

Federal laws, up to and including terminating Federal funding for non-compliant programs and activities.

(c) The Secretary shall, as appropriate and consistent with applicable law, prioritize the allocation of Department of Health and Human Services discretionary grant funding and National Institutes of Health research dollars for programs and activities conducting research to develop treatments that may improve survival—especially survival without impairment—of infants born alive, including premature infants or infants with disabilities, who have an emergency medical condition in need of stabilizing treatment.

(d) The Secretary shall, as appropriate and consistent with applicable law, prioritize the allocation of Department of Health and Human Services discretionary grant funding to programs and activities, including hospitals, that provide training to medical personnel regarding the provision of life-saving medical treatment to all infants born alive, including premature infants or infants with disabilities, who have an emergency medical condition in need of stabilizing treatment.

(e) The Secretary shall, as necessary and consistent with applicable law, issue such regulations or guidance as may be necessary to implement this order.

SEC. 4. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

§ 1395ee. Practicing Physicians Advisory Council; Council for Technology and Innovation

(a) **Repealed. Pub. L. 111-148, title III, § 3134(b)(2), Mar. 23, 2010, 124 Stat. 435**

(b) Council for Technology and Innovation

(1) Establishment

The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as “CMS”).

(2) Composition

The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

(3) Duties

The Council shall coordinate the activities of coverage, coding, and payment processes under this subchapter with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

(4) Executive Coordinator for Technology and Innovation

The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5) who shall serve as the Ex-

ecutive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this subchapter.

(c) Physician-focused payment models

(1) Technical Advisory Committee

(A) Establishment

There is established an ad hoc committee to be known as the “Physician-Focused Payment Model Technical Advisory Committee” (referred to in this subsection as the “Committee”).

(B) Membership

(i) Number and appointment

The Committee shall be composed of 11 members appointed by the Comptroller General of the United States.

(ii) Qualifications

The membership of the Committee shall include individuals with national recognition for their expertise in physician-focused payment models and related delivery of care. No more than 5 members of the Committee shall be providers of services or suppliers, or representatives of providers of services or suppliers.

(iii) Prohibition on Federal employment

A member of the Committee shall not be an employee of the Federal Government.

(iv) Ethics disclosure

The Comptroller General shall establish a system for public disclosure by members of the Committee of financial and other potential conflicts of interest relating to such members. Members of the Committee shall be treated as employees of Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95-521).

(v) Date of initial appointments

The initial appointments of members of the Committee shall be made by not later than 180 days after April 16, 2015.

(C) Term; vacancies

(i) Term

The terms of members of the Committee shall be for 3 years except that the Comptroller General shall designate staggered terms for the members first appointed.

(ii) Vacancies

Any member appointed to fill a vacancy occurring before the expiration of the term for which the member’s predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member’s term until a successor has taken office. A vacancy in the Committee shall be filled in the manner in which the original appointment was made.

(D) Duties

The Committee shall meet, as needed, to provide comments and recommendations to the Secretary, as described in paragraph (2)(C), on physician-focused payment models.

(E) Compensation of members**(i) In general**

Except as provided in clause (ii), a member of the Committee shall serve without compensation.

(ii) Travel expenses

A member of the Committee shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for an employee of an agency under subchapter I of chapter 57 of title 5 while away from the home or regular place of business of the member in the performance of the duties of the Committee.

(F) Operational and technical support**(i) In general**

The Assistant Secretary for Planning and Evaluation shall provide technical and operational support for the Committee, which may be by use of a contractor. The Office of the Actuary of the Centers for Medicare & Medicaid Services shall provide to the Committee actuarial assistance as needed.

(ii) Funding

The Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, such amounts as are necessary to carry out this paragraph (not to exceed \$5,000,000) for fiscal year 2015 and each subsequent fiscal year. Any amounts transferred under the preceding sentence for a fiscal year shall remain available until expended.

(G) Application

Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Committee.

(2) Criteria and process for submission and review of physician-focused payment models**(A) Criteria for assessing physician-focused payment models****(i) Rulemaking**

Not later than November 1, 2016, the Secretary shall, through notice and comment rulemaking, following a request for information, establish criteria for physician-focused payment models, including models for specialist physicians, that could be used by the Committee for making comments and recommendations pursuant to paragraph (1)(D).

(ii) MedPAC submission of comments

During the comment period for the proposed rule described in clause (i), the Medicare Payment Advisory Commission may submit comments to the Secretary on the proposed criteria under such clause.

(iii) Updating

The Secretary may update the criteria established under this subparagraph through rulemaking.

(B) Stakeholder submission of physician-focused payment models

On an ongoing basis, individuals and stakeholder entities may submit to the Committee proposals for physician-focused payment models that such individuals and entities believe meet the criteria described in subparagraph (A).

(C) Committee review of models submitted

The Committee, on a periodic basis—

(i) shall review models submitted under subparagraph (B);

(ii) may provide individuals and stakeholder entities who submitted such models with—

(I) initial feedback on such models regarding the extent to which such models meet the criteria described in subparagraph (A); and

(II) an explanation of the basis for the feedback provided under subclause (I); and

(iii) shall prepare comments and recommendations regarding whether such models meet the criteria described in subparagraph (A) and submit such comments and recommendations to the Secretary.

(D) Secretary review and response

The Secretary shall review the comments and recommendations submitted by the Committee under subparagraph (C) and post a detailed response to such comments and recommendations on the Internet website of the Centers for Medicare & Medicaid Services.

