

Subsec. (b)(7)(B). Pub. L. 111-148, §10304, which directed substitution of “quality and efficiency” for “quality” wherever appearing, was executed by substituting “Quality and efficiency” for “Quality” in subpar. heading to reflect the probable intent of Congress.

Subsec. (b)(7)(B)(i)(I). Pub. L. 111-148, §10322(b), inserted “1395ww(s)(4)(D),” after “1395ww(o)(2).”

Subsec. (b)(8). Pub. L. 111-148, §3014(a)(1), added par. (8).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2020 AMENDMENT

Pub. L. 116-136, div. A, title III, §3802(b), Mar. 27, 2020, 134 Stat. 427, provided that: “The amendments made by subsection (a) [amending this section] shall take effect as if included in the enactment of the Further Consolidated Appropriations Act, 2020 (Public Law 116-94).”

EFFECTIVE DATE OF 2019 AMENDMENT

Pub. L. 116-94, div. N, title I, §102(b), Dec. 20, 2019, 133 Stat. 3096, provided that: “The amendments made by subsection (a) [amending this section] shall take effect as if included in the enactment of the Further Continuing Appropriations Act, 2020, and Further Health Extenders Act of 2019 (Public Law 116-69).”

Pub. L. 116-69, div. B, title IV, §1401(b), Nov. 21, 2019, 133 Stat. 1138, provided that: “The amendments made by subsection (a) [amending this section] shall take effect as if included in the enactment of the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Public Law 116-59).”

EFFECTIVE DATE OF 2018 AMENDMENT

Pub. L. 115-123, div. E, title II, §50206(c)(2), Feb. 9, 2018, 132 Stat. 185, provided that: “The amendments made by this subsection [amending this section] shall apply to reports submitted for years beginning with 2019.”

§ 1395aaa-1. Quality and efficiency measurement

(a) Multi-stakeholder group input into selection of quality and efficiency measures

The Secretary shall establish a pre-rule-making process under which the following steps occur with respect to the selection of quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title:

(1) Input

Pursuant to section 1395aaa(b)(7) of this title, the entity with a contract under section 1395aaa of this title shall convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures described in subparagraph (B) of such paragraph.

(2) Public availability of measures considered for selection

Not later than December 1 of each year (beginning with 2011), the Secretary shall make available to the public a list of quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title that the Secretary is considering under this subchapter.

(3) Transmission of multi-stakeholder input

Pursuant to section 1395aaa(b)(8) of this title, not later than February 1 of each year (beginning with 2012), the entity shall transmit to the Secretary the input of multi-stakeholder groups described in paragraph (1).

(4) Consideration of multi-stakeholder input

The Secretary shall take into consideration the input from multi-stakeholder groups de-

scribed in paragraph (1) in selecting quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title that have been endorsed by the entity with a contract under section 1395aaa of this title and measures that have not been endorsed by such entity.

(5) Rationale for use of quality and efficiency measures

The Secretary shall publish in the Federal Register the rationale for the use of any quality and efficiency measure described in section 1395aaa(b)(7)(B) of this title that has not been endorsed by the entity with a contract under section 1395aaa of this title.

(6) Assessment of impact

Not later than March 1, 2012, and at least once every three years thereafter, the Secretary shall—

(A) conduct an assessment of the quality and efficiency impact of the use of endorsed measures described in section 1395aaa(b)(7)(B) of this title; and

(B) make such assessment available to the public.

(b) Process for dissemination of measures used by the Secretary

(1) In general

The Secretary shall establish a process for disseminating quality and efficiency measures used by the Secretary. Such process shall include the following:

(A) The incorporation of such measures, where applicable, in workforce programs, training curricula, and any other means of dissemination determined appropriate by the Secretary.

(B) The dissemination of such quality and efficiency measures through the national strategy developed under section 280j of this title.

(2) Existing methods

To the extent practicable, the Secretary shall utilize and expand existing dissemination methods in disseminating quality and efficiency measures under the process established under paragraph (1).

(c) Review of quality and efficiency measures used by the Secretary

(1) In general

The Secretary shall—

(A) periodically (but in no case less often than once every 3 years) review quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title; and

(B) with respect to each such measure, determine whether to—

- (i) maintain the use of such measure; or
- (ii) phase out such measure.

