I

117TH CONGRESS
1ST SESSION

H. R. 5394

To require the Secretary of Health and Human Services to establish a new program which ensures meaningful access to claims data by clinician-led clinical data registries, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2021

Mr. BUCSHON (for himself and Ms. SCHRIER) 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

---

A BILL

To require the Secretary of Health and Human Services to establish a new program which ensures meaningful access to claims data by clinician-led clinical data registries, 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.

This part may be cited as the ''Meaningful Access to Federal Health Plan Claims Data Act of 2021''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Clinician-led clinical data registries serve an important role in promoting, facilitating, and conducting medical research and improving quality of healthcare by providing timely and actionable feedback to practitioners on their performance in relation to other practitioners and best clinical practices.

(2) Clinician-led clinical data registries are hindered in their ability to promote medical research and quality improvement by their lack of meaningful access to claims data.

(3) While the Centers for Medicare & Medicaid Services has established programs for providing access to claims data, those programs fail to provide clinician-led clinical data registries with meaningful access to such data.

(4) Ensuring clinician-led clinical data registries meaningful access to claims data will enable such entities to better track patient outcomes over time, expand their ability to assess the safety and effectiveness of medical treatments, and provide them with the information necessary to assess the cost-effectiveness of therapies.

SEC. 3. ENSURING MEANINGFUL ACCESS TO CLAIMS DATA BY CLINICIAN-LED CLINICAL DATA REGISTRIES.

(a) ENSURING MEANINGFUL ACCESS TO CLAIMS DATA.—

(1) ESTABLISHMENT OF A NEW PROGRAM.—

(2) ESTABLISHMENT OF A NEW PROGRAM.—The Secretary shall establish a new program (separate from any existing data access programs, including, without limitation, the Centers for Medicare & Medicaid Services Qualified Entity (in this section, referred to as ''QE'') Program (42 U.S.C. 1395kk(e), 1395kk–2) (in this section, referred to as the ''Medicare Data Sharing for Performance Measurement Program'') and the Research Data Assistance Center (in this section, referred to as the ''ResDAC'') process) under which the Secretary shall, at the request of a clinician-led clinical data registry, provide timely, broad, and continuous access to a database of claims data to such clinician-led clinical data registry for purposes of research, quality of care measurement and reporting to health care providers, linking such data with clinical data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety, and other purposes and uses

described herein or approved by the Secretary. Access to a database of claims data pursuant to this subsection shall not be more restrictive than access to data provided under the QE Program or the ResDAC process.

(3) STREAMLINED APPLICATION PROCESS.—

(A) INITIAL AND RECERTIFICATION APPLICATION.—Prior to gaining access to a database of claims data under the program established in subsection (a), a clinician-led clinical data registry shall submit to the Secretary an application demonstrating that it is qualified (as determined by the Secretary) to use claims data. Upon the Secretary's approval of a clinician-led clinical data registry's application described in this subparagraph, the Secretary shall provide access to a database of claims data to such clinician-led clinical data registry for a period of at least 5 years. After the expiration of the time period described in this subparagraph, the clinician-led clinical data registry shall reapply to access the database of claims data under the program established in subsection (a).

(B) PROCESS.—The Secretary shall establish a streamlined initial application and recer-

tification application process under which the Secretary shall approve or deny the clinician-led clinical data registry's application described in subparagraph (2)(A) within 60 calendar days after receiving the application unless the Secretary demonstrates a compelling reason for needing additional time to complete the process. If the clinician-led clinical data registry's application described in subparagraph (2)(A) is denied, the Secretary shall provide the reason(s) for denial.

(4) APPEAL RIGHTS.—

(A) OPPORTUNITY TO APPEAL.—The Secretary shall develop and maintain a process by which clinician-led clinical data registries may appeal—

(i) the Secretary's decision to deny the clinician-led clinical data registry's application described in subparagraph (2)(A); and

(ii) the Secretary's failure to approve or deny the clinician-led clinical data registry's application described in subparagraph (2)(A) within a reasonable timeframe established by the Secretary.

(B) DEADLINE FOR DECISION.—The Secretary shall render a decision with respect to an appeal filed by a clinician-led clinical data registry pursuant to subparagraph (A) in a timely manner, not to exceed 60 calendar days after the Secretary receives the clinician-led clinical data registry's request for an appeal. Notice of such decision shall be provided to the clinician-led clinical data registry filing the appeal before the conclusion of such 60-day period.

