I

114TH CONGRESS
1ST SESSION

H. R. 3309

To amend titles XVIII and XIX of the Social Security Act to improve the electronic health records meaningful use programs under the Medicare and Medicaid programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2015

Mrs. ELLMERS of North Carolina 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 titles XVIII and XIX of the Social Security Act to improve the electronic health records meaningful use programs under the Medicare and Medicaid programs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Further Flexibility in HIT Reporting and Advancing Interoperability Act'' or the ''Flex-IT 2 Act''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—ALIGNMENT OF MEANINGFUL USE RULEMAKING TO MERIT-BASED INCENTIVE PAYMENT SYSTEM RULEMAKING

SEC. 101. PAUSING MEANINGFUL USE RULEMAKING.

(a) SENSE OF THE CONGRESS.—It is the sense of Congress that the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') should not finalize the proposed rules relating to Stage 3 criteria for the meaningful use of certified EHR technology (as defined in section 3000 of the Public Health Service Act (42 U.S.C. 300jj)) and the issuance of 2015 EHR certifi-

cation criteria and should instead encourage interoperability, usability, and improved outcomes with respect to electronic health records.

(b) NO ISSUANCE OF STAGE 3 CRITERIA OR OF EHR CERTIFICATION CRITERIA BEFORE 2017 UNLESS CONDITIONS MET.—Unless one of the conditions described in subsection (c) has been met, the Secretary shall not issue, prior to January 1, 2017—

(1) any proposed or final rule that would modify the definition of the term ''Meaningful EHR user'' under section 495.4 of title 42, Code of Federal Regulations (or any successor regulation), by adding Stage 3 criteria for eligible professionals or eligible hospitals; or

(2) any proposed or final rule that would add new certification criteria for certified EHR technology under part 170 of title 45, Code of Federal Regulations.

(c) CONDITIONS.—The conditions described in this subsection are the following:

(1) The Secretary certifies that 75 percent of both eligible hospitals and eligible professionals have successfully attested to the Stage 2 criteria established under section 495.6 of title 42, Code of Federal Regulations.

(2) The Secretary promulgates a final rule to implement the Merit-Based Incentive Payment System established under section 1848(q) of the Social Security Act (42 U.S.C. 1395w–4(q)).

(d) FLEXIBILITY TO ADJUST EXISTING MEANINGFUL USE AND CERTIFICATION CRITERIA.—Nothing in this section shall be construed as affecting the authority of the Secretary to change, modify, suspend, or revoke meaningful use and certification criteria effective on the date of the enactment of this Act, including the Stage 2 criteria established under section 495.6 of title 42, Code of Federal Regulations, and the 2014 Edition certified health record criteria under subpart C, part 170 of title 45, Code of Federal Regulations, for any of the following reasons:

(1) The change, modification, suspension, or revocation relates to the recommendations for achieving widespread interoperability made by the Secretary pursuant to section 106 of the Medicare Access and CHIP Reauthorization Act of 2015.

(2) The criteria may negatively impact the quality of care for, or may risk harm to, a patient.

(3) The change, modification, suspension, or revocation is necessary to reflect advances in science or technology, or to improve transparency.

TITLE II—IMPROVING MEANINGFUL USE

SEC. 201. REMOVING THE PASS-FAIL APPROACH OF THE MEDICARE AND MEDICAID MEANINGFUL USE PROGRAM.

(a) ELIGIBLE PROFESSIONALS.—

(1) IN GENERAL.—Section 1848(o)(2) of the Social Security Act (42 U.S.C. 1395w–4(o)(2)) is amended by adding at the end the following new subparagraph:

''(E) CONSIDERATION OF TECHNOLOGICAL AND COST BARRIERS.—In applying clauses (i), (ii), and (iii) of subparagraph (A) to determine whether a professional is using certified EHR technology in a meaningful manner for a period described in such subparagraph for a year after 2015, the Secretary—

''(i) may not require that the professional, in order to be considered a meaningful EHR user for such period, meet every requirement or objective specified pursuant to such clauses but instead shall apply a linear scale;

''(ii) shall establish a method to determine if an eligible professional is a partial

meaningful user consistent with such linear scale; and

''(iii) shall consider differences among professionals (such as differences in the specialties and patient populations of professionals) as well as technological and cost barriers in determining which of the requirements or objectives must be met by the professional during such period in order for the professional to be so considered.''.

