

114TH CONGRESS  
1ST SESSION

# H. R. 1516

To amend title XVIII of the Social Security Act to provide for coverage and payment for complex rehabilitation technology items under the Medicare program, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 19, 2015

Mr. SENSENBRENNER (for himself and Mr. CROWLEY) 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

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## A BILL

To amend title XVIII of the Social Security Act to provide for coverage and payment for complex rehabilitation technology items under the Medicare program, 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 “Ensuring Access to  
5 Quality Complex Rehabilitation Technology Act of 2015”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) Individuals with disabilities and significant  
4 medical conditions such as Cerebral Palsy, Muscular  
5 Dystrophy, Multiple Sclerosis, Spinal Cord Injury,  
6 Amyotrophic Lateral Sclerosis, and Spina Bifida ex-  
7 perience physical, functional, and cognitive chal-  
8 lenges every day.

9 (2) Complex rehabilitation technology items (in  
10 this Act referred to as “CRT items”), including  
11 products such as complex rehabilitation power wheel-  
12 chairs, highly configurable manual wheelchairs,  
13 adaptive seating and positioning systems, and other  
14 specialized equipment, such as standing frames and  
15 gait trainers, enable individuals to maximize their  
16 function and minimize the extent and costs of their  
17 medical care.

18 (3) Access to CRT items and related services  
19 can be threatened by inadequate coding, coverage,  
20 and payment policies for such items and services.  
21 These policies have restricted access to existing com-  
22 plex rehabilitation technology and stifled innovation.  
23 Access challenges have increased over the past sev-  
24 eral years and, without meaningful change to these  
25 policies, will only become greater in the future.

1           (4) Current Medicare policies often fail to ade-  
2           quately address the needs of individuals with disabil-  
3           ities, to consider the range of services furnished by  
4           complex rehabilitation technology suppliers, and to  
5           recognize and account for the complexity and unique  
6           nature of the equipment itself.

7           (5) A significant factor responsible for such ac-  
8           cess challenges is that individually-configurable CRT  
9           items do not have a distinct payment category under  
10          the Medicare program, but instead are classified  
11          within the broad category of durable medical equip-  
12          ment (DME). CRT items serve patients with serious  
13          medical conditions that require a broader range of  
14          services and specialized personnel than what is re-  
15          quired for standard DME. Individually configured  
16          CRT items also require more resources in the areas  
17          of configuring, training, and education to ensure ap-  
18          propriate use and to optimize results.

19          (6) Unlike most DME, a medical model incor-  
20          porating an interdisciplinary team approach is nec-  
21          essary to ensure proper individual configuration and  
22          use of a CRT item. This team typically includes a  
23          physician, a licensed physical or licensed occupa-  
24          tional therapist (with no financial relationship with  
25          the CRT supplier), a qualified CRT professional, the

1 individual using such item, and sometimes a care-  
2 giver for such individual.

3 (7) The Medicare program should recognize the  
4 specialized nature of the CRT service delivery model,  
5 the required supporting processes and technology-re-  
6 lated CRT services, the credentials and competencies  
7 needed by the providing suppliers and critical staff,  
8 and the related costs involved. A separate benefit  
9 category for CRT items would allow for unique cod-  
10 ing, coverage, and payment rules and policies that  
11 address the unique needs of persons with disabilities  
12 and acknowledge the extensive service component.

13 (8) Congress and the Centers for Medicare &  
14 Medicaid Services have previously recognized the  
15 benefits of a separate classification for unique, indi-  
16 vidualy configured products. In 2008, Congress ex-  
17 empted certain CRT items from inclusion in the  
18 Medicare DME competitive bidding program, and  
19 Congress has created a separate and distinct benefit  
20 category for orthotics and prosthetics (custom braces  
21 and artificial limbs), which have their own medical  
22 policies, accreditation standards, and payment cal-  
23 culations.

1 **SEC. 3. ESTABLISHING SEPARATE BENEFIT CATEGORY FOR**  
2 **COMPLEX REHABILITATION TECHNOLOGIES**  
3 **WITHIN MEDICARE.**

4 (a) NEW CATEGORY.—Section 1861 of the Social Se-  
5 curity Act (42 U.S.C. 1395x) is amended—

6 (1) in subsection (s)(2)—

7 (A) in subparagraph (EE), by striking  
8 “and” at the end;

9 (B) in subparagraph (FF), by inserting  
10 “and” at the end; and

11 (C) by inserting after subparagraph (FF)  
12 the following new paragraph:

13 “(GG) complex rehabilitation technology  
14 items (as defined in subsection (iii));”; and

15 (2) by adding at the end the following new sub-  
16 section:

17 “Complex Rehabilitation Technology Item

18 “(iii)(1) The terms ‘complex rehabilitation technology  
19 item’ and ‘CRT item’ mean an item that—

20 “(A) is designed or individually configured for  
21 a specific qualified individual to meet the individ-  
22 ual’s unique—

23 “(i) medical, physical, or functional needs  
24 related to a medical condition; and

25 “(ii) capacities for basic activities of daily  
26 living or instrumental activities of daily living;

1           “(B) is primarily used to serve a medical or  
2 functional purpose and is generally not useful to a  
3 person in the absence of illness or injury; and

4           “(C) requires certain services to ensure appro-  
5 priate design, configuration, and use of such item,  
6 including—

7           “(i) an evaluation of needs and capacities  
8 and matching of the features and functions of  
9 CRT items to the qualified individual who will  
10 use such an item; and

11           “(ii) configuring, fitting, programming, ad-  
12 justing, or adapting the particular complex re-  
13 habilitation technology item for use by such in-  
14 dividual.

