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(Original Signature of Member)

115TH CONGRESS  
2D 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.

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## IN THE HOUSE OF REPRESENTATIVES

Mr. ROSKAM introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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## **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. REQUIRING PRESCRIPTION DRUG PLAN SPONSORS**  
6 **UNDER MEDICARE TO ESTABLISH DRUG**  
7 **MANAGEMENT PROGRAMS FOR AT-RISK**  
8 **BENEFICIARIES.**

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

11 (1) in paragraph (1), by inserting after sub-  
12 paragraph (E) the following new subparagraph:

13 “(F) With respect to plan years beginning  
14 on or after January 1, 2021, a drug manage-  
15 ment program for at-risk beneficiaries described  
16 in paragraph (5).”; and

17 (2) in paragraph (5)(A), by inserting “(and for  
18 plan years beginning on or after January 1, 2021,  
19 a PDP sponsor shall)” after “A PDP sponsor may”.

20 **SEC. 3. ELECTRONIC PRIOR AUTHORIZATION FOR COV-**  
21 **ERED PART D DRUGS.**

22 (a) **INCLUSION IN ELECTRONIC PRESCRIPTION PRO-**  
23 **GRAM.**—Section 1860D–4(e)(2) of the Social Security Act  
24 (42 U.S.C. 1395w–104(e)(2)) is amended by adding at the  
25 end the following new subparagraph:

1                   “(E) ELECTRONIC PRIOR AUTHORIZA-  
2                   TION.—

3                   “(i) IN GENERAL.—Not later than  
4                   January 1, 2021, the program shall pro-  
5                   vide for the secure electronic transmittal  
6                   of—

7                   “(I) a prior authorization request  
8                   from the prescribing health care pro-  
9                   fessional for coverage of a covered  
10                  part D drug for a part D eligible indi-  
11                  vidual enrolled in a part D plan (as  
12                  defined in section 1860D–23(a)(5)) to  
13                  the PDP sponsor or Medicare Advan-  
14                  tage organization offering such plan;  
15                  and

16                  “(II) a response, in accordance  
17                  with this subparagraph, from such  
18                  PDP sponsor or Medicare Advantage  
19                  organization, respectively, to such pro-  
20                  fessional.

21                  “(ii) ELECTRONIC TRANSMISSION.—

22                  “(I) EXCLUSIONS.—For purposes  
23                  of this subparagraph, a facsimile, a  
24                  proprietary payer portal that does not  
25                  meet standards specified by the Sec-

1                   retary, or an electronic form shall not  
2                   be treated as an electronic trans-  
3                   mission described in clause (i).

4                   “(II) STANDARDS.—In order to  
5                   be treated, for purposes of this sub-  
6                   paragraph, as an electronic trans-  
7                   mission described in clause (i), such  
8                   transmission shall comply with tech-  
9                   nical standards adopted by the Sec-  
10                  retary in consultation with the Na-  
11                  tional Council for Prescription Drug  
12                  Programs, other standard setting or-  
13                  ganizations determined appropriate by  
14                  the Secretary, and stakeholders in-  
15                  cluding PDP sponsors, Medicare Ad-  
16                  vantage organizations, health care  
17                  professionals, and health information  
18                  technology software vendors.”.

19                  (b) SENSE OF CONGRESS REGARDING ELECTRONIC  
20                  PRIOR AUTHORIZATION.—It is the sense of the Congress  
21                  that—

22                         (1) there should be increased use of electronic  
23                         prior authorizations for coverage of covered part D  
24                         drugs for part D eligible individuals enrolled in pre-  
25                         scription drug plans under part D of title XVIII of

1 the Social Security Act and MA–PD plans under  
2 part C of such title to reduce access delays by re-  
3 solving coverage issues before prescriptions for such  
4 drugs are transmitted; and

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

10 **SEC. 4. PROGRAM INTEGRITY TRANSPARENCY MEASURES**

11 **UNDER MEDICARE PARTS C AND D.**

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

15 “(i) PROGRAM INTEGRITY TRANSPARENCY MEAS-  
16 URES.—

17 “(1) PROGRAM INTEGRITY PORTAL.—

18 “(A) IN GENERAL.—Not later than two  
19 years after the date of the enactment of this  
20 subsection, the Secretary shall, after consulta-  
21 tion with stakeholders, establish a secure Inter-  
22 net website portal (or other successor tech-  
23 nology) that would allow a secure path for com-  
24 munication between the Secretary, MA plans  
25 under this part, prescription drug plans under

1 part D, and an eligible entity with a contract  
2 under section 1893 (such as a Medicare drug  
3 integrity contractor or an entity responsible for  
4 carrying out program integrity activities under  
5 this part and part D) for the purpose of ena-  
6 bling through such portal (or other successor  
7 technology)—

8 “(i) the referral by such plans of sub-  
9 stantiated fraud, waste, and abuse for ini-  
10 tiating or assisting investigations con-  
11 ducted by the eligible entity; and

12 “(ii) data sharing among such MA  
13 plans, prescription drug plans, and the  
14 Secretary.

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

22 “(i) Providers of services and sup-  
23 pliers that have been referred pursuant to  
24 subparagraph (A)(i) during the previous  
25 12-month period.

