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(Original Signature of Member)

113TH CONGRESS
1ST SESSION

H. R. _____

To amend title XVIII of the Social Security Act to establish appropriateness requirements for certain advanced diagnostic imaging services, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend title XVIII of the Social Security Act to establish appropriateness requirements for certain advanced diagnostic imaging services, 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 “Excellence in Diag-
5 nostic Imaging Utilization Act of 2013”.

1 **SEC. 2. APPROPRIATENESS REQUIREMENTS FOR CERTAIN**
2 **ADVANCED DIAGNOSTIC IMAGING SERVICES.**

3 (a) IN GENERAL.—Section 1834 of the Social Secu-
4 rity Act (42 U.S.C. 1395m) is amended by adding at the
5 end the following new subsection:

6 “(p) APPROPRIATENESS REQUIREMENTS FOR CER-
7 TAIN ADVANCED DIAGNOSTIC IMAGING SERVICES.—

8 “(1) IN GENERAL.—

9 “(A) IN GENERAL.—Beginning with Janu-
10 ary 1, 2015, with respect to applicable ad-
11 vanced diagnostic imaging services furnished in
12 an outpatient setting and for which payment is
13 made under—

14 “(i) the technical or professional com-
15 ponent of the fee schedule established
16 under section 1848(b); or

17 “(ii) the prospective payment system
18 for hospital outpatient department services
19 under section 1833(t),

20 payment for such services may only be made if
21 the requirements of this subsection are met.

22 “(B) APPLICABLE ADVANCED DIAGNOSTIC
23 IMAGING SERVICES.—For purposes of this sub-
24 section, the term ‘applicable advanced diag-
25 nostic imaging services’ means advanced diag-
26 nostic imaging services (as defined in subsection

1 (e)(1)(B)) for which defined appropriate use
2 criteria (and related guidelines) have been—

3 “(i) developed or endorsed by national
4 professional medical specialty societies; and

5 “(ii) selected by the Secretary for pur-
6 poses of this subsection in consultation
7 with national professional medical specialty
8 societies and other stakeholders.

9 “(C) CONSTRUCTION IN INSTANCES OF
10 MULTIPLE APPLICABLE APPROPRIATE USE CRI-
11 TERIA.—Nothing in this subsection shall be
12 construed as preventing the Secretary, in the
13 case that there are multiple appropriate use cri-
14 teria (and related guidelines) that are applica-
15 ble to a particular advanced diagnostic imaging
16 service (or a specific set of clinical indications),
17 from selecting more than one criterion (or more
18 than one guideline) under subparagraph
19 (B)(ii)(II).

20 “(D) PERIODIC REVISION.—The Secretary
21 may periodically revise the list of applicable ad-
22 vanced diagnostic imaging services under this
23 paragraph.

1 “(2) DEVELOPMENT AND MAINTENANCE OF IM-
2 AGING APPROPRIATENESS REGISTRIES BY MEDICAL
3 SPECIALTY SOCIETIES.—

4 “(A) IN GENERAL.—Not later than April
5 1, 2014, the Secretary shall qualify registries
6 that are developed and maintained by national
7 professional medical specialty societies.

8 “(B) REQUIREMENTS.—Registries quali-
9 fied under subparagraph (A) shall meet the fol-
10 lowing requirements:

11 “(i) The registry shall document—

12 “(I) the use of an approved elec-
13 tronic clinical decision support tool (as
14 described in paragraph (3)) in connec-
15 tion with the ordering and perform-
16 ance of an applicable advanced diag-
17 nostic imaging service;

18 “(II) whether orders for applica-
19 ble advanced diagnostic imaging serv-
20 ices were consistent with related ap-
21 propriate use criteria (including an
22 appropriateness score where available
23 from the approved electronic clinical
24 decision support tool);

1 “(III) the clinical indication for
2 the applicable advanced diagnostic im-
3 aging services ordered; and

4 “(IV) in situations where an
5 order for an applicable advanced diag-
6 nostic imaging service is not con-
7 sistent with the related appropriate
8 use criteria, the rationale of the order-
9 ing or furnishing supplier or provider
10 (as the case may be) for such incon-
11 sistency.

