DEPARTMENT OF VETERANS AFFAIRS **8320-01**

38 CFR Part 17

RIN 2900-AQ56

Center for Innovation for Care and Payment

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final a proposed rule amending its regulations that govern VA health care. This final rule establishes parameters and authority for the new Center for Innovation for Care and Payment in its conduct of pilot programs designed to develop innovative approaches to testing payment and service delivery models to reduce expenditures while preserving or enhancing the quality of care furnished by VA.

DATES: **Effective Date:** This rule is effective **[insert date 30 days after the date of publication in the FEDERAL REGISTER].**

FOR FURTHER INFORMATION CONTACT: Michael Akinyele, VA Chief Innovation Officer and Executive Director (Acting), VA Innovation Center (VIC) (008E), 810 Vermont Ave NW, Washington, DC 20420. Michael.Akinyele@va.gov. (202) 461-7271. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On June 6, 2018, section 152 of Public Law 115-182, the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018, or the VA MISSION Act of 2018, amended title 38 of the United States Code (U.S.C.) by adding a new section 1703E, Center for Innovation for Care and Payment. This final rule implements this new authority and establishes the parameters and authority for the new Center for Innovation for Care and Payment (the Center) in its conduct of pilot programs designed to develop innovative approaches to testing payment and service delivery models to reduce expenditures while preserving or enhancing the quality of care furnished by VA.

VA published a proposed rule on the Center on July 29, 2019. 84 FR 36507. The public comment period closed on August 28, 2019. In response to this proposed rule, VA received multiple comments. Several of the comments expressed support for the rule in whole or in part. One comment supported the proposed ability to expand pilot program duration for up to an additional 5 years. The comment suggested that an extended pilot program duration would afford clinicians greater opportunity to improve care and obtain actionable data beyond the initial pilot program duration. One comment supported many elements of the proposed rule: VA's definition of the term reduction in expenditures; the ability to waive applicable regulations along with provisions of law; and VA's ability to extend and expand successful pilot programs. We appreciate the comments' support and make no changes to these provisions.

Many of the comments addressed issues related to implementation or ideas for specific pilot programs; because these are generally outside the scope of the

rulemaking, we make no changes based on these comments. However, we summarize these comments below and address them as appropriate.

Several comments made recommendations on whom VA should consult in developing pilot programs. One comment supported VA's intent to consult with Federal agencies and medical and health experts. The comment encouraged VA to solicit input from professional associations and clinicians to ensure VA obtains a broad swath of input, guidance, and suggestions on innovations and programmatic priorities. The comment further encouraged VA to prioritize health promotion and disease prevention models that focus on keeping people healthy. One comment suggested that the inclusion of nurse practitioners (NP) in VA's consultation with relevant Federal agencies and clinical and analytical experts would be important in developing effective care models. One comment urged VA to collaborate with veterans organizations in local communities to ensure that veterans receive proper notice and information regarding pilot programs. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals. We make no changes based on these comments.

Other comments made recommendations as to what types of pilot programs VA should pursue. One comment encouraged VA to consider models that enhance community design to promote safe physical activity and active forms of transportation for individuals and populations of all ages and abilities. The comment also recommended VA consider the development of a model that directs patients with musculoskeletal disorders to physical therapists for primary assessment in primary care. The comment also recommended that VA consider how it may integrate public

information and performance metrics to assess the quality, timeliness, and patient satisfaction of care and services furnished. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals. We make no changes based on this comment.

One comment supported the use of evidence-based health care models as necessary to make improvements to VA's health care system. The comment stated that finding the right health care model is essential in streamlining veterans' care. The comment encouraged VA to be strategic in creating pilot studies to provide efficient, cost-effective care without sacrificing quality of care. The comment recommended VA health care delivery models adhere to proper guideline requirements for recommended screenings and health promotion initiatives. The comment also encouraged the prioritization of care models addressing common health conditions unique to veterans, such as mental health or substance abuse disorders. The comment also recommended addressing barriers to care including better payment systems with timely reimbursement to non-VA health care providers and competency training for providers to ensure culturally competent care. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals; however, because these comments make no recommendations regarding the specific provisions of this rule, which lays out the parameters of the Center, we make no changes based on these comments.

