



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: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its regulations that govern VA health care. This rule would establish 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: Comments must be received on or before **[insert date 30 days after the date of publication in the FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted through <http://www.Regulations.gov>; by mail or hand-delivery to: Director, Office of Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue, North West, Room 1064, Washington, DC 20420; or by fax to (202) 273-9026. (This is not a toll-free telephone number.) Comments should indicate that they are submitted in response to “RIN 2900-AQ56 Center for Innovation for Care and Payment.”

Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1064, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free telephone number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.Regulations.gov>.

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. Section 1703E(a)(1) establishes the Center for Innovation for Care and Payment (the Center). Section 1703E(a)(2) authorizes the conduct of 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, and subsection (a)(3) requires VA to determine whether such models improve access to, and quality, timeliness, and patient satisfaction of care and services, and create cost savings for VA. Section 1703E(a)(4)

requires that VA test a model in a location where VA determines that the model will address deficits in care (including poor clinical outcomes or potentially avoidable expenditures) for a defined population; it further directs VA to focus on models VA expects to reduce program costs while preserving or enhancing the quality of care received by individuals receiving benefits under chapter 17 of title 38, United States Code. Under section 1703E(a)(4)(C), VA could select those models described in 42 U.S.C. 1315a(b)(2)(B), the authority for the Center for Medicare and Medicaid Innovation. In selecting models for testing, section 1703E(a)(5) permits VA to consider a number of different factors, including whether the model includes a regular process for monitoring and updating patient care plans in a manner that is consistent with the needs and preferences of individuals receiving benefits under chapter 17; whether the model places the individual receiving benefits under chapter 17 (including family members and other caregivers of such individual) at the center of the care team of such individual; whether the model uses technology or new systems to coordinate care over time and across settings; and whether the model demonstrates effective linkage with other public sector payers, private sector payers, or statewide payment models. Section 1703E(a)(6) states that VA may not design models in such a way that would allow the United States to recover or collect reasonable charges from other Federal health care programs, such as Medicare, Medicaid, or TRICARE.

Section 1703E(b) provides that pilot programs must be terminated no later than five (5) years after they begin. Section 1703E(c) directs VA to ensure that each pilot program carried out under this section occurs in an area or areas appropriate for the intended purposes of the pilot program; to the extent practicable, VA should ensure that

pilot programs are located in geographically diverse areas. Section 1703E(d) states that funding for each pilot program must come from appropriations provided in advance in appropriations acts for the Veterans Health Administration (VHA) and information technology systems. Section 1703E(e) requires VA publish information about each pilot program in the Federal Register and to take reasonable actions to provide direct notice to veterans eligible to participate in such pilot programs.

Section 1703E(f) allows VA to waive requirements in subchapters I, II, and III of chapter 17, title 38, U.S.C., as VA determines necessary for the purposes of carrying out pilot programs under this section. Before waiving any such authority, VA will submit to Congress a report on a request for a waiver that describes the specific authorities to be waived, the standard or standards to be used in lieu of the waived authorities, the reasons for such waiver or waivers, and other matters including metrics, cost estimates (both budgets and savings), and schedules.

Section 1703E(g) imposes several restrictions on VA's authority under this section, notably limiting the number of pilot programs (10) that can be carried out concurrently, requiring VA to submit the first pilot program proposal to Congress within 18 months of the enactment of the Caring for Our Veterans Act of 2018 (June 6, 2018), and requiring VA to either modify or terminate a pilot program if VA determines it is not improving the quality of care or producing cost savings. Section 1703E(h) requires VA to conduct an evaluation of each pilot program, and section 1703E(i) requires VA to obtain advice from the Under Secretary for Health and the Special Medical Advisory Group in the development and implementation of any pilot program. VA must also consult representatives of relevant Federal agencies, and clinical and analytical experts

with expertise in medicine and health care management. Finally, section 1703E(j) authorizes VA to expand, through rulemaking, successful pilot programs in duration or scope.

This proposed rule would implement the mandates and authorities of section 1703E, as added by the VA MISSION Act of 2018, by establishing a new § 17.450.

Proposed paragraph (a) would establish the purpose for this section and the organization of the Center. Proposed paragraph (a)(1) would explain that the Center for Innovation for Care and Payment will 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. This would be consistent with section 1703E(a)(2). We would further state that the Center for Innovation for Care and Payment will be operationally independent from any of VA's three administrations and will be responsible for collaborating across VA to develop and implement pilot programs under this section. As further explained in proposed paragraphs (a)(2)-(3), being operationally independent refers to the decision-making authority of the Center regarding the strategic, procedural, and tactical aspects of managing the pilot programs under this section. To ensure the limited number (10) of concurrent pilot programs under this section are not redundant or conflicted by ongoing innovation efforts within any specific administration, the Center for Innovation for Care and Payment will not operate within any specific VA administration but will operate in VA's corporate portfolio.