12 “(ii) The registry shall be structured
13 to allow access to data for future research,
14 provide a centralized analysis of the data
15 submitted, including the impact on utiliza-
16 tion changes for applicable advanced diag-
17 nostic services, and provide connections
18 with existing medical society registries.

19 “(iii) The registry shall generate re-
20 ports on at least a quarterly basis pro-
21 viding feedback to suppliers and providers
22 that order and furnish applicable advanced
23 diagnostic imaging services on the ordering
24 activity of the supplier or provider and re-
25 lated appropriate use criteria metrics.

1 “(C) MULTIPLE QUALIFIED REGISTRIES.—

2 In the case where more than one registry is de-
3 veloped under this paragraph, the Secretary
4 shall ensure that each registry receives stand-
5 ardized data such that the data may be com-
6 bined and compared across registries.

7 “(D) PERIODIC UPDATING.—The Secretary
8 shall periodically update the list of registries
9 qualified under this paragraph.

10 “(3) LISTING OF QUALIFIED SUPPLIERS OF AP-
11 PROVED ELECTRONIC CLINICAL DECISION SUPPORT
12 TOOLS.—

13 “(A) IN GENERAL.—Not later than July 1,
14 2014, the Secretary shall publish a list of quali-
15 fied suppliers of approved electronic clinical de-
16 cision support tools, in accordance with the pro-
17 visions of this paragraph.

18 “(B) STANDARDS.—

19 “(i) IN GENERAL.—The Secretary, in
20 consultation with the medical specialty so-
21 cieties described in paragraph (2)(A), shall
22 establish standards for the approval of
23 electronic clinical decision support tools
24 provided by qualified suppliers.

1 “(ii) STANDARDS.—The standards es-
2 tablished under clause (i) shall include the
3 ability of such tool to—

4 “**(I)** use only standards and
5 guidelines developed by national med-
6 ical specialty societies;

7 “**(II)** capture the clinical indica-
8 tion for the applicable advanced diag-
9 nostic imaging services ordered, se-
10 lected from the related appropriate
11 use criteria;

12 “**(III)** accurately deliver to the
13 ordering clinician appropriate use cri-
14 teria (and related guidelines) for ap-
15 plicable advanced diagnostic imaging
16 services, regardless of the physician
17 specialty (if any) from which the cri-
18 teria or guidelines originated or to
19 which the criteria or guidelines are di-
20 rected;

21 “**(IV)** in the case where there are
22 multiple standards or guidelines appli-
23 cable to a particular service or a spe-
24 cific set of clinical indications, indi-

1 cate the standards or guidelines that
2 are being applied;

3 “(V) determine the appropriate-
4 ness of orders for such services;

5 “(VI) submit standardized data
6 to one or more registries qualified
7 under paragraph (2) that is sufficient
8 for such registries to meet their docu-
9 mentation obligations under that
10 paragraph;

11 “(VII) be regularly and timely
12 updated;

13 “(VIII) generate a unique elec-
14 tronic identifier (referred to in this
15 subsection as a ‘Clinical Decision Sup-
16 port Number’) that documents the
17 fact that the clinical decision support
18 tool was consulted by the ordering
19 supplier or provider in connection
20 with the ordering of an applicable ad-
21 vanced diagnostic imaging service;
22 and

23 “(IX) perform other functions
24 determined to be necessary by the
25 Secretary in consultation with the

1 medical specialty societies described in
2 paragraph (2)(A).