1           “(ii) Providers of services and sup-  
2 pliers who are the subject of an active ex-  
3 clusion under section 1128 or who are sub-  
4 ject to a suspension of payment under this  
5 title pursuant to section 1862(o) or other-  
6 wise.

7           “(iii) Providers of services and sup-  
8 pliers who are the subject of an active rev-  
9 ocation of participation under this title, in-  
10 cluding for not satisfying conditions of par-  
11 ticipation.

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

23           “(C) RULEMAKING.—For purposes of this  
24 paragraph, the Secretary shall, through rule-  
25 making, specify what constitutes substantiated

1 fraud, waste, and abuse, using guidance such as  
2 what is provided in the Medicare Program In-  
3 tegrity Manual 4.7.1. In carrying out this sub-  
4 section, a fraud hotline tip (as defined by the  
5 Secretary) without further evidence shall not be  
6 treated as sufficient evidence for substantiated  
7 fraud, waste, or abuse

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

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



1 trends in identifying suspicious activity. Information  
2 included in each such report shall—

3 “(A) include administrative actions, perti-  
4 nent information related to opioid overpre-  
5 scribing, and other data determined appropriate  
6 by the Secretary in consultation with stake-  
7 holders; and

8 “(B) be anonymized information submitted  
9 by plans without identifying the source of such  
10 information.

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

16 (b) CONTRACT REQUIREMENT TO COMMUNICATE  
17 PLAN CORRECTIVE ACTIONS AGAINST OPIOID OVER-PRE-  
18 SCRIBERS.—Section 1857(e)(4)(C) of the Social Security  
19 Act (42 U.S.C. 1395w–27(e)(4)(C)) is amended by adding  
20 at the end the following new paragraph:

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

23 “(A) IN GENERAL.—Beginning with plan  
24 years beginning on or after January 1, 2021, a  
25 contract under this section with an MA organi-

1           zation shall require the organization to submit  
2           to the Secretary, through the process estab-  
3           lished under subparagraph (B), information on  
4           the investigations and other actions taken by  
5           such plans related to providers of services who  
6           prescribe a high volume of opioids.

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

13          “(C) REGULATIONS.—For purposes of this  
14          paragraph, including as applied under section  
15          1860D–12(b)(3)(D), the Secretary shall, pursu-  
16          ant to rulemaking—

17                 “(i) specify a definition for the term  
18                 ‘high volume of opioids’ and a method for  
19                 determining if a provider of services pre-  
20                 scribes such a high volume; and

21                 “(ii) establish the process described in  
22                 subparagraph (B) and the types of infor-  
23                 mation that shall be submitted through  
24                 such process.”.

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

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

10 **SEC. 5. EXPANDING ELIGIBILITY FOR MEDICATION THER-**  
11 **APY MANAGEMENT PROGRAMS UNDER PART**  
12 **D.**

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

15 (1) by redesignating subclauses (I) through  
16 (III) as items (aa) through (cc), respectively, and  
17 adjusting the margins accordingly;

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

20 (I) Part D eligible individuals  
21 who—”; and

22 (3) by adding at the end the following new sub-  
23 clause:

24 (II) Beginning January 1,  
25 2021, at-risk beneficiaries for pre-

1                    scription drug abuse (as defined in  
2                    paragraph (5)(C)).”.

3 **SEC. 6. MEDICARE NOTIFICATIONS TO OUTLIER PRE-**  
4 **SCRIBERS OF OPIOIDS.**

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

8                    “(D) OUTLIER PRESCRIBER NOTIFICA-  
9                    TION.—

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

22                    “(ii) IDENTIFICATION OF OUTLIER  
23                    PRESCRIBERS OF OPIOIDS.—

24                    “(I) IN GENERAL.—The Sec-  
25                    retary shall, subject to subclause (III),

1 using the valid prescriber National  
2 Provider Identifiers included pursuant  
3 to subparagraph (A) on claims for  
4 covered part D drugs for part D eligi-  
5 ble individuals enrolled in prescription  
6 drug plans under this part or MA-PD  
7 plans under part C and based on the  
8 threshold established under subclause  
9 (II), conduct an analysis to identify  
10 prescribers that are outlier opioid pre-  
11 scribers for a period specified by the  
12 Secretary.

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

1                   “(III) EXCLUSIONS.—The Sec-  
2                   retary may exclude the following indi-  
3                   viduals and prescribers from the anal-  
4                   ysis under this clause:

5                   “(aa) Individuals receiving  
6                   hospice services.

7                   “(bb) Individuals with a  
8                   cancer diagnosis.

9                   “(cc) Prescribers who are  
10                  the subject of an investigation by  
11                  the Centers for Medicare & Med-  
12                  icaid Services or the Office of In-  
13                  specter General of the Depart-  
14                  ment of Health and Human  
15                  Services.

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

21                  “(iv) MODIFICATIONS AND EXPAN-  
22                  SIONS.—

23                  “(I) FREQUENCY.—Beginning 5  
24                  years after the date of the enactment  
25                  of this subparagraph, the Secretary

1                   may change the frequency of the noti-  
2                   fications described in clause (i) based  
3                   on stakeholder input.

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

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