We are strategically positioning the Center as operationally independent to focus on envisioning veteran care and payment requirements in the distant future and

preparing VA to meet the needs of veterans today, as well as in the future; in 2045, for example, the population of veterans in the United States is projected to decline to 12 million. Of the approximately 20 million veterans alive today, VA provides health care for approximately 7 million unique patients each year, including approximately 1 million unique non-veterans. If current trends hold, we anticipate that by 2045, VA would be providing health care to approximately 3.6 million unique veteran patients each year. As such, we anticipate VA would need to re-imagine its current approach to furnishing services and payments for the veterans it hopes to serve in 2045. For the Center to be positioned for success in its mission to re-imagine VA's current approach to furnishing services and payments for veterans, it must enjoy strategic and operational independence from existing processes. In the commercial market, innovation efforts led by incumbents or large enterprises are rarely responsible for creating sustainably disruptive solutions that revolutionize the products or services of the incumbent. This is to be expected, because any new solution that threatens the viability or market position of established products or services is ultimately stifled by the enterprise focus on the near-term objectives of sustaining current products and services in lieu of investing additional time and resources in emerging solutions that could revolutionize product and service offerings to significantly benefit the organization's customers. We believe that creating an autonomous, independent organization with its own brand is the best way to enable corporate innovation to thrive. Autonomy does not mean the Center would work in isolation. 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.

Proposed paragraph (b) would define the terms for this section.

Proposed paragraph (b) would define the term access. Section 1703E(a)(3)(A) directs VA to test payment and service delivery models to determine whether such models improve access to, and quality, timeliness, and patient satisfaction of care and services. Because VA will be testing models to determine whether they improve access, it is important to define the term. We propose to define access as entry into or use of VA services. Entry into would refer to basic eligibility and enrollment, while use of services would refer to the actual receipt of care and services. Access to care is dependent on both availability and adequacy of services as well as barriers (e.g., financial, cultural, etc.) that may interfere with utilization of available services. See Gulliford, M. et al., What Does “Access to Care” Mean? *Journal of Health Services Research and Policy* (2002), available at <https://www.ncbi.nlm.nih.gov/pubmed/12171751>.

We recognize that our beneficiaries face various issues affecting access, including lack of availability of VA services in a specific geographic area or barriers to obtaining care for specific populations. As such, we believe this comprehensive interpretation of access would be of greatest benefit to veterans affected by pilot programs conducted by the Center.

Proposed paragraph (b) would define the term patient satisfaction of care and services to mean the patients’ rating of their experiences of care and services and as further defined in a pilot program proposal. In addition to requiring that we test payment and service delivery models to determine whether they improve access and timeliness, section 1703E(a)(3)(A) also requires that we assess whether the models improve

patient satisfaction, which is a critical indicator of service quality and patient-centric care. The health care industry standard is to assess patients' perception of their health care experience using the Consumer Assessment of Health Providers and Systems (CAHPS) survey, which has been in use since the mid-1990s. For example, the Centers for Medicare and Medicaid Services (CMS) has adopted CAHPS for care delivered in multiple care settings. Each CAHPS survey produces several measures of patient experience. These measures include composite measures, which combine two or more related survey items; rating measures, which reflect respondents' ratings on a scale of 0 to 10; and single-item measures. Measuring patient experience measures what is important to the patient: access, service, and communication. For years VA has been measuring patient satisfaction by focusing on patient experience. VA uses CAHPS to measure veterans' experience of care for outpatient care and VA's Survey of Healthcare Experience of Patients (SHEP) to measure inpatient experience of care. SHEP has been in use for many years and uses the same questions as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), a standardized, nationally-used, public survey that measures inpatient experience of care.

We believe that using these types of patient experience of care measures would be in line with health care industry standards and VA existing practices and would ensure that veterans and providers alike are not burdened with new types of assessments or surveys. In addition, measuring patient perceptions by using the industry-accepted patient experience of care would allow veterans to better understand how the care provided by VA compares to that provided outside of VA by having

equivalent data to make comparisons, as well as how care furnished through the pilot compares with care furnished outside the pilot.

Proposed paragraph (b) would define the term payment models. Section 1703E(a)(2) authorizes VA to carry out innovative approaches to testing payment and service delivery models to reduce expenditures while preserving or enhancing the quality of care furnished by VA. Innovative payment models incorporate different types of arrangements that help lower cost while maintaining or improving the quality of services. We therefore propose to state that the term payment models refers to the types of payment, reimbursement, or incentives that VA deems appropriate for advancing the health and well-being of beneficiaries. Use of the term incentive indicates anything that is intended to motivate service providers to perform better or deliver services in a more favorable manner, which is consistent with the usual dictionary definition. While the term payment models is specifically applicable to service providers, we note that VA could use incentives for patients or other beneficiaries; such an approach would need to be developed through a pilot program proposal.