(2) INCENTIVE PAYMENT.—Section 1848(o)(1)(A)(i) of the Social Security Act (42 U.S.C. 1395w–4(o)(1)(A)(i)) is amended—

(A) by inserting ''or, for 2016, partial meaningful EHR user'' after ''meaningful EHR user''; and

(B) by inserting ''(or, for 2016, in accordance with the linear scale applied pursuant to paragraph (2)(E), equal to not more than)'' after ''equal to''.

(3) PAYMENT ADJUSTMENT.—Section 1848(a)(7)(A)(i) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)(A)(i)) is amended—

(A) by inserting ''or, for such a year after 2015, partial meaningful EHR user'' after ''meaningful EHR user''; and

(B) by inserting ''(or, for such a year after 2015, in accordance with the linear scale applied pursuant to paragraph (2)(E), equal to at least)'' after ''equal to''.

(b) ELIGIBLE HOSPITALS.—

(1) IN GENERAL.—Section 1886(n)(3) of the Social Security Act (42 U.S.C. 1395ww(n)(3)) is amended by adding at the end the following new subparagraph:

''(D) CONSIDERATION OF TECHNOLOGICAL AND COST BARRIERS.—In applying clauses (i), (ii), and (iii) of subparagraph (A) to determine whether a hospital is using certified EHR technology in a meaningful manner for an EHR reporting period for a fiscal year after fiscal year 2015, the Secretary—

''(i) may not require that the hospital, in order to be considered a meaningful EHR user for such period, meet every such requirement or objective specified pursuant to such clauses but instead shall apply a linear scale;

''(ii) shall establish a method to determine if an eligible professional is a partial meaningful user consistent with such linear scale; and

''(iii) shall consider differences among hospitals (such as differences in the type of hospital, specialties available at and patient populations of hospitals) in determining which of the requirements or objectives must be met by the hospital during such period in order for the hospital to be so considered.''.

(2) INCENTIVE PAYMENT.—Section 1886(n)(1) of the Social Security Act (42 U.S.C. 1395ww(n)(1)) is amended—

(A) by inserting ''or, for a fiscal year after fiscal year 2015, partial meaningful EHR user'' after ''meaningful EHR user''; and

(B) by inserting ''(or, for a fiscal year after fiscal year 2015, in accordance with the linear scale applied pursuant to paragraph (2)(D), equal to not more than)'' after ''equal to''.

(3) PAYMENT ADJUSTMENT.—Section 1886(b)(3)(B)(ix)(I) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(ix)(I)) is amended—

(A) in subclause (I)—

(i) by inserting ''or, for a fiscal year after fiscal year 2015, partial meaningful EHR user'' after ''meaningful EHR user''; and

(ii) by inserting ''(or, for a fiscal year after fiscal year 2015, in accordance with the linear scale applied pursuant to section 1886(n)(2)(D), equal to at least)'' after ''equal to''; and

(B) in subclause (III), by inserting ''or, for a fiscal year after fiscal year 2015, partial meaningful EHR user'' after ''meaningful EHR user''.

(c) APPLICATION UNDER MEDICAID.—Section 1903(t)(8) of the Social Security Act (42 U.S.C. 1396b(t)(8)) is amended by inserting after the second sentence the following: ''In doing so, the Secretary shall ensure that the provisions of subparagraph (E) of section 1848(o)(2) and subparagraph (D) of section 1886(n)(3) apply under this title with respect to demonstrating mean-

ingful use in a similar manner as such provisions apply under title XVIII.''.

(d) APPLICATION TO MEDICARE ADVANTAGE.—Section 1853 of the Social Security Act (42 U.S.C. 1395w–23) is amended—

(1) in subsection (l)—

(A) in paragraph (1), by inserting ''or, for a year after 2015, partial meaningful EHR users,'' after ''meaningful EHR users'';

(B) in paragraph (4)(A), by inserting ''(or, for a year after 2015, in accordance with the linear scale applied pursuant to section 1848(o)(2)(E), equal to at least)'' after ''equal to''; and

(C) in paragraph (6), in each of subparagraphs (A) and (B), by inserting ''or, for a year after 2015, partial meaningful EHR user,'' after ''meaningful EHR user''; and

(2) in subsection (m)—

(A) in paragraph (1), by inserting ''or, for a fiscal year after fiscal year 2015, partial meaningful EHR users,'' after ''meaningful EHR users''; and

(B) in paragraph (4)(A), by inserting ''or, for a fiscal year after fiscal year 2015, partial

meaningful EHR users,'' after ''meaningful EHR users''.

