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PHYSICIAN CLINICAL REGISTRY COALITION

July 28, 2021

VIA ELECTRONIC MAIL

The Honorable Richard Neal
House Ways and Means Committee
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin Brady
House Ways and Means Committee
1139 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
House Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

Re: Request for a Hearing on the Implementation of MACRA

Dear Chairmen Neal and Pallone and Ranking Members Brady and McMorris Rodgers:

The undersigned members of the Physician Clinical Registry Coalition ("Coalition") write to request that you convene an oversight hearing to examine the Centers for Medicare and Medicaid Services' ("CMS") implementation of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") as it relates to Qualified Clinical Data Registries ("QCDRs") and clinician-led clinical data registries. The Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes. Most of the Coalition's members have been approved as QCDRs or are working towards achieving QCDR status.

These registries play an essential role in promoting quality of care. QCDRs and clinician-led clinical data registries provide timely and actionable feedback to providers on their performance, speeding and enhancing quality improvement opportunities. The measures developed by QCDRs and clinician-led clinical data registries are meaningful and relevant to participating providers and their patient populations.

MACRA requires the Secretary of Health and Human Services ("Secretary") to encourage the use of QCDRs and certified electronic health record technology ("CEHRT") for reporting measures under the quality performance category of the Merit-Based Incentive Payment System

("MIPS") program.[1] Section 105(b) of MACRA directs the Secretary to provide Medicare claims data to QCDRs "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety." [2]

Given these statutory mandates, it is important that CMS adopt policies that provide meaningful access to Medicare claims data, encourage QCDR participation in the MIPS program, and encourage the development of strong QCDR measures and a framework that support accurate quality data measurement. Over recent years, however, CMS has established policies that contravene the language and intent of MACRA, including policies that disincentivize meaningful specialty measures.

Therefore, we respectfully urge your committees to hold a hearing (or hearings) to examine CMS' implementation of MACRA. Specifically, we recommend that your oversight efforts focus on the CMS policies and reforms discussed below. Although most of these reforms can be accomplished through regulation, we believe that legislative intervention is necessary to ensure that CMS is properly implementing the plain language and intent of MACRA.

Access to Medicare Claims Data

Contrary to Section 105(b) of MACRA, CMS has not provided clinician-led clinical data registries with a meaningful way to gain continuous access to Medicare claims data. CMS initially refused to implement Section 105(b), stating that QCDRs could access Medicare claims data through the Research Data Assistance Center ("ResDAC") process.[3] After the Coalition and other stakeholders expressed concerns regarding the ResDAC process, CMS provided QCDRs with an alternative mechanism for accessing Medicare claims data, by permitting QCDRs to serve as quasi-qualified entities under the Qualified Entity Program.[4] Neither option, however, provides QCDRs with the type of timely, broad, and continuous access to Medicare claims data contemplated by Section 105(b) and necessary for QCDRs to effectively link their outcomes data with Medicare claims data

The ResDAC process does not provide sufficient access to Medicare claims data for quality improvement purposes. The ResDAC process is also slow, costly, and cumbersome. Moreover, CMS' decision to treat QCDRs as quasi-qualified entities for purposes of obtaining access to Medicare claims data does not provide QCDRs (or other clinician-led clinical data registries) with the long-term, continuous, and timely access to Medicare claims data required under Section 105(b). Quasi-qualified entities cannot use Medicare data for research purposes without

[1] MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015).
[2] *Id*. § 105(b)(1)(A).
[3] *See* Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, 81 Fed. Reg. 5,397, 5,408 (Feb. 2, 2016) (proposed rule).
[4] Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, 81 Fed. Reg. 44,456 (July 7, 2016).

submitting a separate research protocol to ResDAC for review and approval. QCDRs and other clinician-led clinical data registries generally need data on a provider-specialty specific and nationwide basis; however, quasi-qualified entity status only provides registries access to provider-wide and state-specific data. In addition, the Qualified Entity Program requirements on eligibility, operations, and governance are extremely lengthy and burdensome. Quasi-qualified entity status only lasts for three years and continued participation in the program requires re-application. Therefore, it does not allow for the continuous access needed for monitoring quality improvement over time.

CMS' failure to properly implement Section 105(b) hinders clinician-led clinical data registries' ability to perform longitudinal and other data analyses for quality improvement, patient safety, cost-effectiveness, and research purposes. Tying Medicare claims data to clinical outcome information would enable clinician-led clinical data registries 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 alternative therapies.

Therefore, we respectfully request that you urge CMS to properly implement Section 105(b) of MACRA. In the alternative, the Coalition urges Congress to consider legislation guaranteeing clinician-led clinical data registries access to Medicare, Medicaid, and State Children's Health Insurance Program claims data for quality improvement, patient safety, and research purposes. Such language could take the form of the draft legislative language attached hereto for your consideration.