Proposed paragraph (b) would define the term pilot program to refer to a pilot program conducted under proposed § 17.450. VA operates programs on a pilot or temporary basis under authorities other than section 1703E, but because these regulations only implement that authority and place requirements or restrictions, or authorize certain functions under section 1703E, we propose to define the term here to avoid any impression that the proposed § 17.450 extends those requirements, restrictions, or authorities to other VA initiatives operated under separate legal authorities.

We aim, through testing innovative payment and service delivery models, to discover novel and innovative ways to deliver services that enhance the quality of care for beneficiaries. Section 1703E(a)(2) refers to testing payment and service delivery models to reduce expenditures while preserving or enhancing the quality of care. We propose to use the term quality enhancement to refer to enhancing the quality of care. We propose in paragraph (b) to state that quality enhancement refers to improvement or improvements in such factors as clinical quality, beneficiary-level outcomes (for example, symptom burden), and functional status, which is indicative of an individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being as documented by improvements in measurement data from a reliable and valid source, such as the electronic health record, and as further defined in a pilot program proposal. Quality enhancements are multi-faceted, and measurements on such enhancements would be tailored to the specific area tested by a pilot program and would be defined in VA's proposal, as required by section 1703E(f)(2)(D).

Similarly, we propose to define quality preservation in paragraph (b) to refer to the maintenance of such factors as clinical quality, beneficiary-level outcomes, and functional status as documented through measurement data from an evidence-based source, and as further defined in a pilot program proposal. Maintenance in this sense would mean continued, sustained, or improved performance by the patient along several dimensions of care as demonstrated by the types of factors described above and as documented through an evidence-based source. Like quality enhancement, specific measurements would be defined in VA's proposal.

We propose to define in paragraph (b) reduction in expenditure. Section 1703E(a)(2) authorizes VA to test payment and service delivery models that lead to a reduction in expenditures while enhancing or preserving the quality of care furnished by VA. Some innovative models will require upfront investment and additional resources that might increase associated expenditures in the near term, but we anticipate the rise in expenditures will be mitigated by corresponding improvements in outcomes and value creation over time. Value creation could occur in multiple scenarios such as through cost reduction, cost avoidance, or reallocation of resources to alternative, higher-value activities. For example, investing in a system that reduces unnecessary or duplicative testing could lead to long term cost avoidance. For these reasons, we propose to state that reduction in expenditure refers to, but is not limited to, cost stabilization, cost avoidance, and/or decreases in long- or short-term spending and as further defined in a pilot program proposal. We would not limit reduction in expenditures to cost stabilization, cost avoidance, and/or decreases in long- or short-term spending in case there are other methods for determining that VA's expenditures have been reduced that do not fit within any of the descriptions above. In considering the impact of a pilot program on expenditures, VA will estimate how the proposal is anticipated to impact VA expenditures and also consider the proposal's potential impact on expenditures for other related Federal programs.

In proposed paragraph (b), we would state that the term service delivery models refers to all methods or programs for furnishing care and services. Section 1703E(a)(2) authorizes VA to develop innovative approaches to testing payment and service delivery models to reduce expenditures while preserving or enhancing the quality of care.

Health care services can be delivered by either VA staff or by non-VA entities or providers, as well as through different modalities (like telehealth) or different models (like VA's Patient-Aligned Care Teams) and the definition proposed here would capture all potential modalities and models for furnishing services and would be the common understanding of this phrase. The term service delivery model generally includes any method for furnishing services, and we believe this is intended to apply broadly given the range of services and support that VA provides to different beneficiaries.

In proposed paragraph (c), we would establish the procedures VA would use to determine the geographic locations where pilot programs would be conducted. Sections 1703E(a)(4)(A) and 1703E(c) require VA to test models and pilot programs in locations where there are deficits in care while ensuring that pilot programs are in geographically diverse areas of the United States. Because different beneficiary populations may have different needs depending on where they live, we believe that geographic location will play a critical role in the design of any pilot program. However, VA cannot yet define the specific factors that we would use to select geographic locations for specific pilot programs. We anticipate the basis for these decisions will vary based upon the goals and objectives of each specific pilot program. For example, if VA were to test a new payment methodology, it may be more appropriate to test it in a portion of the country where providers are already accustomed to being paid in alignment with that model. While market readiness would not serve as the sole reason for geographic location selection, it could be a key factor in selecting specific markets in which to test specific pilot programs. Consequently, we would state in proposed paragraph (c) that VA would 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. We would identify the proposed geographic locations for each pilot program, the rationale for those decisions, and how we believe the selected locations would address deficits in care for a defined population in VA's proposal to Congress to operate the pilot program and a document in the Federal Register.