One comment supported the creation of the Center and noted that it looked forward to having NPs working with VA on the development of new pilot programs. The comment stated than an overarching goal should be to support and create models

providing equal opportunity for participation of clinicians and their patients. The comment suggested including NPs as full participants in pilot programs as one way to increase participation. The comment noted that patient outcomes are improved and cost savings are realized when NPs are utilized to the fullest extent of their educational and clinical training. The comment noted this has been demonstrated in a number of models within the Center for Medicare and Medicaid Innovation. The comment suggested that including NPs as full participants would help VA enhance the quality of care provided to veterans while also reducing expenditures. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals. We make no changes based on this comment.

One comment was broadly supportive of the proposed rule. The comment recommended a specific focus on modernizing drug pricing to allow for greater adoption of more flexible pricing arrangements, greater value for patients, and an improved standard of care. The comment encouraged a shift from rebated and volume discount pricing arrangements to an outcomes/value-based flexible pricing arrangement. The comment also encouraged VA to continue to ensure that existing arrangements for value-based health care are not impacted by this rulemaking. The comment recommended VA assess the ability to increase the amount of value-based health care contracting opportunities within VA systems and encouraged further rulemaking in this area. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals. We make no changes based on this comment.

One comment recommended leveraging existing partnerships to design and test innovations in telehealth, data exchange, care transitions, and other areas. The comment noted that comparative effectiveness studies could identify cost and quality outliers, leading to a mutually beneficial exchange of best practices between VA and community-based providers. We appreciate this input but make no changes based on this comment, which makes no recommendations regarding provisions of the proposed rule.

One comment stated that it believed this new Center has the potential to facilitate additional opportunities to more fully engage massage therapy within veterans' health care, such as providing test cohorts of community-based massage therapists, determining how well massage therapists are receiving provider referrals for massage therapy, assessing outcomes following a treatment cycle, and providing important measurements to add to the research base on massage efficacy and cost-effectiveness for various conditions. The comment also noted the efficacy of massage therapy as a non-pharmacologic approach to pain management, and its recognition in guidelines for non-pharmacologic opioid alternatives by the Attorney General of West Virginia. We appreciate the comment's perspective regarding potential pilot programs but make no changes based on this comment.

One comment recommended VA consider, in developing pilot programs, recommendations made by the Commission on Care established by section 202 of the Veterans Access, Choice, and Accountability Act of 2014 (Public Law 113-146) that have not yet been acted upon by Congress or VA. Other possible pilot programs recommended by the comment included VA prioritizing treatment for service-connected

conditions that are common among veterans, including posttraumatic stress disorder and mental health concerns; modifying VA's personnel system to allow for improved flexibility to respond to market conditions related to compensation, benefits, and recruitment; making VA the secondary payer for all non-service-connected health care in the community; and fully utilizing nurse practitioners and physician assistants to improve access to primary care, enhance quality, and reduce expenditures. We appreciate these recommendations regarding specific pilot programs and will take them under advisement. However, because these deal with specific pilot programs, and not with VA's general authority to operate the Center addressed in this rulemaking, we make no changes based on this comment.

Some comments discussed issues generally raised by other parts of the rule. One comment generally supported the use of patient health care experience tools in determining patient satisfaction but expressed concern that some of these tools are outdated and do not recognize NPs. The comment stated that survey tools omitting NPs would fail to provide accurate health care delivery information. The comment encouraged VA to accurately capture patient satisfaction data by developing updated patient satisfaction tools that include NPs. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals. We make no changes based on this comment.

One comment urged VA to actively seek and fill as many of the new leadership positions within the Center as possible with outside candidates who have experience with designing and creating proven innovative health care delivery solutions and can bring that experience to the Center and to VA. The comment also urged VA to select

internal candidates for the Center's leadership team who can best foster a collaborative environment that inspires effective innovation to enhance how VA delivers health care services to veterans. We make no changes based on this comment.

One comment recommended VA use the same terminology and definitions used by non-VA providers. The comment did not identify any specific terms it believed were inconsistent with industry standards; indeed, it recognized that many of the terms VA proposed are well established and consensus-based definitions. The comment recognized that it may be necessary to use a different definition but urged VA to start with the presumption of aligning terms and definitions. As we explained in our proposed rule, we believe the definitions we proposed are consistent with how these terms are used in the industry, and to the extent there is any variation, we believe our definitions are broader to allow for maximal flexibility in designing and operating pilot programs. We make no changes based on this comment.

One comment proposed VA allow non-VA providers and other stakeholders who are not affiliated with VA to propose pilot ideas. The comment recommended using the Center for Medicare and Medicaid Innovation's process for soliciting ideas as a starting point. The comment recognized that a more open process may take more time but could provide a greater breadth and depth of innovative pilot program concepts. We appreciate this recommendation and anticipate development of a system that would permit this type of voluntary input. We make no changes based on this comment.