(e) APPLICATION TO CRITICAL ACCESS HOSPITALS.—Section 1814(l) of the Social Security Act (42 U.S.C. 1395f(l)) is amended—

(1) in paragraph (3)(A), by inserting ''or, for a fiscal year after 2015, partial meaningful EHR user,'' after ''meaningful EHR user'';

(2) in paragraph (3)(A)(ii)(I), by inserting ''(or, for a fiscal year after fiscal year 2015, in accordance with the linear scale applied pursuant to section 1886(n)(2)(D), equal to not more than)'' after ''equal to''; and

(3) in paragraph (4)—

(A) in subparagraph (A), by inserting ''or, for a fiscal year after 2015, partial meaningful EHR user,'' after ''meaningful EHR user''; and

(B) in subparagraph (B), by inserting ''(or, for a fiscal year after fiscal year 2015, in accordance with the linear scale applied pursuant to section 1886(n)(2)(D), a percent equal to at least the applicable percent)'' after ''applicable percent''.

SEC. 202. ALIGNING QUALITY REPORTING IN THE MEDICARE AND MEDICAID MEANINGFUL USE PROGRAM.

(a) ELIGIBLE PROFESSIONALS.—

(1) TESTING OF MEASURES.—Section 1848(k)(2)(C) of the Social Security Act (42 U.S.C. 1395w–4(k)(2)(C)) is amended by adding at the end the following new clause:

"(iii) TESTING.—After December 31, 2015, the Secretary may only specify a clinical quality measure under this subparagraph if the Secretary has demonstrated, through field tests among multiple and varied eligible professionals, that it is feasible for such professionals to electronically submit valid and accurate information on the measure.".

(2) DEEMED COMPLIANCE IF SATISFY PQRS.—Section 1848(o)(2)(B)(iii) of the Social Security Act (42 U.S.C. 1395w–4(o)(2)(B)(iii)) is amended by adding at the end the following:

"In implementing the preceding sentence, the Secretary shall treat an eligible professional who, for a period under subsection (k) for covered professional services furnished in a year after 2015, satisfies the requirements of clauses (i) or (ii) of subsection (k)(2)(C), or who satisfac-

torily participates in a qualified clinical data registry for a reporting period (as defined in subsection (m)(6)(C)) as determined by the Secretary pursuant to subsection (k)(2)(C) and subsection (m)(3)(D), as satisfying the requirement of subparagraph (A) for the corresponding period described in such subparagraph for such year.''.

(b) ELIGIBLE HOSPITALS.—

(1) TESTING OF MEASURES.—Section 1886(n)(3)(B)(i) of the Social Security Act (42 U.S.C. 1395ww(n)(3)(B)(i)) is amended by adding at the end the following new subclause:

''(III) After September 30, 2015, the Secretary may only select a clinical quality measure under this subparagraph if the Secretary has demonstrated, through field tests in multiple and varied hospitals, that it is feasible for such hospitals to electronically submit valid and accurate information on the measure.''.

(2) DEEMED COMPLIANCE IF SATISFY HOSPITAL INPATIENT QUALITY REPORTING REQUIREMENTS.—Section 1886(n)(3)(B)(iii) of the Social Security Act (42 U.S.C. 1395ww(n)(3)(B)(iii)) is amended by adding at the end the following: ''In im-

plementing the preceding sentence, the Secretary shall treat an eligible hospital that, for a period under subsection (b)(3)(B)(viii) for a fiscal year after fiscal year 2015, satisfies the requirements of such subsection as satisfying the requirement of subparagraph (A) for the corresponding reporting period for such fiscal year.''.

(c) APPLICATION UNDER MEDICAID.—Section 1903(t)(8) of the Social Security Act (42 U.S.C. 1396b(t)(8)), as amended by section 201(c), is further amended in the third sentence—

(1) by inserting ''and the last sentence of subparagraph (B)(iii)'' after ''subparagraph (E)''; and

(2) by inserting ''and the last sentence of subparagraph (B)(i)(III)'' after ''subparagraph (D)''.

SEC. 203. EXPANDING THE HARDSHIP EXCEPTION TO THE MEDICARE EHR PAYMENT ADJUSTMENTS.

(a) ELIGIBLE PROFESSIONALS.—Section 1848(a)(7)(B) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)(B)) is amended to read as follows:

''(B) SIGNIFICANT HARDSHIP EXCEPTION.—

''(i) IN GENERAL.—Subject to clause (ii), the Secretary may, on a case-by-case basis, exempt an eligible professional from

the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access.