15           “(2)(A) The Secretary, in consultation with the Di-  
16 rector of Office on Disability, the Chairman of the Na-  
17 tional Council on Disability, the Executive Director on the  
18 Interagency Committee on Disability, the Director of the  
19 National Institute on Disability and Rehabilitation Re-  
20 search of the Department of Education, and the Co-Chair-  
21 men of the Senior Oversight Committee’s Care Manage-  
22 ment Reform Team of the Department of Defense and the  
23 Veterans Administration, shall, by regulation—

24           “(i) designate items as complex rehabilitation  
25 technology items; and

1           “(ii) establish eligibility criteria to determine if  
2           an individual is a qualified individual based on the  
3           level of physical and functional needs and capacities  
4           related to a medical condition or conditions de-  
5           scribed in subparagraph (E).

6           “(B) The items designated as complex rehabilitation  
7           technology items under subparagraph (A)(i) shall include  
8           items which, as of January 1, 2015 , were classified within  
9           the following HCPCS codes: E0637, E0638, E0641,  
10          E0642, E0986, E1002, E1003, E1004, E1005, E1006,  
11          E1007, E1008, E1009, E1010, E1011, E1014, E1037,  
12          E1161, E1220, E1228, E1229, E1231, E1232, E1233,  
13          E1234, E1235, E1236, E1237, E1238, E1239 E2209,  
14          E2291, E2292, E2293, E2294, E2295, E2300, E2301,  
15          E2310, E2311, E2312, E2313, E2321, E2322, E2323,  
16          E2324, E2325, E2326, E2327, E2328, E2329, E2330,  
17          E2331, E2351, E2373, E2374, E2376, E2377, E2609,  
18          E2610, E2617, E8000, E8001, E8002, K0005, K0835,  
19          K0836, K0837, K0838, K0839, K0840, K0841, K0842,  
20          K0843, K0848, K0849, K0850, K0851, K0852, K0853,  
21          K0854, K0855, K0856, K0857, K0858, K0859, K0860,  
22          K0861, K0862, K0863, K0864, K0868, K0869, K0870,  
23          K0871, K0877, K0878, K0879, K0880, K0884, K0885,  
24          K0886, K0890, K0891, and K0898.

1 “(C)(i) The items designated as complex rehabilita-  
2 tion technology items under subparagraph (A)(i) shall in-  
3 clude each item that—

4 “(I) as of January 1, 2015, was classified with-  
5 in the HCPCS codes under clause (ii); and

6 “(II) the Secretary, acting in consultation with  
7 suppliers and manufacturers of CRT items, deter-  
8 mines which items should be removed from such  
9 code and assigned a new HCPCS code because such  
10 item is a complex rehabilitation technology item.

11 “(ii) The HCPCS codes under this clause are the fol-  
12 lowing: E0143, E0950, E0951, E0952, E0955, E0956,  
13 E0957, E0960, E0967, E0978, E0990, E1015, E1016,  
14 E1028, E01029, E1030, E2205, E2208, E2231, E2368,  
15 E2369, E2370, E2605, E2606, E2607, E2608, E2613,  
16 E2614, E2615, E2616, E2620, E2621, E2624, E2625,  
17 K0004, K0009, K0040, K0108, and K0669.

18 “(D) The Secretary may not designate as a complex  
19 rehabilitation technology item—

20 “(i) adaptive equipment to operate motor vehi-  
21 cles;

22 “(ii) prosthetic devices described in subsection  
23 (s)(8); or

24 “(iii) orthotics and prosthetics described in sub-  
25 section (s)(9).

1 “(E) The Secretary shall publish guidelines and im-  
2 plement a process to facilitate the submission of com-  
3 prehensive coding proposals addressing CRT items to be  
4 submitted to the CMS HCPCS Work Group and included  
5 in the HCPCS Work Group public meetings.

6 “(F) In establishing the eligibility criteria under sub-  
7 paragraph (A)(ii), the Secretary shall include appropriate  
8 physical and functional needs and capacities arising from  
9 any of the following medical conditions:

10 “(i) Congenital disorders, progressive or degen-  
11 erative neuromuscular diseases, or injuries or trau-  
12 ma that result in significant physical or functional  
13 needs and capacities.