Proposed paragraph (d) would define limitations on the authority of the Center. These limitations would only apply to pilot programs under this section. Again, VA operates pilot programs under different authorities, and these limits would not affect such other pilot programs, nor would these other pilot programs affect the activities of the Center. Section 1703E(g) establishes several of VA's limitations in carrying out pilot programs through the Center. Section 1703E(g)(1) states that VA may not carry out more than 10 pilot programs concurrently. We propose to interpret this in paragraph (d)(1) to mean that VA cannot actively operate more than 10 pilot programs at one time. Conducting pilot programs requires advance preparation, as well as data analysis following the completion of a pilot program. VA proposes to exclude the time involved with this preparatory and post-program analysis by considering the operation of a pilot program as only the time of active operation. This would ensure that VA is able to operate the maximum number of pilot programs at any one time and mitigate potential delays to launching new pilot programs that could improve quality and reduce cost during the preparatory and post-pilot analysis effort of other pilot programs.

In proposed paragraph (d)(2), we would state that, unless VA determines it to be necessary and informs the appropriate Committees of Congress, VA would not obligate

more than \$50 million in any fiscal year to operate all the pilot programs under this section. This is consistent with section 1703E(d) and section 1703E(g)(2), which state that, subject to notification and approval conditions, VA may not expend more than \$50 million in any fiscal year in the conduct of the pilot programs operated under this section. Funding required to operate the pilot programs includes all administrative and overhead costs, including measurement and evaluation, as well as the funding required to implement the specific payment or service delivery models being tested. We propose to interpret the term “expend” under section 1703E(g)(2) to mean “obligate.” This interpretation accounts for the legal requirement to record obligations that may result in immediate or future expenditures (outlays). An “obligation” is a definite commitment that creates a legal liability for payment. At the time that VA incurs a liability (e.g., signing a contract) it records the full amount of its legal liability against currently-available funds pursuant to the recording statute, 31 U.S.C. 1501(a)(1). The timing of the incurrence of an obligation is generally within the agency’s control, while the timing of the liquidation of the obligation is largely outside of the agency’s control, due to factors such as contractor performance and billing. Thus, interpreting “expend” to mean “outlay” rather than “obligate” would frustrate the legislative intent of authorizing up to \$50 million per fiscal year to carry out the pilot programs. We note that paragraph (d)(2) would not condition VA’s obligation of more than \$50 million upon approval of the Chairmen of the Committees on Veterans’ Affairs of the House of Representatives and the Senate, as is contemplated in section 1703E(g)(2)(B)(iii). As noted in the President’s Signing Statement, issued upon enactment of the VA MISSION Act of 2018, under the separation of powers, the Congress may not make the approval of Members

of Congress a precondition to the execution of the law. See Statement of the President, June 6, 2018, available online: <https://www.whitehouse.gov/briefings-statements/statement-by-the-president-3/>. VA, accordingly, treats the section 1703E(g)(2)(B)(iii) approval requirement as advisory and non-binding, but may submit the required report to the appropriate Congressional Committees before exceeding the spending cap, if VA determines that the additional expenditure is necessary to carry out the pilot programs. For the public's awareness, coordination and approval of funding sources under section 1703E(d) for pilot programs will occur prior to public notice.

In proposed paragraph (e), we would define VA's waiver authority to conduct pilot programs. Section 1703E provides a unique ability for VA, temporarily and in certain locations, to amend effectively its statutory authority when carrying out pilot programs under this section. Specifically, section 1703E(f)(1) allows VA to waive any provisions of law in subchapters I, II, and III of chapter 17, title 38 U.S.C., i.e., sections 1701 through 1730C, as VA determines necessary solely for the purposes of carrying out this section with respect to testing models. However, VA cannot unilaterally waive these authorities; it must propose a waiver and describe a proposed pilot program in a report to Congressional leadership, and only upon Congress' approval may VA carry out the pilot program. VA must submit the first request for a waiver by December 6, 2019, as required by section 1703E(g)(3).

Proposed paragraph (e) would clarify VA's authority regarding the waiver provisions in section 1703E(f). In proposed paragraph (e), we would state that VA's waiver authority includes both the authority to propose the removal of provisions of law or the addition of provisions of law. VA is a creature of law, and thus only has the

authority granted to it by statute. Some statutes are restrictive, in that they provide a general authority and then place conditions upon the use of that authority. For example, section 1705 of title 38, U.S.C., defines VA's patient enrollment system and identifies those veterans who are eligible to enroll and in which priority group such veterans will be enrolled. Under this authority, VA could propose to waive some specific provision of law by proposing to act as though such language that is in the statute were not there. At the same time, because VA is limited by its legal authority to only carry out those functions authorized by law, we propose to include in VA's waiver authority the ability to include additional language creating new authority for VA to act, or restricting language currently authorizing or requiring VA to act. For example, section 1708 of title 38, U.S.C., authorizes VA to provide temporary lodging in certain situations and for certain persons. VA could use this waiver authority to propose to include additional groups of eligible beneficiaries under this regulation.