3 “(C) DESIGN.—An approved electronic
4 clinical decision support tool under this para-
5 graph—

6 “(i) may use a web-based portal, or be
7 imbedded into an electronic health record
8 system or other health information tech-
9 nology tool; and

10 “(ii) shall meet the privacy and secu-
11 rity standards under the regulations pro-
12 mulgated pursuant to the Health Insur-
13 ance Portability and Accountability Act of
14 1996.

15 “(D) USAGE AND CONVENIENT ACCESS RE-
16 QUIREMENTS.—The Secretary shall only include
17 in the list published under this paragraph ap-
18 proved electronic clinical decision support tools
19 provided by suppliers who—

20 “(i) attest that they have obtained
21 permission to incorporate appropriate use
22 criteria (and related guidelines) developed
23 by national medical specialty societies; and

1 “(ii) demonstrate that they can pro-
2 vide convenient access to such a tool via a
3 secure web-based portal at no cost to—

4 “(I) suppliers and providers who
5 order and furnish applicable advanced
6 diagnostic imaging services under this
7 title; and

8 “(II) the Federal government.

9 “(E) PERIODIC UPDATING.—The Secretary
10 shall periodically update the list of qualified
11 suppliers of approved electronic clinical decision
12 support tools that meet the standards estab-
13 lished under subparagraph (B) and the other
14 requirements of this paragraph.

15 “(4) CONSULTATION REQUIREMENT.—The Sec-
16 retary shall require that, as a condition of participa-
17 tion in the program under this title, suppliers and
18 providers who order an applicable advanced diag-
19 nostic imaging service shall agree to consult an ap-
20 proved electronic clinical decision support tool listed
21 pursuant to paragraph (3) in connection with such
22 order.

23 “(5) PAYMENT FOR SERVICES CONTINGENT
24 UPON REGISTRY SUBMISSION.—

1 “(A) IN GENERAL.—With respect to an ap-
2 plicable advanced diagnostic imaging service,
3 payment for the technical or professional com-
4 ponent of such service under the fee schedule
5 established under section 1848(b) or under the
6 prospective payment system for hospital out-
7 patient department services under section
8 1833(t) may only be made if the documentation
9 accompanying any such claim for payment dem-
10 onstrates that an approved electronic clinical
11 decision support tool listed pursuant to para-
12 graph (3) was consulted and the required infor-
13 mation was submitted to a registry qualified
14 under paragraph (2).

15 “(B) DEMONSTRATION OF COMPLIANCE.—
16 Compliance with the requirements under sub-
17 paragraph (A) may be demonstrated by the in-
18 clusion of a Clinical Decision Support Number
19 with the claim for payment.

20 “(6) EXEMPTIONS.—

21 “(A) SIGNIFICANT HARDSHIP EXEMP-
22 TION.—The Secretary may, on a case-by-case
23 basis, exempt a supplier or provider to whom
24 this subsection would otherwise apply if the
25 Secretary determines, subject to annual re-

1 newal, that compliance with this subsection
2 would result in a significant hardship, such as
3 in the case of a supplier or provider who lacks
4 access to an electronic records system or high-
5 speed Internet access.

6 “(B) EMERGENCY SERVICES EXEMP-
7 TION.—Applicable advanced diagnostic imaging
8 services ordered emergently as part of an emer-
9 gency medical evaluation shall not be subject to
10 the requirements of this subsection.

11 “(C) CLARIFICATION OF INAPPLICABILITY
12 TO INPATIENT SERVICES.—Advanced diagnostic
13 imaging services ordered for inpatients and for
14 which payment is made under part A are not
15 subject to the requirements of this subsection.

16 “(7) LIMITATIONS.—The Secretary may not
17 utilize the authority provided under this subsection
18 to—

19 “(A) impose any requirement that a sup-
20 plier or provider obtain approval to order an
21 advanced diagnostic imaging service before per-
22 forming such service or any other requirement
23 for prior authorization with respect to such
24 service; or

1 “(B) use approved electronic clinical deci-
2 sion support tools to make claims payment de-
3 terminations under this title.