14 “(ii) Spinal cord injury, traumatic brain injury,  
15 cerebral palsy, muscular dystrophy, spina bifida,  
16 osteogenesis imperfecta, arthrogyrosis, amyotrophic  
17 lateral sclerosis, multiple sclerosis, demyelinating  
18 disease, myelopathy, myopathy, progressive muscular  
19 atrophy, anterior horn cell disease, post-polio syn-  
20 drome, cerebellar degeneration, dystonia, Hunting-  
21 ton’s disease, or spinocerebellar disease.

22 “(iii) Certain types of amputation, paralysis, or  
23 paresis that result in significant physical or func-  
24 tional needs and capacities.

25 “(G)(i) For 2016, the Secretary shall publish—

1           “(I) a list of items designated under subpara-  
2           graph (A)(i) and the HCPCS codes for such items;  
3           and

4           “(II) the eligibility criteria established under  
5           subparagraph (A)(ii).

6           “(ii) For 2017 and each subsequent year, the Sec-  
7           retary shall publish any necessary updates to such list (in-  
8           cluding additions of new CRT items and any changes in  
9           applicable HCPCS codes) and to such eligibility criteria.

10          “(H) The Secretary shall make available, on a public  
11          Web site, the process by which the Secretary will consider  
12          requests from members of the public that the Secretary—

13                 “(i) designate an item as a CRT item under  
14                 subparagraph (A)(i); or

15                 “(ii) amend the eligibility criteria established  
16                 under subparagraph (A)(ii).

17          “(3) For purposes of this subsection:

18                 “(A) The term ‘capacity for basic activities of  
19                 daily living’ means an individual’s capacity to safely  
20                 participate in mobility and self-care activities includ-  
21                 ing—

22                         “(i) maintaining and changing body posi-  
23                         tion;

24                         “(ii) transferring to or from one surface to  
25                         another;

- 1                   “(iii) walking;
- 2                   “(iv) moving from place to place using mo-
- 3                   bility equipment, in a safe and timely manner;
- 4                   “(v) washing one’s self;
- 5                   “(vi) caring for the body;
- 6                   “(vii) toileting;
- 7                   “(viii) dressing;
- 8                   “(ix) eating;
- 9                   “(x) drinking;
- 10                  “(xi) looking after one’s health; and
- 11                  “(xii) carrying, moving, and handling ob-
- 12                  jects to perform and participate in other activi-
- 13                  ties under this subparagraph and subparagraph
- 14                  (B).
- 15                  “(B) The term ‘capacity for instrumental activi-
- 16                  ties of daily living’ means an individual’s capacity to
- 17                  safely participate in life situations in the home and
- 18                  community, including—
- 19                   “(i) communicating;
- 20                   “(ii) moving around using transportation;
- 21                   “(iii) acquiring necessities, goods, and
- 22                   services;
- 23                   “(iv) performing household tasks;
- 24                   “(v) caring for household members and
- 25                   family members;

1           “(vi) caring for household objects;

2           “(vii) engaging in education, work, employ-  
3           ment and economic life; and

4           “(viii) participating in community, social,  
5           and civic activities.

6           “(C) The term ‘HCPCS’ refers to the Health  
7           Care Procedure Coding System.

8           “(D) The term ‘individually-configured’ means,  
9           with respect to an item, that—

10           “(i) the item has features, adjustments, or  
11           modifications specific to the individual who uses  
12           such item or the item is used in combination  
13           with other CRT items specific to the individ-  
14           ual’s needs; and

15           “(ii) the supplier of such item must meas-  
16           ure the individual and configure, fit, program,  
17           adjust, or adapt the item, as appropriate, so  
18           that the item is consistent with—

19           “(I) an assessment or evaluation of  
20           the individual by an appropriate licensed  
21           clinician;

22           “(II) the written order required under  
23           section 1834(r)(2)(B)(i); and

24           “(III) medical condition, physical and  
25           functional needs and capacities, and body

1 size of the individual who will use the item,  
2 the period for which such individual will  
3 need such item, and the intended use of  
4 such item by such individual.

5 “(E) The term ‘qualified individual’ means an  
6 individual who—

7 “(i) is enrolled under part B; and

8 “(ii) has physical and functional needs and  
9 capacities that arise from a medical condition  
10 that meet the eligibility criteria established by  
11 the Secretary under paragraph (2)(A)(ii).”.

12 **SEC. 4. PAYMENT RULES.**

13 Section 1834 of the Social Security Act (42 U.S.C.  
14 1395m) is amended by adding at the end the following:

15 “(r) COVERAGE AND PAYMENT FOR CRT ITEMS.—

16 “(1) GENERAL RULE FOR PAYMENT.—

17 “(A) IN GENERAL.—Not later than the  
18 date that is one year after the date of the en-  
19 actment of this subsection, subject to subpara-  
20 graph (B), the Secretary shall determine a pay-  
21 ment system that shall apply to CRT items—

22 “(i) with HCPCS codes that were as-  
23 signed to the item under section  
24 1861(iii)(2)(C)(i)(II);

1 “(ii) for which no HCPCS code was  
2 assigned prior to such date; or

3 “(iii) which, prior to such date, was  
4 classified under a miscellaneous HCPCS  
5 code.