We propose to allow VA to propose new or different standards under the waiver authority of section 1703E(f). We believe this is authorized by section 1703E(f)(1), which authorizes VA to waive such requirements in subchapters I, II, or III of chapter 17 of title 38, U.S.C. These requirements, as explained above, may either be explicit, which would require their removal, or implicit, which would require the addition of further language. Moreover, we believe this interpretation is further supported by section 1703E(f)(2)(B), which requires VA, in proposing the waiver of authority for a pilot program, to identify the standard or standards to be used in the pilot program in lieu of the waived authorities. We believe this language authorizes VA both to suggest additional standards or the removal of standards as well. We believe that if Congress or

the public disagreed with the scope of this authority, Congress could simply choose to not approve VA's waiver request, so there is little to no risk associated with this interpretation.

We also would state that VA may propose to waive any provision of law in any provision codified in or included as a note to any section in subchapters I through III of chapter 17, title 38, U.S.C. Some laws are codified in a title of the United States Code. For example, section 1710 of title 38, U.S.C., defines eligibility for hospital, nursing home, and domiciliary care. Other laws are not codified but are included as notes to codified provisions when they deal with similar or general subject matters. For example, section 205 of Public Law 111-163 established a pilot program on assistance for child care for certain veterans receiving health care. Section 205 of Public Law 111-163 is included as a note to section 1710 of title 38, U.S.C. Proposed paragraph (e) would allow VA to propose to waive provisions in either the text of section 1710 (for example, relating to eligibility for hospital, nursing home, or domiciliary care) or a note to section 1710 (for example, relating to the pilot program on assistance for child care for certain veterans receiving health care). We believe this is authorized by section 1703E(f)(1), which authorizes VA to waive such requirements in subchapters I, II, and III of this chapter. When citing to a public law that appears as a note to a codified provision of law, we include the U.S.C. section and identify this as a note; public laws are assigned as notes to codified provisions of law by the Office of the Law Revision Counsel in the U.S. House of Representatives. This recognizes that these public laws are requirements in, or at least related to, the section of law. We also believe that if Congress or the public disagreed with the scope of this authority, Congress could

simply choose to not approve VA's waiver request, so the risk associated with this interpretation is limited. In other words, if VA proposed to modify a note to a section of law and Congress did not think we had the authority to do that, or disagreed with VA on policy grounds, it would simply not approve the waiver request and the provision would not be waived.

Finally, in paragraph (e)(1), we propose, upon Congressional approval of a waiver of a provision of law under this section, that VA will also deem waived any applicable provision of regulation implementing such law as identified in VA's pilot program proposal. We believe this would be a necessary component to exercising the statutory authority granted by section 1703E(f)(1), which allows VA to waive "such requirements" in subchapters I, II, and III of chapter 17 as the Secretary determines necessary solely for the purposes of carrying out this section with respect to testing models. We believe regulations interpreting and implementing specific statutory provisions in subchapters I, II, and III are "requirements" within the context of this authority. It would be paradoxical for VA to test innovative approaches to payment and service delivery if VA could waive provisions of statute but not corresponding, and potentially more limiting, regulations promulgated by VA. For example, if VA proposed to waive a provision in section 1712 concerning dental care, and Congress approved such a proposal, VA could also waive any regulatory requirements (such as those found in 38 CFR 17.160) that implemented the provision of law waived by VA through the pilot program.

Under proposed paragraph (e)(2), VA would publish a document in the Federal Register with information about, and soliciting public comment on, each proposed pilot

program so that the public has an opportunity to comment on VA's proposals while Congressional approval is pending. VA would then publish a document in the Federal Register to inform the public of any approved pilot programs, as required by section 1703E(e)(1). While this is not required by law, we believe this would be prudent practice to ensure that the public also has an opportunity to submit comments directly to VA regarding pending pilot program proposals and to inform their Members of Congress if they have any issues or concerns so that Congress can appropriately decide whether or not to approve a requested waiver of authority for the Center.