(5) BROAD AND TIMELY ACCESS TO DATA.—The Secretary shall structure its database of claims data to allow for various data set queries, including, but not limited to, provider-specific claims data, clinical specialty-specific claims data, state-specific claims data, and nationwide claims data. The Secretary shall promptly make available to a clinician-led clinical data registry access to claims data requested by such clinician-led clinical data registry within a reasonable timeframe, not to exceed 30 calendar days, after the Secretary approves the request from the clinician-led clinical data registry.

(b) PERMISSIBLE USES OF CLAIMS DATA.—Clinician-led clinical data registries may—

(1) make available to the public reports evaluating the performance of providers of services and suppliers using the claims data provided to such clinician-led clinical data registry under subsection (a) in combination with registry data;

(2) use claims data received under subsection (a) combined with registry data to conduct additional non-public analyses and provide or charge an access fee for such analyses to authorized users for non-public use;

(3) provide or charge an access fee for data sets that link claims data received under subsection (a) with registry data to authorized users for non-public use; and

(4) provide or charge an access fee for claims data received under subsection (a) to authorized users for non-public use.

(c) FEES.—

(1) CLAIMS DATA PROVIDED TO CLINICIAN-LED CLINICAL DATA REGISTRIES.—Claims data shall be provided to a clinician-led clinical data registry under subsection (a) at a reasonable fee based on the cost of providing such data to the clinician-led clinical data registry. Such fee shall be based at least in part on the number of patients included in

the claims data provided to such clinician-led clinical data registry. Any fee collected pursuant to the preceding sentence shall be deposited in the Centers for Medicare & Medicaid Services Program Management Account.

(2) ANALYSES AND DATA PROVIDED TO AUTHORIZED USERS.—Clinician-led clinical data registries may charge a reasonable, cost-based fee for providing to authorized users claims data, data sets linking claims data with registry data, or analyses described in subsection (b).

(d) PROTECTION OF INFORMATION.—

(1) PRIVACY, SECURITY, AND DISCLOSURE LAWS.—The Secretary shall provide access to a database of claims data pursuant to subsection (a) in accordance with applicable information, privacy, security, and disclosure laws, including, without limitation, the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, as amended by the Privacy and Security provisions set forth in Section 13400 of the Health Information Technology for Economic and Clinical Health Act, Public Law 111–5, the regulations promulgated thereunder codified at 45 CFR Parts 160 and 164, and subparagraphs (A) through (B) of section

105(a)(3) of the Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. 1395kk–2(a)(3)).

(2) PROHIBITION ON USING ANALYSES OR DATA FOR MARKETING PURPOSES.—An authorized user shall not use analyses or data provided or sold under paragraphs (2) through (4) of subsection (b) for marketing purposes.

(3) NO REDISCLOSURE OF ANALYSES OR DATA.—An authorized user in receipt of an analysis or datum provided or sold under paragraphs (2) through (4) of subsection (b) shall comply with section 105(a)(5) of Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. 1395kk–2(a)(5)).

(4) OPPORTUNITY FOR PROVIDERS OF SERVICES AND SUPPLIERS TO REVIEW.—Prior to a clinician-led clinical data registry using, providing, or charging an access fee for claims data, data sets linking claims data with registry data, or analyses described in subsection (b), to the extent that such data, data sets, or analyses would individually identify a provider of services or supplier who is not being provided or sold such data, data sets, or analyses, such clinician-led clinical data registry shall confidentially make available such data, data sets, or analyses to such provider of services or supplier and

provide such provider of services or supplier with the opportunity to appeal and correct errors.

(e) DATA USE AGREEMENT.—A clinician-led clinical data registry and an authorized user shall enter into a data use agreement regarding the use or disclosure of any claims data or data sets that link claims data with registry data that the clinician-led clinical data registry is providing or charging an access fee to the authorized user under paragraphs (3) through (4) of subsection (b). Such agreement shall include the requirements and prohibitions described in section 105(a)(4) of the Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. 1395kk–2(a)(4)).

(f) ASSESSMENT FOR A BREACH.—

(1) IN GENERAL.—In the case of a breach of a data use agreement, the Secretary shall impose an assessment on the clinician-led clinical data registry and the authorized user.

(2) ASSESSMENT.—The assessment under subsection (f)(1) shall be in an amount up to $100 for each individual entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act or enrolled for benefits under part B of such title for whom the clinician-led clinical data registry provided data on to the authorized user.