(3) Rule of construction

Nothing in this subsection shall be construed to impact the development or testing of models under this subchapter or subchapters XI, XIX, or XXI.

(Aug. 14, 1935, ch. 531, title XVIII, § 1868, as added Pub. L. 101-508, title IV, § 4112, Nov. 5, 1990, 104 Stat. 1388-64; amended Pub. L. 108-173, title IX, § 942(a), Dec. 8, 2003, 117 Stat. 2420; Pub. L. 111-148, title III, § 3134(b)(2), Mar. 23, 2010, 124 Stat. 435; Pub. L. 114-10, title I, § 101(e)(1), Apr. 16, 2015, 129 Stat. 115; Pub. L. 115-123, div. E, title X, § 51003(b), Feb. 9, 2018, 132 Stat. 295.)

Editorial Notes**REFERENCES IN TEXT**

The Ethics in Government Act of 1978, referred to in subsec. (c)(1)(B)(iv), is Pub. L. 95-521, Oct. 26, 1978, 92 Stat. 1824. Title I of the Act is set out in the Appendix to Title 5, Government Organization and Employees. For complete classification of this Act to the Code, see Short Title note set out under section 101 of Pub. L. 95-521 in the Appendix to Title 5 and Tables.

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (c)(1)(G), is section 14 of Pub. L. 92-463, which is set out in the Appendix to Title 5, Government Organization and Employees.

PRIOR PROVISIONS

A prior section 1395ee, act Aug. 14, 1935, ch. 531, title XVIII, § 1868, as added July 30, 1965, Pub. L. 89-97, title

I, §102(a), 79 Stat. 329, provided for creation of a National Medical Review Committee, functions of such Committee, including submission of annual reports to the Secretary and Congress, employment of technical assistance, and for availability of assistance and data, prior to repeal by Pub. L. 90-248, title I, §164(c), Jan. 2, 1968, 81 Stat. 874.

AMENDMENTS

2018—Subsec. (c)(2)(C). Pub. L. 115-123 amended subpar. (C) generally. Prior to amendment, text read as follows: “The Committee shall, on a periodic basis, review models submitted under subparagraph (B), prepare comments and recommendations regarding whether such models meet the criteria described in subparagraph (A), and submit such comments and recommendations to the Secretary.”

2015—Subsec. (c). Pub. L. 114-10 added subsec. (c).

2010—Subsec. (a). Pub. L. 111-148 struck out subsec. (a) which related to the Practicing Physicians Advisory Council.

2003—Pub. L. 108-173, §942(a)(1), inserted “; Council for Technology and Innovation” in section catchline.

Subsec. (a). Pub. L. 108-173, §942(a)(2)-(4), inserted subsec. heading, redesignated existing provisions as par. (1), substituted “in this subsection” for “in this section”, and redesignated former subsecs. (b) and (c) as pars. (2) and (3), respectively.

Subsec. (b). Pub. L. 108-173, §942(a)(5), added subsec. (b). Former subsec. (b) redesignated par. (2) of subsec. (a).

Subsec. (c). Pub. L. 108-173, §942(a)(4), redesignated subsec. (c) as par. (3) of subsec. (a).

Statutory Notes and Related Subsidiaries

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

§ 1395ff. Determinations; appeals

(a) Initial determinations

(1) Promulgations of regulations

The Secretary shall promulgate regulations and make initial determinations with respect to benefits under part A or part B in accordance with those regulations for the following:

(A) The initial determination of whether an individual is entitled to benefits under such parts.

(B) The initial determination of the amount of benefits available to the individual under such parts.

(C) Any other initial determination with respect to a claim for benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made, for an item or service under such parts, an initial determination made by a quality improvement organization under section 1320c-3(a)(2) of this title, and an initial determination made by an entity pursuant to a contract (other than a contract under section 1395w-22 of this title) with the Secretary to administer

provisions of this subchapter or subchapter XI.

(2) Deadlines for making initial determinations

(A) In general

Subject to subparagraph (B), in promulgating regulations under paragraph (1), initial determinations shall be concluded by not later than the 45-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a claim for benefits from an individual as described in paragraph (1). Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 45-day period.

(B) Clean claims

Subparagraph (A) shall not apply with respect to any claim that is subject to the requirements of section 1395h(c)(2) or 1395u(c)(2) of this title.

(3) Redeterminations

(A) In general

In promulgating regulations under paragraph (1) with respect to initial determinations, such regulations shall provide for a fiscal intermediary or a carrier to make a redetermination with respect to a claim for benefits that is denied in whole or in part.

(B) Limitations

(i) Appeal rights

No initial determination may be reconsidered or appealed under subsection (b) unless the fiscal intermediary or carrier has made a redetermination of that initial determination under this paragraph.

(ii) Decisionmaker

No redetermination may be made by any individual involved in the initial determination.

(C) Deadlines

(i) Filing for redetermination

A redetermination under subparagraph (A) shall be available only if notice is filed with the Secretary to request the redetermination by not later than the end of the 120-day period beginning on the date the individual receives notice of the initial determination under paragraph (2).

(ii) Concluding redeterminations

Redeterminations shall be concluded by not later than the 60-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a request for a redetermination. Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 60-day period.

(D) Construction

For purposes of the succeeding provisions of this section a redetermination under this paragraph shall be considered to be part of the initial determination.

(4) Requirements of notice of determinations

With respect to an initial determination insofar as it results in a denial of a claim for benefits—