Under proposed paragraph (f), VA would establish procedures regarding notice of eligibility requirements. Specifically, we would state that VA would take reasonable actions to provide direct notice to veterans eligible to participate in pilot programs operated under this section and would provide general notice to other individuals eligible to participate in a pilot program. We would further state that VA also would announce methods of notice in the Federal Register document published by VA for each proposed and approved pilot program. While section 1703E(e)(2) directs VA to take reasonable actions to provide direct notice to veterans eligible to participate in such pilot programs, we note that other provisions in section 1703E refer more broadly to individuals that are eligible for benefits. See, e.g., 1703E(a)(4)(B), (a)(5)(A)-(B), (j)(2). Consequently, we read the requirement in section 1703E(e)(2) to create an obligation to take reasonable actions to provide direct notice to veterans eligible to participate in pilot programs on the assumption that VA would have more information about veterans, while VA would provide general information to notify any other individuals eligible to participate in a pilot program. For example, one pilot program could expand access to

benefits for family members or caregivers of veterans; in this case, VA would provide notice to the veterans in the area where the pilot program is operating and would provide other general information as well to reach the caregivers or family members. Another example would be a pilot program involving certain community providers or other private entities; VA would provide general information to the community so that interested parties could inquire or participate. The exact nature of the notice will vary depending upon the type of pilot program involved, and so VA will announce how it intends to inform the public, in particular, other eligible individuals and entities, through the document it publishes in the Federal Register for each pilot program. Other forms of more direct communication could include mailed letters, emails, announcements to local Veterans Service Organizations, and posting of information on the websites of VA medical centers, the VA Innovation Center website, and other online sources.

In proposed paragraph (g), VA would describe generally how it would evaluate and report on the pilot programs. Specifically, VA would evaluate each pilot program operated under this section and report its findings. Section 1703E(h) requires VA to conduct an evaluation of each model tested, including at a minimum an analysis of the quality of care furnished and the changes in spending because of that model. VA is required to make the results of the tested model available to the public in a timely fashion. Once again, because each pilot program will vary in terms of the specific outcomes involved and how it will achieve those outcomes, VA is not proposing a discrete list of measures, but will include more specific information with each proposal for a pilot program. VA proposes to base its evaluation of pilot programs on quantitative data, qualitative data, or both, depending upon the nature of the pilot program. Different

types of data may be more appropriate for different pilot program models, but each type of data is instructive and could help VA determine if VA is improving access to, and the quality, timeliness and patient satisfaction of care and services, as well as creating cost savings for VA. Whenever appropriate, such evaluation will also include a survey of participants or beneficiaries to determine their satisfaction with the pilot program; this participant feedback likely would be subject to the Paperwork Reduction Act and would provide direct input regarding the effects of the pilot program. We propose to make the evaluation results available to the public on the VA Innovation Center website at <https://www.innovation.va.gov/>. The schedule of the release will be indicated in the proposal for each pilot program. By law, VA is required to make the results of the tested model available to the public in a timely fashion, but we again note that each model will naturally have different lengths of time for data collection and analysis. Some pilot programs may allow for real-time, or close to real-time reporting of information (for example, costs or number of appointments), while others may experience lags between an action under the pilot program and health outcomes (for example, 6-month or 12-month morbidity or mortality data). VA will identify the measures and timelines for public reporting in its pilot program proposal submission to Congress and its document in the Federal Register.

In proposed paragraph (h), VA would establish a process in regulation for the expansion of pilot programs. Section 1703E(j) authorizes VA through rulemaking to expand in scope or duration, including nationwide implementation, pilot programs if the expansion is expected to reduce spending without reducing the quality of care, or to improve the quality of patient care without increasing spending. Furthermore, VA is only

permitted to expand a pilot program if the pilot program does not deny or limit the coverage or provision of benefits for individuals under chapter 17. We propose to establish through regulation a general process for expanding the scope or duration of pilot programs instead of requiring separate rulemakings for each expansion for several reasons. First, the promulgation of regulations is a lengthy process, taking on average 18-22 months for a proposed and final rule to be published and effective. Given the limitations on the length of time a pilot program could operate under this authority of only 5 years, this would effectively require VA to decide at the halfway point of a pilot program, and possibly before that, as to whether or not to expand. This may not be enough time for VA as a practical matter, which could either lead to the expansion of pilot programs that ultimately prove unsuccessful or the inability to expand pilot programs that do prove to be successful. Second, if VA were required to publish new regulations for each pilot program it wished to expand, VA's regulations would become cluttered with rules that would only be applicable for limited periods of time and locations. This would likely result in confusion regarding these provisions. Finally, we believe that by regulating the process we would use to expand pilot programs, we are meeting the requirements of the law, which does not expressly require VA proceed through notice and comment rulemaking for each expansion, but merely states that VA may expand pilot programs "through rulemaking". This requirement merely obligates VA to allow the public to comment on how expansion would occur, which this proposal would do. Moreover, and as further discussed below, VA is taking other measures to provide the public and Congress an opportunity to review and comment on VA's

proposal for expansion, which we believe would result in an opportunity for feedback similar to a subsequent notice and comment rulemaking.