(2) Considerations

In conducting the review under paragraph (1), the Secretary shall take steps to—

(A) seek to avoid duplication of measures used; and

(B) take into consideration current innovative methodologies and strategies for quality and efficiency improvement prac-

tices in the delivery of health care services that represent best practices for such quality and efficiency improvement and measures endorsed by the entity with a contract under section 1395aaa of this title since the previous review by the Secretary.

(d) Rule of construction

Nothing in this section shall preclude a State from using the quality and efficiency measures identified under sections 1320b-9a and 1320b-9b of this title.

(e) Development of quality and efficiency measures

The Administrator of the Center for Medicare & Medicaid Services shall through contracts develop quality and efficiency measures (as determined appropriate by the Administrator) for use under this chapter. In developing such measures, the Administrator shall consult with the Director of the Agency for Healthcare Research and Quality.

(f) Hospital acquired conditions

The Secretary shall, to the extent practicable, publicly report on measures for hospital-acquired conditions that are currently utilized by the Centers for Medicare & Medicaid Services for the adjustment of the amount of payment to hospitals based on rates of hospital-acquired infections.

(g) Technical expert panel review of opioid and opioid use disorder quality measures

(1) In general

Not later than 180 days after October 24, 2018, the Secretary shall establish a technical expert panel for purposes of reviewing quality measures relating to opioids and opioid use disorders, including care, prevention, diagnosis, health outcomes, and treatment furnished to individuals with opioid use disorders. The Secretary may use the entity with a contract under section 1395aaa(a) of this title and amend such contract as necessary to provide for the establishment of such technical expert panel.

(2) Review and assessment

Not later than 1 year after the date the technical expert panel described in paragraph (1) is established (and periodically thereafter as the Secretary determines appropriate), the technical expert panel shall—

(A) review quality measures that relate to opioids and opioid use disorders, including existing measures and those under development;

(B) identify gaps in areas of quality measurement that relate to opioids and opioid use disorders, and identify measure development priorities for such measure gaps; and

(C) make recommendations to the Secretary on quality measures with respect to opioids and opioid use disorders for purposes of improving care, prevention, diagnosis, health outcomes, and treatment, including recommendations for revisions of such measures, need for development of new measures, and recommendations for including such measures in the Merit-Based Incentive Pay-

ment System under section 1395w-4(q) of this title, the alternative payment models under section 1395l(z)(3)(C) of this title, the shared savings program under section 1395jjj of this title, the quality reporting requirements for inpatient hospitals under section 1395ww(b)(3)(B)(viii) of this title, and the hospital value-based purchasing program under section 1395ww(o) of this title.

(3) Consideration of measures by Secretary

The Secretary shall consider—

(A) using opioid and opioid use disorder measures (including measures used under the Merit-Based Incentive Payment System under section 1395w-4(q) of this title, measures recommended under paragraph (2)(C), and other such measures identified by the Secretary) in alternative payment models under section 1395l(z)(3)(C) of this title and in the shared savings program under section 1395jjj of this title; and

(B) using opioid measures described in subparagraph (A), as applicable, in the quality reporting requirements for inpatient hospitals under section 1395ww(b)(3)(B)(viii) of this title, and in the hospital value-based purchasing program under section 1395ww(o) of this title.

(4) Prioritization of measure development

The Secretary shall prioritize for measure development the gaps in quality measures identified under paragraph (2)(B).

(5) Prioritization of measure endorsement

The Secretary—

(A) during the period beginning on October 24, 2018, and ending on December 31, 2023, shall prioritize the endorsement of measures relating to opioids and opioid use disorders by the entity with a contract under subsection (a) of section 1395aaa of this title in connection with endorsement of measures described in subsection (b)(2) of such section; and

(B) on and after January 1, 2024, may prioritize the endorsement of such measures by such entity.

(Aug. 14, 1935, ch. 531, title XVIII, §1890A, as added and amended Pub. L. 111-148, title III, §§3013(b), 3014(b), title X, §§10303(b), 10304, Mar. 23, 2010, 124 Stat. 383, 385, 938; Pub. L. 115-271, title VI, §6093, Oct. 24, 2018, 132 Stat. 4001.)