Two comments expressed differing interpretations of provisions in the proposed rule concerning the operational independence of the Center. One comment supported the Center's operational independence from VA's three administrations because this

would grant it the appropriate access and decision-making authority to work across the entire VA system to re-imagine care delivery, break and eliminate internal systemic barriers, create efficiencies, and improve care for veterans. Another comment, however, supported the Center being operationally independent from VA while also collaborating with VA. These comments indicate this language was unclear, so VA is revising paragraph (a) to remove the reference to and definition of operational independence. VA will retain the language in the proposed rule from paragraph (a)(3), now redesignated as paragraph (a)(2), that the Center will not operate within any specific administration. This should emphasize the Center's role within VA, but as an organization that can break and eliminate internal barriers, create efficiencies, and improve care for veterans. We further clarify that the Center is part of VA and acts at the direction of the Secretary, so it is not "independent" from VA; in the proposed rule, we stated that the Center will report through the Office of the Secretary of Veterans Affairs and ultimately the President of the United States and does not have the unilateral authority to execute pilot programs. (84 FR 36507, 36508.)

Effect of Rulemaking

The Code of Federal Regulations, as revised by this rulemaking, represents the exclusive legal authority on this subject. No contrary rules or procedures will be authorized. All VA guidance will be read to conform with this rulemaking if possible or, if not possible, such guidance will be superseded by this rulemaking.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This final rule adopts regulations that are largely procedural, and will not, without Congressional approval of a pilot program proposal from VA, result in any change in benefits or services by themselves. Thus, this final rule will not have a significant economic impact on qualifying non-VA entities or providers. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866, 13563 and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The Office of Information and Regulatory Affairs has determined that this rulemaking is a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at http://www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at http://www.va.gov/orpm by following the link for VA Regulations Published from FY 2004 through FYTD. This final rule is not subject to the requirements of Executive Order 13771 because this final rule is expected to result in no more than de minimis costs.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are as follows: 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; and 64.022, Veterans Home Based Primary Care

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Signing Authority

The Secretary of Veterans Affairs approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Pamela Powers, Chief of Staff, Department of Veterans Affairs, approved this document on October 4, 2019, for publication.

Dated: October 23, 2019.

Michael P. Shores,
Director,
Office of Regulation Policy & Management,
Office of the Secretary,
Department of Veterans Affairs.

For the reasons set forth in the preamble, we amend 38 CFR part 17 as follows:

PART 17 – MEDICAL

1. The authority citation for part 17 is amended by adding an entry for § 17.450 in numerical order to read in part as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

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Section 17.450 is also issued under 38 U.S.C. 1703E.

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2. Add an undesignated center heading and § 17.450 to read as follows.

Center for Innovation for Care and Payment

§ 17.450 Center for Innovation for Care and Payment.

(a) Purpose and organization. The purpose of this section is to establish procedures for the Center for Innovation for Care and Payment.

(1) The Center for Innovation for Care and Payment will be responsible for working across VA to carry out pilot programs to develop innovative approaches to testing payment and service delivery models to reduce expenditures while preserving or enhancing the quality of care furnished by VA.

(2) The Center for Innovation for Care and Payment will not operate within any specific administration but will operate in VA's corporate portfolio to ensure the limited

number of concurrent pilot programs under this section are not redundant of or conflicted by ongoing innovation efforts within any specific administration.

(b) Definitions. The following definitions apply to this section.

Access refers to entry into or use of VA services.

Patient satisfaction of care and services refers to patients' rating of their experiences of care and services and as further defined in a pilot program proposal.

Payment models refer to the types of payment, reimbursement, or incentives that VA deems appropriate for advancing the health and well-being of beneficiaries.

Pilot program refers to a pilot program conducted under this section.

Quality enhancement refers to improvement or improvements in such factors as clinical quality, beneficiary-level outcomes, and functional status as documented through improvements in measurement data from a reliable and valid source, and as further defined in a pilot program proposal.

Quality preservation refers to the maintenance of such factors as clinical quality, beneficiary-level outcomes, and functional status as documented through maintenance of measurement data from an evidence-based source, and as further defined in a pilot program proposal.

Reduction in expenditure refers to, but is not limited to, cost stabilization, cost avoidance, or decreases in long- or short-term spending, and as further defined in a pilot program proposal. NOTE: VA will also consider the proposal's potential impact on expenditures for other related Federal programs; however, this potential impact will not count against the limitation in paragraph (d)(2) of this section.