6 “(B) CONSIDERATIONS.—In determining  
7 the payment system under subparagraph (A),  
8 the Secretary—

9 “(i) may disregard the freezes on CPI  
10 increases to the payment amounts for du-  
11 rable medical equipment that occurred be-  
12 fore the date of the enactment of this sub-  
13 section, when determining the payment  
14 amount for CRT items;

15 “(ii) shall ensure that the payment  
16 amounts for CRT items under such system  
17 are adequate to provide qualified individ-  
18 uals with access to such items and to en-  
19 courage innovation, taking into account—

20 “(I) the unique needs of qualified  
21 individuals for access to CRT items;

22 “(II) the unique complexity of  
23 CRT items; and

24 “(III) the resources and staff  
25 needed to provide appropriate indi-

1                   vidual configuration of CRT items for  
2                   a qualified individual; and

3                   “(iii) shall provide that CRT codes  
4                   will be paid on a purchase basis with a  
5                   beneficiary rental basis option.

6                   “(C) EXCLUSIVE PAYMENT RULE.—This  
7                   subsection shall constitute the exclusive provi-  
8                   sion of this title for payment for CRT items  
9                   under this part or under part A to a home  
10                  health agency.

11                  “(D) LIMITATION ON PAYMENT.—No pay-  
12                  ment shall be made under this subsection for a  
13                  CRT item unless such CRT item—

14                         “(i) is provided to a qualified indi-  
15                         vidual;

16                         “(ii) meets the clinical conditions for  
17                         coverage established under paragraph (2);  
18                         and

19                         “(iii) is furnished by a supplier ac-  
20                         credited pursuant to paragraph (3).

21                  “(2) CLINICAL CONDITIONS FOR COVERAGE.—

22                         “(A) IN GENERAL.—The Secretary shall  
23                         establish standards for clinical conditions for  
24                         payment for CRT items under this subsection.

1           “(B) REQUIREMENTS.—The standards es-  
2           tablished under subparagraph (A) shall require  
3           the following:

4                   “(i) WRITTEN ORDER.—

5                           “(I) IN GENERAL.—A qualified  
6                           ordering practitioner shall provide a  
7                           written order for a CRT item for a  
8                           qualified individual before the Sec-  
9                           retary may provide payment for such  
10                          item for such individual under this  
11                          subsection.

12                          “(II) CRT EVALUATION.—In the  
13                          case of a CRT item that is cat-  
14                          egorized by the Secretary, for pur-  
15                          poses of the program under this title,  
16                          as a manual wheelchair or a power  
17                          wheelchair, and is to be provided to a  
18                          qualified individual who has a diag-  
19                          nosis specified under subparagraph  
20                          (C), the qualified ordering practitioner  
21                          may not provide a written order under  
22                          subclause (I) unless the qualified indi-  
23                          vidual has undergone a CRT evalua-  
24                          tion conducted by a licensed physical  
25                          therapist or occupational therapist

1 who has no financial relationship with  
2 the CRT supplier. The performance of  
3 such a CRT evaluation by a licensed  
4 physical or occupational therapist  
5 shall not be subject (or counted to-  
6 wards) the limitation on certain ther-  
7 apy services under section 1833(g).

8 “(ii) DOCUMENTATION OF MEDICAL  
9 NECESSITY.—A qualified ordering practi-  
10 tioner who provides a written order under  
11 clause (i) shall maintain documentation of  
12 the medical necessity of such order for a  
13 period of seven years and shall make such  
14 documentation available to the Secretary  
15 upon request. The documentation of med-  
16 ical necessity under this clause shall in-  
17 clude—

18 “(I) evidence that the individual  
19 for whom the order was written has  
20 physical and functional needs and ca-  
21 pacities related to a medical condition  
22 that meet the eligibility criteria estab-  
23 lished under section  
24 1861(iii)(2)(A)(ii); and

1                   “(II) evidence of any CRT eval-  
2                   uation required under clause (i)(II).

3                   “(C) SPECIFICATION OF DIAGNOSIS FOR  
4                   CRT EVALUATION.—The Secretary, in consulta-  
5                   tion with relevant parties (including the agen-  
6                   cies listed in section 1861(iii)(2)(A), physicians,  
7                   licensed physical therapists, licensed occupa-  
8                   tional therapists, and suppliers of complex reha-  
9                   bilitation technologies) shall specify the diag-  
10                  noses and other medical presentations for which  
11                  the requirement for a CRT evaluation under  
12                  subparagraph (B)(i)(II) shall apply.

13                  “(D) COVERAGE DETERMINATIONS.—In  
14                  developing the standards under subparagraph  
15                  (A), the coverage of CRT items with respect to  
16                  an individual shall be based on—

17                         “(i) the specific medical, physical, and  
18                         functional needs of the individual;

19                         “(ii) the individual’s capacities for  
20                         safe participation in basic activities of  
21                         daily living and instrumental activities of  
22                         daily living in all routinely encountered en-  
23                         vironments (as such terms are defined in  
24                         section 1861(iii)(3)); and

1           “(iii) the individual’s expected pro-  
2           gression of such needs and capacities.