Editorial Notes

AMENDMENTS

2018—Subsec. (g). Pub. L. 115-271 added subsec. (g).

2010—Pub. L. 111-148, §10304, substituted “quality and efficiency” for “quality” wherever appearing in text.

Subsec. (e). Pub. L. 111-148, §3013(b), added subsec. (e).

Subsec. (f). Pub. L. 111-148, §10303(b), added subsec. (f).

§ 1395bbb. Conditions of participation for home health agencies; home health quality

(a) Conditions of participation; protection of individual rights; notification of State entities; use of home health aides; medical equipment; individual's plan of care; compliance with Federal, State, and local laws and regulations

The conditions of participation that a home health agency is required to meet under this subsection are as follows:

(1) The agency protects and promotes the rights of each individual under its care, including each of the following rights:

(A) The right to be fully informed in advance about the care and treatment to be provided by the agency, to be fully informed in advance of any changes in the care or treatment to be provided by the agency that may affect the individual's well-being, and (except with respect to an individual adjudged incompetent) to participate in planning care and treatment or changes in care or treatment.

(B) The right to voice grievances with respect to treatment or care that is (or fails to be) furnished without discrimination or reprisal for voicing grievances.

(C) The right to confidentiality of the clinical records described in section 1395x(o)(3) of this title.

(D) The right to have one's property treated with respect.

(E) The right to be fully informed orally and in writing (in advance of coming under the care of the agency) of—

(i) all items and services furnished by (or under arrangements with) the agency for which payment may be made under this subchapter,

(ii) the coverage available for such items and services under this subchapter, subchapter XIX, and any other Federal program of which the agency is reasonably aware,

(iii) any charges for items and services not covered under this subchapter and any charges the individual may have to pay with respect to items and services furnished by (or under arrangements with) the agency, and

(iv) any changes in the charges or items and services described in clause (i), (ii), or (iii).

(F) The right to be fully informed in writing (in advance of coming under the care of the agency) of the individual's rights and obligations under this subchapter.

(G) The right to be informed of the availability of the State home health agency hotline established under section 1395aa(a) of this title.

(2) The agency notifies the State entity responsible for the licensing or certification of the agency of a change in—

(A) the persons with an ownership or control interest (as defined in section 1320a-3(a)(3) of this title) in the agency,

(B) the persons who are officers, directors, agents, or managing employees (as defined

in section 1320a-5(b) of this title) of the agency, and

(C) the corporation, association, or other company responsible for the management of the agency.

Such notice shall be given at the time of the change and shall include the identity of each new person or company described in the previous sentence.

(3)(A) The agency must not use as a home health aide (on a full-time, temporary, per diem, or other basis), any individual to provide items or services described in section 1395x(m) of this title on or after January 1, 1990, unless the individual—

(i) has completed a training and competency evaluation program, or a competency evaluation program, that meets the minimum standards established by the Secretary under subparagraph (D), and

(ii) is competent to provide such items and services.

For purposes of clause (i), an individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of such a program, there has been a continuous period of 24 consecutive months during none of which the individual provided items and services described in section 1395x(m) of this title for compensation.

(B)(i) The agency must provide, with respect to individuals used as a home health aide by the agency as of July 1, 1989, for a competency evaluation program (as described in subparagraph (A)(i)) and such preparation as may be necessary for the individual to complete such a program by January 1, 1990.

(ii) The agency must provide such regular performance review and regular in-service education as assures that individuals used to provide items and services described in section 1395x(m) of this title are competent to provide those items and services.

(C) The agency must not permit an individual, other than in a training and competency evaluation program that meets the minimum standards established by the Secretary under subparagraph (D), to provide items or services of a type for which the individual has not demonstrated competency.

(D)(i) The Secretary shall establish minimum standards for the programs described in subparagraph (A) by not later than October 1, 1988.

(ii) Such standards shall include the content of the curriculum, minimum hours of training, qualification of instructors, and procedures for determination of competency.

(iii) Such standards may permit approval of programs offered by or in home health agencies, as well as outside agencies (including employee organizations), and of programs in effect on December 22, 1987; except that they may not provide for the approval of a program offered by or in a home health agency which, within the previous 2 years—

(I) has been determined to be out of compliance with subparagraph (A), (B), or (C);