Initially, we propose in paragraph (h)(1) that VA would only meet the statutory requirement of expecting a pilot program to reduce spending without reducing the quality of care or to improve the quality of patient care without increasing spending based upon an analysis of the data collected for the specific pilot and developed pursuant to proposed paragraph (g). VA also would have to provide such results to Congress through an interim report and to the public through a document in the Federal Register. This would be consistent with the general structure of the Center's authority, as any decisions regarding expansion would have to be based on publicly available data. Similarly, VA would have to decide that expansion would not deny or limit the coverage or provision of benefits for individuals under chapter 17. This is a statutory requirement, and VA's basis for making this determination would be available for public scrutiny prior to any expansion taking place. VA would propose that it would not expand a pilot program until 60 days after submitting an interim report to Congress and publishing a document in the Federal Register regarding its intent to expand a pilot program. This would provide Congress and the public 60 days to evaluate the data VA would be using as the basis for such an expansion. In the event the public or Congress do not believe the data support expansion, they would have this time to inform VA of such views. Upon the completion of the 60-day period, if VA still finds that the statutory prerequisites for expansion have been met, VA could expand a pilot program in either scope or duration, as noted below.

Proposed paragraph (h)(2) would define how VA could expand a pilot program in scope. Proposed paragraph (h)(2) would authorize VA to 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. These are the general dimensions that we believe could be expanded, as that term is used in section 1703E(j). Expansion is generally defined to mean becoming larger or more extensive, and these are the likely areas of a pilot program that could become larger or more extensive. For example, if VA were conducting a pilot program related to mental health services in Alaska for homeless veterans, and VA proposed to expand the pilot under paragraph (h)(1), VA could expand to include new beneficiary populations (e.g., non-homeless veterans), conditions (e.g., additional health services), or geographic locations (e.g., outside Alaska), among others. We would permit some flexibility in the forms that expansion could occur in case there are features of a pilot program that could be made larger or more extensive that do not fall within one of these categories. Again, without knowing exactly what pilot programs will be proposed, we are unable now to state definitively in what ways we could expand such a pilot program.

In proposed paragraph (h)(3), we propose the conditions under which VA could extend the duration of a pilot program. In general, section 1703E(b) limits pilot programs to 5 years of operation. Section 1703E(j)(1), however, authorizes VA to extend the duration of a pilot program if the conditions for expansion discussed above are also met. We propose to authorize VA to extend the duration of a pilot program for

up to an additional 5 years. Such extension would be subject to the same requirements related to the evaluation and reporting of data that would apply to a pilot program within the first 5 years of operation under proposed paragraph (g). We propose limiting the expansion of a pilot program to an additional 5 years because Congress recognized the potential for making successful pilots permanent in section 1703E(f)(2)(G) when it required VA to report on the feasibility and advisability of making a pilot program permanent, but there is no indication Congress intended to allow for pilot programs to run in perpetuity. Moreover, the very nature of a pilot program is that it has a beginning and an end date. Finally, on a practical and legal level, because pilot programs under this section would involve the waiver of one or more provisions of law, we believe it would create confusion over time if a pilot program were operated indefinitely without express statutory authority. We believe the balance of powers is best preserved when Congress affirmatively establishes VA's parameters through law.

In proposed paragraph (i), VA would establish its authority to make minor modifications to pilot programs approved by Congress. Section 1703E(g)(5)(A) establishes VA's options (proposing a modification to Congress for approval or terminating the pilot program) when the Secretary determines that a pilot program is not improving the quality of care or producing cost savings, but it and the rest of section 1703E are silent in terms of VA's authority to modify pilot programs when VA has not made a determination regarding whether the pilot program is improving the quality of care or producing cost savings. We anticipate there may be pilot programs that we operationalize in a way that becomes administratively difficult to continue; alternatively, some pilot programs may be operationalized in a way that does not produce clear data

that would allow VA to determine if the pilot program is improving the quality of care or producing cost savings. Under proposed paragraph (i), VA could modify the pilot program in a manner that is consistent with the parameters of Congressional approval without seeking further Congressional approval for the change. Modifications that would be consistent with the parameters of Congressional approval would vary based on each pilot program, but we offer a few examples for the public's understanding. For example, VA may plan to operate a pilot program in a particular location, but later determine that this location is unsuitable for reasons beyond VA's control. For example, an anticipated pilot site may be unavailable due to a natural disaster, or interest in participation in the pilot program may be inadequate to support valid results. In these cases, it would seem a poor use of government resources to continue attempting to operate the pilot program while waiting for a subsequent Act of Congress to allow VA to select another location. As another example, VA may want to conduct a pilot program offering a particular service, but VA may later determine this service is not appropriate while another similar service would be. VA plans to submit proposals to Congress that provide it enough information to know what it is authorizing, while still providing some flexibility for VA to address potential minor corrections without further Congressional approval. In identifying geographic locations for the pilot program under paragraph (c) of this section, for example, rather than identifying specifically the VA medical centers or facilities that would participate, we anticipate providing the general criteria VA will use to identify locations (e.g., urban areas, rural areas, highly rural areas; areas near military bases; facilities with academic affiliates, etc.) and possibly a list of facilities that could meet those requirements. This would allow VA to select another suitable location if