4 “(8) RULEMAKING REGARDING PATIENT SAFE-
5 TY.—The Secretary shall promulgate regulations to
6 address situations in which a supplier or provider,
7 prior to performing an applicable advanced diag-
8 nostic imaging service for an individual, reasonably
9 believes that the service ordered, if performed, would
10 pose a safety risk to the individual and that a dif-
11 ferent imaging service is more appropriate under the
12 circumstances. Such regulations shall define cir-
13 cumstances in which the supplier or provider may
14 change the order to an imaging service the supplier
15 or provider determines is more appropriate.”.

16 (b) COMPLIANCE WITH APPROPRIATENESS REG-
17 ISTRY TREATED AS SATISFACTORY QUALITY REPORT-
18 ING.—Section 1848(m)(3) of the Social Security Act (42
19 U.S.C. 1395w–4(m)(3)) is amended—

20 (1) by redesignating subparagraph (F) as sub-
21 paragraph (H); and

22 (2) by inserting after subparagraph (E) the fol-
23 lowing new subparagraphs:

1 “(F) SATISFACTORY REPORTING MEAS-
2 URES THROUGH PARTICIPATION IN IMAGING AP-
3 PROPRIATENESS REGISTRY.—

4 “(i) IN GENERAL.—For 2015 and
5 subsequent years, the Secretary shall treat
6 an eligible professional described in clause
7 (ii) as satisfactorily submitting data on
8 quality measures under subparagraph (A)
9 if, instead of reporting measures under
10 subsection (k)(2)(C), the eligible profes-
11 sional provides evidence, in a form and
12 manner specified by the Secretary, dem-
13 onstrating that the registry submission re-
14 quirements under section 1833(p)(5) have
15 been complied with with respect to not less
16 than 90 percent of claims for applicable
17 advanced diagnostic imaging services (as
18 defined in section 1833(p)(1)(B)) sub-
19 mitted by the eligible professional in the
20 year.

21 “(ii) ELIGIBLE PROFESSIONAL DE-
22 SCRIBED.—For purposes of clause (i), an
23 eligible professional described in this clause
24 is an eligible professional who furnishes
25 the technical or professional component of

1 applicable advanced diagnostic imaging
2 services (as so defined).

3 “(G) SATISFACTORY REPORTING MEAS-
4 URES THROUGH PARTICIPATION IN IMAGING AP-
5 PROPRIATENESS REGISTRY.—

6 “(i) IN GENERAL.—For 2015 and
7 subsequent years, the Secretary shall treat
8 an eligible professional described in clause
9 (ii) as satisfactorily submitting data on
10 quality measures under subparagraph (A)
11 if, in lieu of reporting measures under sub-
12 section (k)(2)(C), the eligible professional
13 provides evidence, in a form and manner
14 specified by the Secretary, demonstrating
15 that they have complied with the consulta-
16 tion requirements under section 1833(p)(4)
17 with respect to not less than 90 percent of
18 claims for applicable advanced diagnostic
19 imaging services (as so defined) submitted
20 by the eligible professional in the year.

21 “(ii) ELIGIBLE PROFESSIONAL DE-
22 SCRIBED.—For purposes of clause (i), an
23 eligible professional described in this clause
24 is an eligible professional who orders appli-

1 cable advanced diagnostic imaging services
2 (as so defined).”.

3 (c) CONFORMING AMENDMENT.—Section
4 1833(t)(16) of the Social Security Act (42 U.S.C.
5 1395l(t)(16)) is amended by adding at the end the fol-
6 lowing new subparagraph:

7 “(E) APPLICATION OF APPROPRIATENESS
8 REQUIREMENTS FOR CERTAIN ADVANCED DIAG-
9 NOSTIC IMAGING SERVICES.—For provisions re-
10 lating to the application of appropriateness re-
11 quirements for certain advanced diagnostic im-
12 aging services, see section 1834(p).”.