''(ii) REQUIRED EXCEPTION.—Subject to clause (iii), beginning for 2015, the Secretary shall, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, the eligible professional—

''(I) encounters unforeseen circumstances (including technological difficulties and other disruptive situations) that present barriers to compliance with the requirement for being a meaningful EHR user;

''(II) changes certified EHR technology vendors, or changes from

self-developed electronic health records to certified EHR technology from a vendor;

''(III) is an anesthesiologist, radiologist, pathologist, hospitalist, or is in any other physician specialty or subspecialty identified through rulemaking as a specialty or subspecialty that presents physicians in the specialty or subspecialty with unique difficulties in complying with such requirement;

''(IV) is at or near retirement age (as defined by the Secretary); or

''(V) is not able to be in compliance with any such requirement because the certified EHR technology used by such professional is not capable of sending, receiving, and seamlessly incorporating data from other certified EHR technology.

''(iii) LIMITATION.—In no case may an eligible professional be granted an exemption under this subparagraph for more than 5 years.''.

(b) ELIGIBLE HOSPITALS.—Section 1886(b)(3)(B)(ix)(II) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(ix)(II)) is amended to read as follows:

"(II)(aa) Subject to item (cc), the Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital to be a meaningful EHR user during such fiscal year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access.

"(bb) Subject to item (cc), beginning for fiscal year 2015, the Secretary shall, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that the hospital encounters unforeseen circumstances (including

technological difficulties and other disruptive situations) that present barriers to compliance with the requirement for such hospital to be a meaningful EHR user during such fiscal year, changes certified EHR technology vendors, changes from self-developed electronic health records to certified EHR technology from a vendor, or is not able to be in compliance with any such requirement because the certified EHR technology used by such hospital is not capable of sending, receiving, and seamlessly incorporating data from other certified EHR technology.

''(cc) In no case may a hospital be granted an exemption under this subclause for more than 5 years.''.

SEC. 204. PROMOTING INTEROPERABILITY THROUGH EHR CERTIFICATION PROCESS.

Section 3004(a)(1) of the Public Health Service Act (42 U.S.C. 300jj–14(a)(1)) is amended by adding at the end the following new sentence: ''The Secretary may not propose adoption of such standards, implementation speci-

fications, or certification criteria unless such standards, implementation specifications, or certification criteria, respectively, have been successfully tested for widespread use by end users for at least a one-year period.''.

SEC. 205. IMPROVING THE TIMING OF THE ADOPTION OF MORE STRINGENT MEASURES OF MEANINGFUL USE UNDER THE MEDICARE AND MEDICAID MEANINGFUL USE PROGRAM.

(a) ELIGIBLE PROFESSIONALS.—Section 1848(o)(2) of the Social Security Act (42 U.S.C. 1395w–4(o)(2)), as amended by section 201(a), is further amended—

(1) in subparagraph (A), in the matter following clause (iii), by striking ''shall seek'' and inserting ''shall, in accordance with subparagraph (F), seek''; and

(2) by adding at the end the following new subparagraph:

''(F) PROVISIONS RELATING TO INCREASED STRINGENCY OF MEASURES.—The Secretary shall implement the last sentence of subparagraph (A) (relating to requirements for more stringent measures of meaningful use selected under this paragraph) in accordance with the following:

"(i) ENSURING PREDICTABILITY.—Subject to clause (ii), in the case that the Secretary selects measures of meaningful use, including any objectives associated with such measures, the Secretary may not change or modify such selection for a period of three years.

"(ii) FLEXIBILITY TO ADJUST CERTAIN MEASURES.—

"(I) PERMISSIBLE REASON FOR CHANGES OR MODIFICATIONS TO MEASURES.—The Secretary may change or modify a measure of meaningful use before the end of the three-year period described in clause (i) if the Secretary makes one or more of the following determinations:

"(aa) The measure may negatively impact the quality of care for, or may risk harm to, a patient.

"(bb) There is a new hardship demonstrated by eligible professionals specific to the measure.

''(cc) An adjustment to the measure is necessary to reflect advances in science or technology.

''(II) REQUEST FOR REVIEW OF CLINICAL QUALITY MEASURES.—The Secretary shall establish a process under which stakeholders may, in the case that new information is available with respect to a clinical quality measure selected by the Secretary for quality reporting under subparagraph (A)(iii), request that the Secretary change or modify such measure for a reason described in subclause (I).''.

(b) ELIGIBLE HOSPITALS.—Section 1886(n)(3) of the Social Security Act (42 U.S.C. 1395ww(n)(3)), as amended by section 201(b), is further amended—

(1) in subparagraph (A), in the matter following clause (iii), by striking ''shall seek'' and inserting ''shall, in accordance with subparagraph (E), seek''; and

(2) by adding at the end the following new subparagraph:

"(E) PROVISIONS RELATING TO INCREASED STRINGENCY OF MEASURES.—The Secretary shall implement the last sentence of subparagraph (A) (relating to requirements for more stringent measures of meaningful use selected under this paragraph) in accordance with the following:

"(i) ENSURING PREDICTABILITY.—Subject to clause (ii), in the case that the Secretary selects measures of meaningful use, including any objectives associated with such measures, the Secretary may not change or modify such selection for a period of three years.