3           “(E) CONTRACTOR INDIVIDUALIZED CON-  
4           SIDERATION.—The Secretary shall instruct  
5           Medicare contractors to provide individual con-  
6           sideration in cases that may lack one of the di-  
7           agnoses identified, but that exhibit comparable  
8           functional presentations or deficits or (or both)  
9           and where the need for CRT items has been  
10          documented by the qualified clinical profes-  
11          sional.

12          “(F) PAYMENT FOR RESIDENTS OF  
13          SKILLED NURSING FACILITIES.—In the case of  
14          a qualified individual who is a resident of a  
15          skilled nursing facility, payment may only be  
16          made under this subsection for a CRT item for  
17          such individual if such CRT item is required as  
18          part of a plan of care to allow the transition of  
19          such individual from the skilled nursing facility  
20          to a home or community setting.

21          “(3) ESTABLISHMENT OF QUALITY STAND-  
22          ARDS.—

23          “(A) ESTABLISHMENT.—The Secretary  
24          shall establish, through regulation, quality  
25          standards for suppliers of CRT items. Such

1 standards shall be applied prospectively and  
2 shall be published on the Internet Web site of  
3 the Centers for Medicare and Medicaid Serv-  
4 ices.

5 “(B) CONSULTATION.—In establishing the  
6 quality standards under subparagraph (A), the  
7 Secretary shall consult with relevant parties (in-  
8 cluding clinicians, consumer groups, suppliers,  
9 and manufacturers).

10 “(C) REQUIREMENTS OF STANDARDS.—In  
11 establishing the quality standards under sub-  
12 paragraph (A), the Secretary shall require that  
13 the suppliers of CRT items meet the following  
14 requirements:

15 “(i) DME STANDARDS.—The supplier  
16 complies with all of the standards that are  
17 applicable to suppliers of durable medical  
18 equipment under subsection (a)(20) and  
19 suppliers of medical equipment and sup-  
20 plies under subsection (j).

21 “(ii) QUALIFIED CRT PROFES-  
22 SIONAL.—The supplier of a CRT item  
23 makes available, in each service area  
24 served by such supplier, at least one quali-  
25 fied CRT professional to—

1           “(I) analyze the needs and capacities of individuals for a CRT item in  
2           collaboration with the clinical team;

3           “(II) assist in selecting an appropriate CRT item for such individual,  
4           given such needs and capacities; and

5           “(III) provide technology-related  
6           training to such individual in the  
7           proper use and maintenance of the  
8           CRT items.

9           “(iii) TRIAL EQUIPMENT.—The supplier of the CRT item provides the qualified individual with appropriate equipment for trial and simulation, if a physician, licensed physical therapist, or licensed occupational therapist determines that the provision of such equipment is necessary.

10           “(iv) INFORMATION ON SERVICE AND REPAIR.—The supplier of the CRT item provides the qualified individual with written information on accessing service and repair for the CRT item before the CRT item is ordered for the individual.

11           “(v) REPAIR.—The supplier of a CRT  
12           item—

1           “(I) makes available, in each  
2           service area served by such supplier,  
3           at least one qualified CRT service  
4           technician to service and repair CRT  
5           items that—

6                   “(aa) are furnished by such  
7                   supplier; and

8                   “(bb) at the time of the  
9                   need for repair, are located in a  
10                  service area of the supplier; or

11           “(II) if the qualified individual  
12           lives outside the service area served by  
13           such supplier at the time of order of  
14           the CRT item, the supplier shall dis-  
15           close in writing to the qualified indi-  
16           vidual that the supplier does not pro-  
17           vide repair service for such item and  
18           provide contact information for enti-  
19           ties that do provide such repair serv-  
20           ice.

21           “(vi) RENTAL EQUIPMENT.—If pay-  
22           ment is allowed under paragraph (6), the  
23           supplier of the CRT item provides tem-  
24           porary rental equipment to the qualified  
25           individual when the supplier is repairing a

1 qualified individual's CRT item that was  
2 paid for under this subsection.

3 “(4) APPLICATION OF STANDARDS AND AC-  
4 CREDITATION PROGRAM FOR SUPPLIERS OF CRT  
5 ITEMS.—

6 “(A) IN GENERAL.—

7 “(i) REQUIREMENT FOR PROVIDER OR  
8 SUPPLIER NUMBER.—The Secretary shall  
9 not provide a supplier of CRT items with  
10 a provider or supplier number to submit  
11 claims for payment under this title unless  
12 the supplier is in compliance with the  
13 standards under paragraph (3).

14 “(ii) REQUIREMENT FOR PAYMENT.—  
15 Payment shall not be made under this part  
16 for CRT items furnished by a supplier un-  
17 less the supplier is in compliance with the  
18 standards under paragraph (3).