needed. Similarly, for services that VA might provide, or populations of beneficiaries that might be included, we would attempt to describe these generally enough to allow for further modification as needed to either specify another service or another population. We are sensitive to Congress' need to conduct oversight and to understand clearly what it is authorizing when it approves a waiver, and so we limit VA's ability to modify a pilot program to changes that are consistent with the parameters of Congress' initial approval. VA could not, for example, modify a Congressionally approved pilot program on beneficiary travel to become a pilot program on the provision of care to beneficiaries otherwise ineligible for VA care. Such a change would clearly be outside the parameters of Congress' initial approval.

In proposed paragraph (j), we would define the conditions for termination of pilot programs. As noted before, section 1703E(g)(5)(A) establishes that, when the Secretary determines that a pilot program is not improving the quality of care or producing cost savings, VA's options include proposing a modification to Congress for approval or terminating the pilot program. In proposed paragraph (j), we would use the terms quality enhancement and quality preservation to reflect the statutory language related to improving the quality of care, and we would use the term reduction in expenditures to reflect the statutory language related to producing cost savings. These substitutions would be consistent with the terms as they would be defined through paragraph (b) of this section. We would also clarify that a modification that can only be achieved through submission of a new waiver request to Congress would be distinct from a modification under paragraph (i) of this section, as just discussed. Congress specifically recognized that not all pilot programs will meet or exceed their primary goals

of enhancing or preserving care while reducing costs. Under proposed paragraph (j), VA would, upon determining 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) or through modification under paragraph (i), terminate the pilot program within 30 days of submitting an interim report to Congress stating such determination. VA also would publish a document in the Federal Register regarding the pilot program's termination, and we would notify participants in the same manner that we notified them under paragraph (f) of their initial eligibility for the pilot program. This would ensure determinations regarding expansion and termination are made using the same methodology. This 30-day period is the maximum amount of time permitted by section 1703E(g)(5)(A)(ii).

Effect of Rulemaking

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

Paperwork Reduction Act

This rulemaking does not contain any provisions constituting collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would 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 proposed rule would 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. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” which requires review by the Office of Management and Budget (OMB), as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise

interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.”

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 proposed rule is not expected to be subject to the requirements of Executive Order 13771 because this proposed rule is expected to result in no more than de minimis costs.

Executive Order 12866 also directs agencies to “in most cases . . . include a comment period of not less than 60 days.” This regulation aims to test innovative payment and service delivery models that will maintain or enhance the quality of care for beneficiaries while reducing cost. Providing a 30-day comment period will allow VA to begin pilot programs more quickly, thereby increasing opportunities for access to quality, cost-effective care to participating beneficiaries. The regulations proposed here 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. Moreover, we believe that the requirement to receive Congressional approval for any

waiver of authority, and VA's proposal to publish specific pilot program proposals in the Federal Register for public comment while Congressional approval is pending, should provide the public a more meaningful opportunity to comment on the actual pilot programs implemented under section 1703E. For these reasons, we believe that 30 days would be a sufficient period of time for the public to comment on this rulemaking. In sum, providing a 60-day public comment period instead of a 30-day public comment period would be against public interest. For the above reasons, VA issues this rule with a 30-day public comment period. VA will consider and address comments that are received within 30 days of the date this proposed rule is published in the Federal Register.

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 proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

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, or designee, 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. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on April 10, 2019, for publication.

Dated: July 23, 2019

Consuela Benjamin,

Regulations Development Coordinator,
Office of Regulation Policy & Management,
Office of the Secretary,
Department of Veterans Affairs.

For the reasons set forth in the preamble, we propose to 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 to read in part as follows:

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

* * * * *

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

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2. Add an undesignated center heading immediately following § 17.417 to read as follows:

Center for Innovation for Care and Payment

3. Add a new § 17.450 to read as follows.

§ 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 operationally independent from any of VA's administrations and 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) For purposes of this paragraph (a), operational independence refers to the strategic, procedural, and tactical aspects of managing the pilot programs under this section.

(3) 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 section 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, upon Congressional approval, including waiving any provisions of law in any provision codified in or included as a note to any section in subchapters I, II, or III of chapter 17, title 38, U.S.C.

(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 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. 2019-15891 Filed: 7/26/2019 8:45 am; Publication Date: 7/29/2019]