AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 3726

OFFERED BY MR. BRADY OF TEXAS

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the "Stark Administrative3 Simplification Act of 2017".

4 SEC. 2. ALTERNATIVE SANCTIONS FOR TECHNICAL NON5 COMPLIANCE WITH STARK RULE UNDER
6 MEDICARE.

7 Section 1877 of the Social Security Act (42 U.S.C.
8 1395nn) is amended by adding at the end the following
9 new subsection:

10 "(j) Self-disclosure Protocols.—

11 "(1) IN GENERAL.—Beginning one year after
12 the date of the enactment of this subsection—

"(A) an entity or individual may voluntarily disclose a compensation arrangement with
actual or potential inadvertent technical noncompliance with subsection (a)(1) (as defined in
paragraph (3)(G)) pursuant to either the selfreferral disclosure protocol (defined in para-

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graph (2)) or the alternative protocol for technical noncompliance under paragraph (3);

3 "(B) disclosures voluntarily withdrawn 4 from the alternative protocol for technical noncompliance may be submitted to the self-refer-6 ral disclosure protocol; and

7 "(C) an entity that, prior to the establishment of the alternative protocol for technical 8 9 noncompliance, disclosed to the self-referral dis-10 closure protocol a compensation arrangement 11 that was in inadvertent technical noncompliance 12 with subsection (a)(1), may elect, not later than one year after such alternative protocol is 13 14 established, to withdraw such disclosure from 15 the self-referral disclosure protocol and instead 16 submit the disclosure to such alternative pro-17 tocol.

18 (2)Self-referral DISCLOSURE PRO-19 TOCOL.—The term 'self-referral disclosure protocol' or 'SRDP' means the protocol specified in section 20 21 6409 of Public Law 111–148.

((3) 22 **ALTERNATIVE** PROTOCOL FOR 23 INADVERTANT TECHNICAL NONCOMPLIANCE.

24 "(A) IN GENERAL.—The Secretary shall 25 establish, not later than one year after the date

1 of the enactment of this subsection, an alter-2 native protocol for technical noncompliance (in this subsection referred to as the 'APTN') to 3 4 enable entities to disclose arrangements that 5 were previously in inadvertent technical non-6 compliance with subsection (a)(1) and, upon the 7 Secretary's acceptance of the disclosure, make 8 payment of a civil monetary penalty. Payment 9 of such civil monetary penalty for an arrange-10 ment shall resolve only overpayments due and 11 owing as a result of such arrangement's inad-12 vertent technical noncompliance with this sec-13 tion. The provisions of section 6409 of Public 14 Law 111–148 shall not apply to this subsection. 15 "(B) DISCLOSURE REQUIREMENTS.—Ar-16 rangements disclosed to the APTN must— 17 "(i) involve only inadvertent technical 18 noncompliance with subsection (a)(1) that 19 was ended by termination or expiration of 20 the arrangement, or by action of the par-21 ties to the arrangement to resolve the tech-22 nical noncompliance, prior to the date of 23 submission of the disclosure to the APTN; 24 "(ii) be made in the form and manner 25 specified by the Secretary on the public

1	Internet website of the Centers for Medi-
2	care & Medicaid Services and include de-
3	scriptions of—
4	"(I) the compensation arrange-
5	ment that was in technical noncompli-
6	ance with subsection $(a)(1)$;
7	"(II) how and when the technical
8	noncompliance with subsection $(a)(1)$
9	was ended or the arrangement was
10	otherwise terminated; and
11	"(III) how the remuneration paid
12	under the compensation arrangement
13	being disclosed was—
14	"(aa) consistent with the
15	fair market value of the items
16	and services that were provided
17	under the compensation arrange-
18	ment; and
19	"(bb) not determined in a
20	manner that directly or indirectly
21	takes into account the volume or
22	value of referrals or other busi-
23	ness generated between the par-
24	ties;

1	"(iii) include a form settlement agree-
2	ment provided by the Secretary signed by
3	the entity; and
4	"(iv) include a certification from the
5	entity that, to the best of the entity's
6	knowledge, the information provided is
7	truthful information and is based on a
8	good faith effort to bring the matter to the
9	Secretary's attention.
10	"(C) ACCEPTANCE OR REJECTION OF DIS-
11	CLOSURE BY THE SECRETARY.—The following
12	rules shall apply to the acceptance or rejection
13	of a disclosure under the APTN:
14	"(i) The Secretary shall accept or re-
15	ject a complete, accurate, and timely dis-
16	closure.
17	"(ii) Upon receipt of a disclosure, the
18	Secretary shall notify the disclosing party
19	of such receipt.
20	"(iii) The Secretary may request addi-
21	tional information from the disclosing
22	party.
23	"(iv) Upon acceptance by the Sec-
24	retary, the Secretary shall notify the dis-
25	closing party in writing of such acceptance.