(3) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to this subsection shall be deposited in the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t).

(g) DISCOVERY OR ADMISSION AS EVIDENCE.—Claims data released to a clinician-led clinical data registry under subsection (a) shall not be subject to discovery or admission as evidence in judicial or administrative proceedings without consent of the applicable provider of services or supplier.

SEC. 4. REPORT TO CONGRESS.

Not later than 2 years after the date of enactment of this Act, and annually thereafter, the Secretary shall submit to Congress a report on the extent to which clinician-led clinical data registries are afforded meaningful access to claims data.

SEC. 5. DEFINITIONS.

In this Act:

(1) AUTHORIZED USER.—The term ''authorized user'' shall have the meaning ascribed to it in section 105(a)(9)(A) of the Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. 1395kk–2(a)(9)(A)), as well as a government agency or other governmental entity, researchers, entities that seek

data for purposes of complying with regulations or other requirements of the Federal Food and Drug Administration, and other entities approved by the Secretary.

(2) CLAIMS DATA.—The term ''claims data'' shall have the meaning ascribed to the term ''data'' in section 105(b)(1)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. 1395kk–2(b)(1)(B)).

(3) CLINICIAN-LED CLINICAL DATA REGISTRY.—The term ''clinician-led clinical data registry'' shall have the meaning ascribed to it in section 4005(b) of the 21st Century Cures Act.

(4) DATA USE AGREEMENT.—The term ''data use agreement'' means an agreement described in subsection (e) of section 3.

(5) NON-PUBLIC USE.—The term ''non-public use'' means for the purposes of—

(A) promoting, facilitating, and conducting medical research; assisting providers of services and suppliers to improve patient safety and to develop and participate in quality and patient care improvement activities, including developing new models of care;

(B) assisting clinician-led clinical data registries in developing and reporting quality measures to health care providers quality measures;

(C) educating a government agency or other governmental entity; and

(D) supporting clinical trials and other activities necessary to comply with pre- or post-market approval or adverse event reporting requirements or conditions imposed by the Federal Food and Drug Administration; and other purposes approved by the Secretary.

(6) PROVIDER OF SERVICES.—The term ''provider of services'' shall have the meaning ascribed to it in section 1861(u) of the Social Security Act (42 U.S.C. 1395x(u)).

(7) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Humans Services.

(8) SUPPLIER.—The term ''supplier'' shall have the meaning ascribed to it in section 1861(d) of the Social Security Act (42 U.S.C. 1395x(d)).

SEC. 6. REGULATIONS.

The Secretary shall promulgate not later than 1 year after the enactment of this Act, final regulations to implement the provisions of the preceding sections of this Act.

SEC. 7. COVERAGE OF PROMISING NEW TECHNOLOGIES UNDER THE MEDICARE PROGRAM.

(a) NON-EXCLUSION OF ITEMS AND SERVICES FURNISHED UNDER ACCESS WITH DATA COLLECTION.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)) is amended—

(1) in subparagraph (O), by striking at the end ''and'';

(2) in subparagraph (P), by striking the semicolon at the end and inserting '', and''; and

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

''(Q)(i) in the case of items and services for which evidence is promising but not definitive to determine that the items and services are reasonable and necessary for the diagnosis or treatment of illness of injury or to improve the functioning of a malformed body member, which are not reasonable and necessary for evidence collection to determine that the reasonable and necessary standard in subparagraph (A) is met; and

''(ii) for purposes of this subparagraph, evidence collection may include—

''(I) evidence of appropriateness, impact on quality of life, effectiveness, safety

or other outcomes as determined by the Secretary; and

''(II) evidence derived from real world data repositories, patient registries, cohort studies, randomized controlled trials, or other studies as determined by the Secretary;

''(iii) the evidence collection described in clause (ii) shall be evidence collection approved by the Secretary acting through the Administrator of the Centers for Medicare & Medicaid Services in collaboration with the Director of the Agency for Healthcare Research and Quality as meeting the priorities of this title as set forth under Section 1142;

''(iv) such evidence collection shall be time-limited to a period of no more than 5 years, unless the Secretary deems that extension is needed to address remaining gaps in evidence;

''(v) such evidence collection shall be accessible, include outcomes relevant to patients, and have transparent governance; and

''(vi) such evidence collection shall be referred to as 'Access with Data Collection'.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished after December 31, 2021.

○