"(ii) FLEXIBILITY TO ADJUST CERTAIN MEASURES.—

"(I) PERMISSIBLE REASON FOR ADJUSTMENTS TO MEASURES.—The Secretary may change or modify a measure of meaningful use before the end of the three-year period described in clause (i) if the Secretary makes one or more of the following determinations:

"(aa) The measure may negatively impact the quality of care for, or may risk harm to, a patient.

"(bb) There is a new hardship demonstrated by eligible hospitals specific to the measure.

"(cc) An adjustment to the measure is necessary to reflect advances in science or technology.

"(II) REQUEST FOR REVIEW OF CLINICAL QUALITY MEASURES.—The Secretary shall establish a process under which stakeholders may, in the case that new information is available with respect to a clinical quality measure selected by the Secretary for quality reporting under subparagraph (A)(iii), request that the Secretary change or modify such measure for a reason described in subclause (I).".

(c) APPLICATION UNDER MEDICAID.—Section 1903(t)(8) of the Social Security Act (42 U.S.C.

1396b(t)(8)), as amended by sections 201(c) and 202(c), is further amended in the third sentence—

(1) by striking ''and the last sentence of subparagraph (B)(iii)'' and inserting '', the last sentence of subparagraph (B)(iii), and subparagraph (F)''; and

(2) by striking ''and the last sentence of subparagraph (B)(i)(III)'' and inserting '', the last sentence of subparagraph (B)(i)(III), and subparagraph (E)''.

SEC. 206. THREE-MONTH EHR REPORTING PERIODS FOR THE MEDICARE AND MEDICAID EHR INCENTIVE PAYMENT PROGRAMS.

(a) EHR REPORTING PERIOD.—

(1) ELIGIBLE PROFESSIONALS.—Section 1848(a)(7)(E)(ii) of the Social Security Act (42 U.S.C. 1395w–4(a)(7)(E)(ii)) is amended by adding at the end the following: ''Such period (or periods) shall consist of a three-month reporting period, without regard to the payment year or the stage criteria (as established under section 495.6 of title 42, Code of Federal Regulations) involved.''.

(2) ELIGIBLE HOSPITALS.—Subsections (b)(3)(B)(ix)(IV) and (n)(6)(A) of section 1886 of the Social Security Act (42 U.S.C. 1395ww) are

each amended by adding at the end the following: ''Such period (or periods) shall consist of a three-month reporting period, without regard to the payment year or the stage criteria (as established under section 495.6 of title 42, Code of Federal Regulations) involved.''.

(3) APPLICATION UNDER MEDICAID.—Section 1903(t)(8) of the Social Security Act (42 U.S.C. 1396b(t)(8)), as amended by sections 201(c), 202(c), and 205(c), is further amended by adding at the end the following new sentence: ''Such reporting periods shall consist of a three-month reporting period, without regard to payment year or the stage criteria (as established under section 495.6 of title 42, Code of Federal Regulations).''.

(b) REGULATIONS.—Not later than 3 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to carry out the amendments made by subsection (a). Such regulations shall apply beginning with the 2016 EHR reporting period.

SEC. 207. PROVIDING ELIGIBLE PROFESSIONALS AND ELIGIBLE HOSPITALS THE OPTION TO MEET A MORE ADVANCED STAGE OF MEANINGFUL USE.

(a) MEANINGFUL EHR USER.—A ''meaningful EHR user'', as defined under section 495.4 of title 24, Code of Federal Regulations, shall include eligible professionals and eligible hospitals who demonstrate meaningful use of certified EHR technology by meeting the applicable objectives and associated measures of either of the following:

(1) The stage of meaningful use that the eligible professional or eligible hospital is scheduled to meet during the applicable ''EHR reporting period'', as such term is defined under section 495.4 of title 24, Code of Federal Regulations.

(2) Any other stage of meaningful use, provided that such stage of meaningful use selected by the eligible professional or eligible hospital is more advanced than the stage of meaningful use that the eligible professional or eligible hospital is scheduled to meet during the applicable EHR reporting period.

(b) DEFINITION.—In this subparagraph, the term ''stage of meaningful use'' means the stage criteria established by the Secretary of Health and Human Services

under section 495.6 of title 42, Code of Federal Regulations.

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