1	"(v) The disclosure shall be rejected
2	if—
3	"(I) the disclosing party fails to
4	furnish the additional information re-
5	quested by the Secretary in such form
6	and manner as the Secretary may
7	specify; or
8	"(II) in the Secretary's sole de-
9	termination, the noncompliance dis-
10	closed did not meet the disclosure re-
11	quirements specified in subparagraph
12	(B).
13	"(vi) The disclosure shall be accepted
13 14	"(vi) The disclosure shall be accepted if the Secretary—
14	if the Secretary—
14 15	if the Secretary— "(I) has issued a written notice
14 15 16	if the Secretary— "(I) has issued a written notice to the disclosing party that the disclo-
14 15 16 17	if the Secretary— "(I) has issued a written notice to the disclosing party that the disclo- sure is determined to satisfy the re-
14 15 16 17 18	if the Secretary— "(I) has issued a written notice to the disclosing party that the disclo- sure is determined to satisfy the re- quirements for disclosures under this
14 15 16 17 18 19	if the Secretary— "(I) has issued a written notice to the disclosing party that the disclo- sure is determined to satisfy the re- quirements for disclosures under this section; or
 14 15 16 17 18 19 20 	if the Secretary— "(I) has issued a written notice to the disclosing party that the disclo- sure is determined to satisfy the re- quirements for disclosures under this section; or "(II) has not rejected a complete,
 14 15 16 17 18 19 20 21 	if the Secretary— "(I) has issued a written notice to the disclosing party that the disclo- sure is determined to satisfy the re- quirements for disclosures under this section; or "(II) has not rejected a complete, accurate, and timely disclosure that

1	fication of receipt by the Secretary of
2	the disclosure.
3	"(vii) In determining whether to ac-
4	cept a disclosure, the Secretary may rea-
5	sonably rely on the information and certifi-
6	cations included in the disclosure.
7	"(D) RULE FOR WITHDRAWAL OF DISCLO-
8	sure.—Prior to acceptance or rejection of a
9	disclosure by the Secretary, an entity may vol-
10	untarily withdraw such disclosure from the
11	APTN.
12	"(E) Civil monetary penalties pursu-
13	ANT TO THE ALTERNATIVE PROTOCOL FOR
14	TECHNICAL NONCOMPLIANCE.—
15	"(i) IN GENERAL.—Subject to clause
16	(ii), for each arrangement disclosed under
17	this subsection and accepted under sub-
18	paragraph (C), the Secretary shall impose
19	a single civil monetary penalty of—
20	"(I) $$5,000$, in the case in which
21	disclosure of the inadvertent tech-
22	nically noncompliant compensation ar-
23	rangement was submitted to the Sec-
24	retary not later than the date that is
25	one year after the initial date of inad-

vertent technical noncompliance with
subsection $(a)(1)$; or
((II) \$10,000, in the case in
which the disclosure of the technically
noncompliant compensation arrange-
ment was submitted to the Sec-
retary—
"(aa) after the date that is
more than one year after the ini-
tial date of the entity's inad-
vertent technical noncompliance
with subsection $(a)(1)$; and
"(bb) not after the date that
is 3 years (or, in the case of a
disclosure submitted after the
5th year for which this sub-
section applies, the date that is 2
years) from the initial date of the
entity's inadvertent technical
noncompliance with subsection
(a)(1).
"(ii) Special rule for entities
THAT DISCLOSED TO THE APTN AFTER
WITHDRAWING A DISCLOSURE FROM THE
SRDP.—In the case of an entity that elects

1	under paragraph $(1)(C)$ to withdraw a dis-
2	closure from the self-referral disclosure
3	protocol and instead submit the disclosure
4	to the APTN under this subsection, in de-
5	termining the applicable civil monetary
6	penalty under clause (i), the date of disclo-
7	sure to the self-referral disclosure protocol
8	(as defined in paragraph (2)) shall be sub-
9	stituted for the date of disclosure to the
10	APTN.
11	"(F) Relation to advisory opinions.—
12	The APTN shall be separate from the advisory
13	opinion process set forth in regulations imple-
14	menting subsection (g) of this section.
15	"(G) Publication on internet website
16	OF APTN INFORMATION.—Not later than one
17	year after the date of the enactment of this sec-
18	tion, the Secretary shall post information on the
19	public Internet website of the Centers for Medi-
20	care & Medicaid Services to inform relevant
21	stakeholders of how to disclose and make pay-
22	ment of a civil monetary penalty for inadvertent
23	technical noncompliance with subsection $(a)(1)$.
24	"(H) DEFINITIONS.—In this subsection:

1	"(i) TECHNICAL NONCOMPLIANCE.—
2	The term 'technical noncompliance with
3	subsection $(a)(1)$ ' means, with respect to a
4	compensation arrangement, that—
5	"(I) the arrangement is not
6	signed by one or more parties to the
7	arrangement;
8	"(II) following the expiration of
9	the arrangement, the arrangement
10	was a holdover arrangement for a pe-
11	riod longer than permitted in regula-
12	tions issued by the Secretary; or
13	"(III) the contemporaneous writ-
14	ten documentation evidencing the
15	terms of the arrangement identifies
16	the parties to the arrangement and
17	the items, services, space, or equip-
18	ment, as applicable, but is not suffi-
19	cient to satisfy the writing require-
20	ment of an applicable exception.
21	"(ii) INADVERTENT.—The term 'inad-
22	vertent' means, with respect to a com-
23	pensation arrangement that is in non-
24	compliance, that an entity that is a party
25	to the compensation arrangement did not

1	know or should not have known of the non-
2	compliance.
3	"(I) Administration.—Chapter 35 of
4	title 44, United States Code, shall not apply to
5	this subsection.
6	"(J) Implementation.—Notwithstanding
7	any other provision of law, the Secretary may
8	implement the provisions of this paragraph by
9	program instruction or otherwise.".

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