Measure Testing

CMS recently finalized a policy that a QCDR measure must be face valid to be approved for the 2024 MIPS payment year.[5] To be approved starting in the 2025 MIPS payment year, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for all subsequent MIPS payment year for which it is approved.[6] A QCDR measure must be fully tested to be included in an MIPS Value Pathway for the 2024 MIPS payment year and subsequent years.[7]

We understand and agree with CMS's desire that all QCDR measures be appropriate, reliable, and valid. However, these specific testing requirements are unnecessarily excessive for some QCDRs and/or measures, and contrary to the MACRA's requirement to encourage the use of

[5] 42 C.F.R. § 414.1400(b)(3)(v)(C)(1). "Face validity" is the "extent to which a measure appears to reflect what it is supposed to measure 'at face value.' It is a subjective assessment by experts about whether the measure reflects its intended assessment." CMS, *CMS Measures Management System Blueprint: Version 16.0* (Sept. 2020), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.
[6] 42 C.F.R. § 414.1400(b)(3)(v)(C)(1).
[7] *Id*. § 414.1400(b)(3)(v)(C)(2).

QCDRs for reporting measures. The cost of measure testing is significant and is an expense that nonprofit medical societies, particularly small specialties, cannot bear. These requirements impose unreasonable cost and other burdens on QCDRs, and such costs are already causing many QCDRs to reduce or cease measure development or to leave the program.

These requirements fail to recognize that quality measures submitted by QCDRs are created by subject matter experts, undergo significant expert vetting, and are supported by literature, guidelines, and preliminary data, thus providing implicit face validity for each measure. Prior to these policies, QCDRs typically reviewed performance data before and after implementing a measure in the registry. This, along with the recently implemented requirement to demonstrate measure development expertise, should give CMS confidence regarding QCDR measures that are submitted by medical societies. The Coalition believes that CMS should adopt a more strategic and flexible approach to MIPS and QCDR measure selection and testing, including allowing alternative testing approaches and additional time to collect data for testing, in order to ensure that measures are appropriate, reliable, and valid.

Data Validation Requirements

Beginning with the 2021 performance year, QCDRs and qualified registries must conduct data validation audits for the payment year before submitting any data for that payment year to CMS for purposes of the MIPS program.[8] If a data validation audit identifies one or more deficiencies or data errors, the QCDR or qualified registry must conduct a targeted audit into the impact and root cause of each deficiency or data error and correct such deficiencies or data errors prior to the submission of data for that MIPS payment year.[9]

The Coalition appreciates the importance of reporting true, accurate, and complete data. We are concerned, however, that the data validation and targeted audit requirements contravene MACRA's directive to encourage the use of QCDRs for reporting measures. CMS's policies regarding data validation and targeted audits—particularly now that they apply to not only the quality category, but also the Promoting Interoperability ("PI") and Improvement Activities ("IA") performance categories—are unnecessarily complicated, costly, and burdensome for QCDRs, qualified registries, and clinicians. These policies also fail to recognize that QCDRs and qualified registries employ rigorous internal quality data controls and conduct external audits to ensure the accuracy of data. CMS's policies impose considerable burden on clinicians given that the agency has not provided adequate guidance on validating PI and IAs, that not all IAs are reported electronically, and that PI is largely out of the control of registries.

[8] *Id*. § 414.1400(b)(2)(iv), (c)(2)(iii).
[9] *Id*. § 414.1400(b)(2)(v), (c)(2)(iv).

Harmonization

Beginning with the 2022 MIPS payment year, in circumstances where similar, multiple QCDR measures exist, CMS may provisionally approve the QCDR measure for one year with the condition that the QCDRs must address certain areas of duplication with other approved QCDR measures or MIPS quality measures for subsequent years.[10] If QCDRs cannot collaborate to harmonize their measures, CMS may reject the duplicative QCDR measure.[11]

CMS has failed to implement adequate safeguards to ensure that measure harmonization occurs only when it is clinically appropriate to do so. This has resulted in specialty societies being forced to "harmonize" their QCDR measure with other distinct and non-risk stratified measures, ultimately at the disadvantage of specialists who are left with fewer meaningful measures to report. The Coalition recommends that CMS implement appropriate safeguards to ensure that measure harmonization occurs only when doing so is clinically appropriate.

In addition, CMS has not implemented a formal process for appealing decisions regarding measure harmonization. An appeal process would give QCDRs an opportunity to provide CMS with additional information, including if there is a clinical rationale for why measures should not be harmonized or if a measure is an appropriate derivative work of another existing measure. If the measure owner can provide a documented clinical rationale for keeping the measures separate, then CMS should not require measure harmonization.

