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Medical

Book I

Title 38, Parts 17, 46, 47, 51–53,
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Supplement No. 125

Covering period of *Federal Register* issues
through November 1, 2019

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GENERAL INSTRUCTIONS

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Code of Federal Regulations

Title 38, Parts 17, 46, 47, 51–53, 58–64, 70, 71, and 200

Medical

Supplement No. 125

5 November 2019

Covering the period of Federal Register issues
through November 1, 2019

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FILING INSTRUCTIONS

**Book I, Supplement No. 125
November 5, 2019**

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I-17 to I-18

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§17.450

(adding 17.450)

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HIGHLIGHTS

Book I, Supplement No. 125 November 5, 2019

Supplement Highlights references: Where substantive changes are made in the text of regulations, the paragraphs of *Highlights* sections are cited at the end of the relevant section of text. Thus, if you are reading §17.100, you will see a note at the end of that section which reads: “Supplement *Highlights* references—37(1).” This means that paragraph 1 of the *Highlights* section in Supplement No. 37 contains information about the changes made in §17.100. By keeping and filing the *Highlights* sections, you will have a reference source explaining all substantive changes in the text of the regulations.

Supplement frequency: Beginning 1 January 2000, supplements for this Book I will be issued *every month* during which a final rule addition or modification is made to the parts of Title 38 covered by this book. Supplements will be numbered consecutively as issued.

Modifications in this supplement include the following:

1. On 25 October 2019, the VA published a final rule effective 25 November 2019, to adopt 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. Changes:

- Added §17.450.

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

Section 17.35 is also issued under 38 U.S.C. 1724

Section 17.38 is also issued under 38 U.S.C. 1703.

Section 17.46 is also issued under 38 U.S.C. 1710.

Section 17.52 is also issued under 38 U.S.C. 1701, 1703, 1710, 1712, and 3104.

Section 17.55 is also issued under 38 U.S.C. 513, 1703, and 1728.

Section 17.56 is also issued under 38 U.S.C. 1703 and 1728.

Sections 17.61 through 17.74, 38 U.S.C. 501, and as noted in specific sections.

Section 17.105 is also issued under 38 U.S.C. 501, 1721, 1722A, 1724, and 1725A.

Section 17.108 is also issued under 38 U.S.C. 501, 1703, 1710, 1725A, and 1730A.

Section 17.110 is also issued under 38 U.S.C. 501, 1703, 1710, 1720D, 1722A, and 1730A.

Section 17.111 is also issued under 38 U.S.C. 101(28), 501, 1701(7), 1703, 1710, 1710B, 1720B, 1720D, and 1722A.

Section 17.125 is also issued under 38 U.S.C. 7304

Section 17.169 is also issued under 38 U.S.C. 1712C.

Sections 17.380, 17.390 and 17.412 are also issued under sec. 260, Pub. L. 114-223, 130 Stat. 857 and §236, div. J, Pub. L 115-141, 132 Stat. 348.

Section 17.410 is also issued under 38 U.S.C. 1787.

Section 17.415 is also issued under 38 U.S.C. 7301, 7304, 7402, and 7403.

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

Sections 17.640 and 17.647 are also issued under sec. 4, Pub. L. 114-2, 129 Stat. 30.

Sections 17.641 through 17.646 are also issued under 38 U.S.C. 501(a) and sec. 4, Pub. L. 114-2, 129 Stat. 30.

Section 17.417 also issued under 38 U.S.C. 1701 (note), 1709A, 1712A (note), 1722B, 7301, 7330A, 7401-7403, 7406 (note).

Section 17.655 also issued under 38 U.S.C. 501(a), 7304, 7405.

Sections 17.4000 through 17.4040 also issued under 38 U.S.C. 1703, 1703B, and 1703C.

Section 17.4100 et seq. is also issued under 38 U.S.C. 1703A.

Section 17.4600 is also issued under 38 U.S.C. 1725A.

Ed. Note: Nomenclature changes to Part 17 appear at 61 FR 7216, Feb. 27, 1996

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(ii) The beneficiary is receiving services in a State other than the health care provider's State of licensure, registration, or certification;

(iii) The health care provider is delivering services in a State other than the health care provider's State of licensure, registration, or certification;

(iv) The health care provider is delivering services either on or outside VA property;

(v) The beneficiary is receiving services while she or he is located either on or outside VA property;

(vi) The beneficiary has or has not previously been assessed, in person, by the health care provider; or

(vii) Other State requirements would prevent or impede the practice of health care providers delivering telehealth to VA beneficiaries.

(c) *Preemption of State law.* To achieve important Federal interests, including, but not limited to, the ability to provide the same complete health care and hospital service to beneficiaries in all States under 38 U.S.C. 7301, this section preempts conflicting State laws relating to the practice of health care providers when such health care providers are practicing telehealth within the scope of their VA employment. Any State law, rule, regulation or requirement pursuant to such law, is without any force or effect on, and State governments have no legal authority to enforce them in relation to, this section or decisions made by VA under this section.

[83 FR 21906, May 11, 2018]

Supplement *Highlights* reference: 115(1).

§ 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.

[84 FR 57329, Oct. 25, 2019]

Supplement *Highlights* reference: 125(1).

[Reserved]

Confidentiality of Healthcare: Quality Assurance Review Records

Authority: 38 U.S.C. 5705.

Source: §§17.500-17.511 appear at 59 FR 53355, Oct. 24, 1994, unless otherwise noted.

§17.500 General.

(a) Section 5705, title 38, United States Code was enacted to protect the integrity of the VA's medical quality assurance program by making confidential and privileged certain records and documents generated by this program and information contained therein. Disclosure of quality assurance records and documents made confidential and privileged by 38 U.S.C. 5705 and the regulations in §§17.500 through 17.511 may only be made in accordance with the provisions of 38 U.S.C. 5705 and those regulations.

(b) The purpose of the regulations in §§17.500 through 17.511 is to specify and provide for the limited disclosure of those quality assurance documents which are confidential under the provisions of 38 U.S.C. 5705.

(c) For purposes of the regulations in §§17.500 through 17.511, the VA's medical quality assurance program consists of systematic healthcare reviews carried out by or for VA for the purpose of improving the quality of medical care or improving the utilization of healthcare resources in VA medical facilities. These review activities may involve continuous or periodic data collection and may relate to either the structure, process, or outcome of health care provided in the VA.

(d) Nothing in the regulations in §§17.500 through 17.511 shall be construed as authority to withhold any record or document from a committee or subcommittee of either House of Congress or any joint committee or subcommittee of Congress, if such record or document pertains to any matter within the jurisdiction of such committee or joint committee.

(e) The regulations in §§17.500 through 17.511 do not waive the sovereign immunity of the United States, and do not waive the confidentiality provisions and disclosure restrictions of 38 U.S.C. 5705. (Authority: 38 U.S.C. 5705)