19 “(B) APPLICATION OF ACCREDITATION RE-  
20 QUIREMENT.—In implementing quality stand-  
21 ards under paragraph (3), the Secretary shall  
22 require suppliers furnishing CRT items, on or  
23 after one year after the standards are published  
24 under such paragraph, directly or as a subcon-  
25 tractor for another entity—

1           “(i) to comply with such standards;  
2           and

3           “(ii) to have submitted to the Sec-  
4           retary evidence of accreditation by an ac-  
5           creditation organization designated under  
6           subparagraph (C) demonstrating that the  
7           supplier is complying with such standards.

8           “(C) DESIGNATION OF INDEPENDENT AC-  
9           CREDITATION ORGANIZATIONS.—Not later than  
10          the date that is one year after the date on  
11          which the Secretary implements the quality  
12          standards under paragraph (3), the Secretary  
13          shall designate and approve one or more inde-  
14          pendent accreditation organizations that—

15                 “(i) are approved under subsection  
16                 (a)(20)(B); and

17                 “(ii) the Secretary has determined  
18                 have the capability to assess whether sup-  
19                 pliers of CRT items meet the quality  
20                 standards established under paragraph (3).

21           “(5) CODING SYSTEM FOR COMPLEX REHABILI-  
22          TATION TECHNOLOGIES.—

23                 “(A) IN GENERAL.—The Secretary shall,  
24                 in consultation with suppliers and manufactur-  
25                 ers of CRT items, establish a formal process to

1 allow submission of CRT code set modification  
2 requests by stakeholder groups for comprehen-  
3 sive coding changes related to entire policy  
4 groups. This process shall include a specific ap-  
5 plication, public meeting participation and an  
6 appeals process. The Secretary shall then, in  
7 consultation with suppliers and manufacturers  
8 of CRT items, establish a HCPCS coding sub-  
9 set that shall utilize and include HCPCS codes  
10 described in section 1861(iii)(2) for CRT items  
11 for which payment may be made under this  
12 subsection.

13 “(B) TREATMENT OF EXISTING PROD-  
14 UCTS.—

15 “(i) IN GENERAL.—With respect to  
16 CRT items for which payment was avail-  
17 able under this title before the effective  
18 date of the amendments made by Ensuring  
19 Access to Quality Complex Rehabilitation  
20 Technology Act of 2015, the Secretary  
21 shall assign such items to a code in the  
22 coding subset established under subpara-  
23 graph (A).

24 “(ii) UPDATES.—After the initial as-  
25 signment under clause (i), the Secretary

1 may decide to reassign additional product  
2 categories, or items within those cat-  
3 egories, that exist before the date of the  
4 enactment of this subsection to the CRT  
5 coding subset.

6 “(iii) CONSULTATION.—Before mak-  
7 ing reassignments of CRT items under  
8 clause (ii), the Secretary shall consult with  
9 suppliers and manufacturers of such items.  
10 The Secretary shall not require manufac-  
11 turers of CRT items for which payment  
12 was available under this title before the ef-  
13 fective date of the amendments made by  
14 the Ensuring Access to Quality Complex  
15 Rehabilitation Technology Act of 2015 to  
16 submit requests for reassignment of the  
17 code for such product to the coding subset  
18 under subparagraph (A) as long as—

19 “(I) no changes have been made  
20 to the code definitions, required code  
21 characteristics or test requirements;  
22 and

23 “(II) the item was previously  
24 verified to meet the code require-  
25 ments.

1           “(C) REMOVING COMPLEX REHABILITA-  
2           TION TECHNOLOGY FROM DME CODES.—The  
3           Secretary shall, in consultation with suppliers  
4           and manufacturers of CRT items—

5                   “(i) remove from the coding subset for  
6                   durable medical equipment any CRT items  
7                   that are included in the coding subset  
8                   under subparagraph (A); and

9                   “(ii) assign new codes to such CRT  
10                  items based on technological differences to  
11                  support adequate access to meet clinical  
12                  outcomes and for purposes of including  
13                  such items in the subset under subpara-  
14                  graph (A).

15          “(D) NEW TECHNOLOGY.—

16                  “(i) IN GENERAL.—The Secretary  
17                  shall update as needed the HCPCS level II  
18                  process used to modify the code set to in-  
19                  clude CRT items for the purposes of estab-  
20                  lishing new codes and determining prod-  
21                  ucts to be classified as CRT items. In de-  
22                  termining if a product is a CRT item, the  
23                  Secretary shall consider—

24                          “(I) if the product is novel;

1                   “(II) the clinical application of  
2                   the product; and

3                   “(III) the ability of the product  
4                   to address the unique needs and ca-  
5                   pacities of a qualified individual.

6                   “(ii) INCLUSION OF CODES IN LIST.—  
7                   The Secretary shall include the codes es-  
8                   tablished in clause (i) in the list under sec-  
9                   tion 1861(iii)(2)(F).

