 “(v) OPIOIDS DEFINED.—For pur-
13 poses of this subparagraph, the term
14 ‘opioids’ has such meaning as specified by
15 the Secretary through program instruction
16 or otherwise.”.

17 **SEC. 6. NO ADDITIONAL FUNDS AUTHORIZED.**

18 No additional funds are authorized to be appro-
19 priated to carry out the requirements of this Act and the
20 amendments made by this Act. Such requirements shall
21 be carried out using amounts otherwise authorized to be
22 appropriated.

 Amend the title so as to read: “A bill to amend title
XVIII of the Social Security Act to require electronic
prior authorization for covered part D drugs and to pro-

vide for other program integrity measures under parts C and D of the Medicare program.”.