Service delivery models refer to all methods or programs for furnishing care or services.

(c) Geographic locations. VA will make decisions regarding the location of each pilot program based upon the appropriateness of testing a specific model in a specific area while taking efforts to ensure that pilot programs are operated in geographically diverse areas of the country. VA will include in its proposal to Congress and publish a document in the Federal Register identifying the geographic locations proposed for each pilot program, the rationale for those selections, and how VA believes the selected locations will address deficits in care for a defined population.

(d) Limitations. In carrying out pilot programs under this section, VA will not:

(1) Actively operate more than 10 pilot programs at the same time; and

(2) Consistent with 38 U.S.C. 1703E(d), obligate more than $50 million in any fiscal year in the conduct of the pilot programs (including all administrative and overhead costs, such as measurement, evaluation, and expenses to implement the pilot programs themselves) operated under this section, unless VA determines it to be necessary and submits a report to the appropriate Committees of Congress that sets forth the amount of, and justification for, the additional expenditure.

(e) Waiver of authorities. In carrying out pilot programs under this section, VA may waive statutory provisions by adding to or removing from statutory text in subchapters I, II, and III of chapter 17, title 38, U.S.C., upon Congressional approval, including waiving any provisions of law in any provision codified in or included as a note to any section in subchapter I, II, or III of chapter 17, title 38.

(1) Upon Congressional approval of the waiver of a provision of law under this section, VA will also deem waived any applicable provision of regulation implementing such law as identified in VA's pilot program proposal.

(2) VA will publish a document in the Federal Register providing information about, and seeking comment on, each proposed pilot program upon its submission of a proposal to Congress for approval. VA will publish a document in the Federal Register to inform the public of any pilot programs that have been approved by Congress.

(f) Notice of eligibility. VA will take reasonable actions to provide direct notice to veterans eligible to participate in a pilot program operated under this section and will provide general notice to other individuals eligible to participate in a pilot program. VA will announce its methods of providing notice to veterans, the public, and other individuals eligible to participate through the document it publishes in the Federal Register for each proposed and approved pilot program.

(g) Evaluation and reporting. VA will evaluate each pilot program operated under this section and report its findings. Evaluations may be based on quantitative data, qualitative data, or both. Whenever appropriate, evaluations will include a survey of participants or beneficiaries to determine their satisfaction with the pilot program. VA will make the evaluation results available to the public on the VA Innovation Center website on the schedule identified in VA's proposal for the pilot program.

(h) Expansion of pilot programs. VA may expand a pilot program consistent with this paragraph (h).

(1) VA may expand the scope or duration of a pilot program if, based on an analysis of the data developed pursuant to paragraph (g) of this section for the pilot

program, VA expects the pilot program to reduce spending without reducing the quality of care or improve the quality of patient care without increasing spending. Expansion may only occur if VA determines that expansion would not deny or limit the coverage or provision of benefits for individuals under 38 U.S.C. chapter 17. Expansion of a pilot program may not occur until 60 days after VA has published a document in the Federal Register and submitted an interim report to Congress stating its intent to expand a pilot program.

(2) VA may expand the scope of a pilot program by modifying, among other elements of a pilot program, the range of services provided, the qualifying conditions covered, the geographic location of the pilot program, or the population of eligible participants in a manner that increases participation in or benefits under a pilot program.

(3) In general, pilot programs are limited to 5 years of operation. VA may extend the duration of a pilot program by up to an additional 5 years of operation. Any pilot program extended beyond its initial 5-year period must continue to comply with the provisions of this section regarding evaluation and reporting under paragraph (g) of this section.

(i) Modification of pilot programs. The Secretary may modify elements of a pilot program in a manner that is consistent with the parameters of the Congressional approval of the waiver described in paragraph (e) of this section. Such modification does not require a submission to Congress for approval under paragraph (e) of this section.

(j) Termination of pilot programs. If VA determines that a pilot program is not producing quality enhancement or quality preservation, or is not resulting in the

reduction of expenditures, and that it is not possible or advisable to modify the pilot program either through submission of a new waiver request under paragraph (e) of this section or through modification under paragraph (i) of this section, VA will terminate the pilot program within 30 days of submitting an interim report to Congress that states such determination. VA will also publish a document in the Federal Register regarding the pilot program's termination.

[FR Doc. 2019-23484 Filed: 10/24/2019 8:45 am; Publication Date: 10/25/2019]