10                  “(E) MISCELLANEOUS CODE FOR INNOVA-  
11                  TION AND LOCAL COVERAGE DETERMINA-  
12                  TIONS.—The coding subset established under  
13                  subparagraph (A) shall include at least one mis-  
14                  cellaneous code for items not otherwise classi-  
15                  fied.

16                  “(F) ESTABLISHMENT OF ADEQUATE  
17                  HCPCS CODES TO REFLECT SPECIALIZED NA-  
18                  TURE OF CRT.—The Secretary shall ensure that  
19                  HCPCS codes exist (or are developed) to rep-  
20                  resent the specialized nature of CRT, including  
21                  codes to represent custom CRT manual and  
22                  power wheelchairs and modifications to CRT  
23                  manual and power wheelchair frames, and mis-  
24                  cellaneous codes for CRT manual and power  
25                  wheelchairs that are otherwise classified.

1 “(6) REPLACEMENT OF CRT ITEMS.—

2 “(A) IN GENERAL.—Payment shall be  
3 made for the replacement of a CRT item (or for  
4 the replacement of any part of such item) with-  
5 out regard to continuous use or useful lifetime  
6 restrictions established under section  
7 1834(a)(7)(C) for items of durable medical  
8 equipment if a qualified ordering practitioner  
9 determines that the provision of a replacement  
10 item (or a replacement part of such an item) is  
11 necessary because—

12 “(i) there was a change in the physio-  
13 logical condition of the qualified individual  
14 to whom such item was provided;

15 “(ii) there was an irreparable change  
16 in the condition of the CRT item (or, in  
17 the case of the replacement of a part, in  
18 the part of the CRT item); or

19 “(iii) the CRT item requires repairs  
20 and the cost of such repairs would be more  
21 than 50 percent of the cost of a replace-  
22 ment of the CRT item.

23 “(B) DEFERRAL TO PROVIDERS.—

24 “(i) IN GENERAL.—Subject to clause  
25 (ii), if a qualified ordering practitioner de-

1           termines that a replacement of the CRT  
2           item, or the replacement of a part of a  
3           CRT item, is necessary pursuant to sub-  
4           paragraph (A), the replacement item or  
5           part is deemed to be reasonable and nec-  
6           essary for purposes of section  
7           1862(a)(1)(A).

8           “(ii) EXCEPTION FOR ITEMS UNDER 3  
9           YEARS OLD.—If the CRT item that is  
10          being replaced (or the part of the CRT  
11          item that is being replaced) under subpara-  
12          graph (A) is less than 3 years old (cal-  
13          culated from the date on which the quali-  
14          fied individual began to use the CRT item  
15          or part), the Secretary may require the  
16          qualified ordering practitioner to provide  
17          confirmation of necessity of the replace-  
18          ment item or replacement part, as the case  
19          may be.

20          “(7) PAYMENT FOR TEMPORARY RENTAL.—

21                 “(A) IN GENERAL.—If a CRT item owned  
22                 by a qualified individual needs to be repaired,  
23                 payment may be made under this subsection for  
24                 the temporary rental of a CRT item while the

1 CRT item owned by such individual is being re-  
2 paired.

3 “(B) BASIS; LIMITATION.—Payment per-  
4 mitted under subparagraph (A) shall be made  
5 on a monthly basis, and the period of rental  
6 may not exceed two months.

7 “(C) PAYMENT AMOUNT.—The amount of  
8 payment allowed under subparagraph (A) for a  
9 month for the rental of a CRT item shall be 10  
10 percent of the purchase price for the CRT item.

11 “(8) DEFINITIONS.—For purposes of this sub-  
12 section:

13 “(A) HCPCS.—The term ‘HCPCS’ refers  
14 to the Health Care Procedure Coding System.

15 “(B) QUALIFIED CRT PROFESSIONAL.—

16 “(i) IN GENERAL.—The term ‘quali-  
17 fied CRT professional’ means an individual  
18 who—

19 “(I) is certified by the Rehabili-  
20 tation Engineering and Assistive  
21 Technology Society of North America  
22 as an assistive technology professional  
23 or is certified by another organization  
24 designated by the Secretary (acting in  
25 consultation with relevant parties) as

1 providing a certification that is equiv-  
2 alent to, or more stringent than, the  
3 assistive technology professional cer-  
4 tification; and

5 “(II) beginning two years after  
6 the establishment of the designation  
7 under clause (ii), achieves an addi-  
8 tional designation that demonstrates  
9 the individual’s competencies and ex-  
10 perience in supplying CRT items.

11 “(ii) ESTABLISHMENT.—Not later  
12 than one year after the date of the enact-  
13 ment of this subsection, the Secretary, act-  
14 ing in consultation with relevant parties,  
15 shall establish the additional designation  
16 under clause (i)(II).

17 “(iii) RELEVANT PARTIES.—For pur-  
18 poses of this subparagraph, the term ‘rel-  
19 evant parties’ includes clinicians, consumer  
20 groups, CRT suppliers, and CRT manufac-  
21 turers.