Topped Out Measures

The Coalition has concerns regarding the effect of topped out measures—a measure with a median performance rate of 95% or higher.[12] Beginning with the 2020 performance period, considerations for whether to remove a QCDR measure from the program include whether the QCDR measure is topped out.[13] In addition, beginning with the 2023 MIPS payment year, CMS may approve QCDR measures for two years by attaining approval status by satisfying QCDR measure considerations and requirements.[14] CMS, however, may revoke a QCDR measure's second year approval upon annual review if the QCDR measure is found to be topped out.[15]

If CMS determines that many of a subspecialty's MIPS measures are topped out, it may not be possible for a subspecialty to maintain a QCDR due to the lack of measures. Moreover, measures are expensive to develop, test, and submit to CMS. Congress created the QCDR mechanism to fill critical gaps in the traditional quality measure sets and to ensure that clinicians

[10] *Id*. § 414.1400(b)(3)(v)(E).
[11] *Id*.
[12] *Id*. § 414.1305.
[13] *Id*. § 414.1400(b)(3)(vii).
[14] *Id*. § 414.1400(b)(3)(vi).
[15] *Id*.

have access to measures that are more meaningful and relevant to their specialty. CMS's policy concerning topped out measures creates an effect that is counter to the statutory purpose of QCDRs being innovative and targeted to the needs of different specialties. In addition, CMS's policy fails to reward physicians' sustained excellence in providing care.

Rather than removing topped-out measures, or even imposing scoring caps on such measures, CMS should consider a more appropriate transition period to extend the utility of "topped-out" measures.

Incentivizing Clinical Data and Measure Testing Participation

In accordance with MACRA's directive to encourage the use of QCDRs for reporting measures, CMS should provide more meaningful credit/incentivization for clinical data and measure testing participation. Clinician reporting contributes to real world data. In addition, CMS should provide improvement activity credit to practices that test measures prior to submission.

CMS Cooperative Agreements with QCDRs

CMS should enter into cooperative agreements with QCDRS to develop, improve, and expand quality measures for MIPS. CMS currently relies heavily on contractors to develop specialty-specific quality measures without specialty organizations' active input. For measures that have been developed by specialty organizations, CMS has required changes that do not support specialty-specific physicians. It would make more sense, where appropriate, for CMS to collaborate directly with specialty society QCDRs that already have the clinical expertise and infrastructure in place to assist with new measure development.

MIPS Value Pathway ("MVP") Program

CMS's efforts to design, evaluate, and implement the MVP program must comply with the language and spirit of MACRA. The Coalition appreciates the agency's commitment to working collaboratively with stakeholders to develop MVPs that are clinically relevant and meaningful to specialties and subspecialties and patients. The development and implementation of MVPs place a tremendous strain on the financial and administrative resources of specialty societies and their clinical data registries. To ensure that resources are appropriately invested, the Coalition urges CMS to provide greater transparency in the MVP approval process and a longer transition period for this new program.

* * *

The Coalition appreciates your consideration of our request. If you have any questions, please contact Rob Portman or Leela Baggett at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or Leela.Baggett@PowersLaw.com).

Respectfully submitted,

American Academy of Dermatology Association
American Academy of Ophthalmology
American Academy of Physical Medicine & Rehabilitation
American Association of Neurological Surgeons/Congress of Neurological Surgeons
American College of Gastroenterology
American College of Radiology
American College of Rheumatology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Urological Association
Association for Clinical Oncology
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Center for Professionalism & Value in Health Care
The Society of Thoracic Surgeons

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PHYSICIAN CLINICAL REGISTRY COALITION

Meaningful Access to Federal Health Plan Claims Data Act
Legislative Language

SEC. 1. SHORT TITLE

This Act may be cited as the "Meaningful Access to Federal Health Plan Claims Data Act."

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 and 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.—The Secretary shall establish a new program (separate from any existing data access programs, including, without limitation, the Centers for Medicare and Medicaid Services Qualified Entity (QE) Program (42 U.S.C. §§ 1395kk(e), 1395kk-2) (also known as the Medicare Data Sharing for Performance Measurement Program) and the Research Data Assistance Center (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, 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.

(2) 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 recertification 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.

(3) 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 (3)(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.

(4) 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 sell such analyses to authorized users for non-public use;

(3) Provide or sell data sets that link claims data received under subsection (a) with registry data to authorized users for non-public use; and

(4) Provide or sell 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 and 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 section 105(a)(3)(A)-(B) of Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. § 1395kk-2(a)(3)(A)-(B)).

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

(3) NO REDISCLOSURE OF ANALYSES OR DATA.—An authorized user in receipt of an analysis or datum provided or sold under subparagraphs (b)(2)-(4) 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 selling 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 selling to the authorized user under subparagraphs (b)(3)-(4). 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 subparagraph (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 section (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 every year 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 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; assisting clinician-led clinical data registries in developing quality measures; educating a government agency or other governmental entity; 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 this Act.