22 “(C) QUALIFIED CRT SERVICE TECHN-  
23 CIAN.—The term ‘qualified CRT service techni-  
24 cian’ means an individual who—

1           “(i) is factory-trained by the manufac-  
2           turers of the CRT items being offered by  
3           the supplier of such items;

4           “(ii) is trained and educated (includ-  
5           ing through on-the-job training) to assem-  
6           ble, fit, program, service, and repair CRT  
7           items; and

8           “(iii) on an annual basis, completes at  
9           least 10 hours of continuing education spe-  
10          cific to the assembly, fitting, programming,  
11          service, and repair of CRT items.

12          “(D) QUALIFIED INDIVIDUAL.—The term  
13          ‘qualified individual’ has the meaning given  
14          such term in section 1861(iii)(3)(E).

15          “(E) QUALIFIED ORDERING PRACTI-  
16          TIONER.—The term ‘qualified ordering practi-  
17          tioner’ means a physician (as defined in section  
18          1861(r)), a physician assistant, nurse practi-  
19          tioner, or a clinical nurse specialist (as those  
20          terms are defined in section 1861(aa)(5)).

21          “(F) QUALIFIED LICENSED CLINICIAN.—  
22          The term ‘qualified licensed clinician’ means a  
23          licensed physical therapist or occupational ther-  
24          apist or physician who possesses specialized  
25          training and experience in providing seating

1           and mobility services and the skills to perform  
2           all aspects of the evaluation described in para-  
3           graph (2)(B)(i)(II).”.

4 **SEC. 5. CONFORMING AMENDMENTS.**

5           (a) **EXCLUSION FROM THE IN-HOME USE LIMITA-**  
6 **TION FOR DME.**—Section 1861(n) of the Social Security  
7 Act (42 U.S.C. 1395x(n)) is amended by adding at the  
8 end the following: “For 2016 and subsequent years, such  
9 term does not include complex rehabilitation technologies  
10 (as defined in subsection (iii)).”.

11           (b) **EXEMPTION FROM COMPETITIVE ACQUI-**  
12 **SITION.**—Section 1847(a)(7) of the Social Security Act (42  
13 U.S.C. 1395w–3(a)(7)) is amended by adding at the end  
14 the following new subparagraph:

15                   “(C) **CRT ITEMS.**—For 2016 and subse-  
16                   quent years, complex rehabilitation technology  
17                   items (as defined in section 1861(iii)).”.

18           (c) **EXEMPTION FROM SNF CONSOLIDATED BILL-**  
19 **ING.**—Section 1888(e)(2)(A)(iii) of the Social Security Act  
20 (42 U.S.C. 1395yy(e)(2)(A)(iii)) is amended by adding at  
21 the end the following:

22                           “(VI) Complex rehabilitation  
23                           technology items (as defined in section  
24                           1861(iii)) if delivered to an inpatient  
25                           for use during the stay in the skilled

1 nursing facility as part of the plan of  
2 care to allow the transition of such  
3 qualified individuals from the skilled  
4 nursing facility setting to the home  
5 and community.”.

6 (d) PAYMENT EXCLUSIONS.—Section 1834(a) of the  
7 Social Security Act (42 U.S.C. 1395m(a)) is amended—

8 (1) in paragraph (4), by adding at the end the  
9 following sentence “For 2016 and subsequent years,  
10 the items covered by this paragraph shall not include  
11 complex rehabilitation technology items (as defined  
12 in section 1861(iii)).”;

13 (2) in paragraph (7)(A), by adding at the end  
14 the following: “For fiscal year 2016 and subsequent  
15 years, the previous sentence shall not apply to  
16 power-driven wheelchairs that are designated as  
17 CRT items under section 1861(iii).”; and

18 (3) in paragraph (16), by inserting at the end  
19 the following: “The Secretary shall impose (and,  
20 may, as allowed by the second sentence of this para-  
21 graph, waive) the requirements of the first sentence  
22 of this paragraph to suppliers of complex rehabilita-  
23 tion technology items, except that, in order to avoid  
24 duplicate bonds, the Secretary shall not impose such  
25 requirements with respect to suppliers of complex re-

1       habilitation technology items if such suppliers also  
2       participate in the Medicare program as suppliers of  
3       durable medical equipment.”.

4       (e) REQUIREMENTS FOR SUPPLIERS OF MEDICAL  
5 EQUIPMENT AND SUPPLIES.—Section 1834(j)(5) of the  
6 Social Security Act (42 U.S.C. 1395m(j)(5)) is amend-  
7 ed—

8           (1) by redesignating subparagraphs (E) and  
9       (F) as subparagraphs (F) and (G), respectively;

10          (2) by inserting after subparagraph (D) the fol-  
11       lowing new subparagraph:

12                   “(E) complex rehabilitation technology  
13       items (as defined in section 1861(iii));”.

14 **SEC. 6. EFFECTIVE DATE.**

15       The amendments made by this Act shall apply to  
16 items and services furnished on or after January 1, 2016.

○