

first date the newly designated organization assumes the duties of a network administrative organization for that area.”

REPORT ON ESTABLISHMENT OF NATIONAL END STAGE RENAL DISEASE REGISTRY

Pub. L. 99-509, title IX, §9335(i)(2), Oct. 21, 1986, 100 Stat. 2032, provided that: “The Secretary of Health and Human Services shall submit to the Congress, no later than April 1, 1987, a full report on the progress made in establishing the national end stage renal disease registry under the amendment made by paragraph (1) [amending this section] and shall establish such registry by not later than January 1, 1988.”

DEADLINE FOR ESTABLISHMENT OF PROTOCOLS ON REUSE OF DIALYZER FILTERS

Pub. L. 99-509, title IX, §9335(k)(2), Oct. 21, 1986, 100 Stat. 2033, as amended by Pub. L. 100-203, title IV, §4036(c)(1)(A), Dec. 22, 1987, 101 Stat. 1330-79, provided that: “The Secretary of Health and Human Services shall establish the protocols described in section 1881(f)(7)(A) of the Social Security Act [42 U.S.C. 1395rr(f)(7)(A)] by not later than October 1, 1987 (or July 1, 1988, with respect to protocols that relate to the reuse of bloodlines).”

[Pub. L. 100-203, title IV, §4036(c)(1)(B), Dec. 22, 1987, 101 Stat. 1330-79, provided that: “The amendment made by subparagraph (A) [amending section 9335(k)(2) of Pub. L. 99-509, set out above] shall be effective as if included in the enactment of section 9335(k)(2) of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99-509].”]

LIMITATION ON MERGER OF END STAGE RENAL DISEASE NETWORKS

Pub. L. 99-272, title IX, §9214, Apr. 7, 1986, 100 Stat. 180, provided that: “The Secretary of Health and Human Services shall maintain renal disease network organizations as authorized under section 1881(c) of the Social Security Act [42 U.S.C. 1395rr(c)], and may not merge the network organizations into other organizations or entities. The Secretary may consolidate such network organizations, but only if such consolidation does not result in fewer than 14 such organizations being permitted to exist.”

**§ 1395rr-1. Medicare coverage for individuals exposed to environmental health hazards**

**(a) Deeming of individuals as eligible for medicare benefits**

**(1) In general**

For purposes of eligibility for benefits under this subchapter, an individual determined under subsection (c) to be an environmental exposure affected individual described in subsection (e)(2) shall be deemed to meet the conditions specified in section 426(a) of this title.

**(2) Discretionary deeming**

For purposes of eligibility for benefits under this subchapter, the Secretary may deem an individual determined under subsection (c) to be an environmental exposure affected individual described in subsection (e)(3) to meet the conditions specified in section 426(a) of this title.

**(3) Effective date of coverage**

An Individual<sup>1</sup> who is deemed eligible for benefits under this subchapter under paragraph (1) or (2) shall be—

(A) entitled to benefits under the program under Part<sup>1</sup> A as of the date of such deeming; and

(B) eligible to enroll in the program under Part<sup>1</sup> B beginning with the month in which such deeming occurs.

**(b) Pilot program for care of certain individuals residing in emergency declaration areas**

**(1) Program; purpose**

**(A) Primary pilot program**

The Secretary shall establish a pilot program in accordance with this subsection to provide innovative approaches to furnishing comprehensive, coordinated, and cost-effective care under this subchapter to individuals described in paragraph (2)(A).

**(B) Optional pilot programs**

The Secretary may establish a separate pilot program, in accordance with this subsection, with respect to each geographic area subject to an emergency declaration (other than the declaration of June 17, 2009), in order to furnish such comprehensive, coordinated and cost-effective care to individuals described in subparagraph (2)(B) who reside in each such area.

**(2) Individual described**

For purposes of paragraph (1), an individual described in this paragraph is an individual who enrolls in part B, submits to the Secretary an application to participate in the applicable pilot program under this subsection, and—

(A) is an environmental exposure affected individual described in subsection (e)(2) who resides in or around the geographic area subject to an emergency declaration made as of June 17, 2009; or

(B) is an environmental exposure affected individual described in subsection (e)(3) who—

(i) is deemed under subsection (a)(2); and

(ii) meets such other criteria or conditions for participation in a pilot program under paragraph (1)(B) as the Secretary specifies.

**(3) Flexible benefits and services**

A pilot program under this subsection may provide for the furnishing of benefits, items, or services not otherwise covered or authorized under this subchapter, if the Secretary determines that furnishing such benefits, items, or services will further the purposes of such pilot program (as described in paragraph (1)).

**(4) Innovative reimbursement methodologies**

For purposes of the pilot program under this subsection, the Secretary—

(A) shall develop and implement appropriate methodologies to reimburse providers for furnishing benefits, items, or services for which payment is not otherwise covered or authorized under this subchapter, if such benefits, items, or services are furnished pursuant to paragraph (3); and

(B) may develop and implement innovative approaches to reimbursing providers for any benefits, items, or services furnished under this subsection.

**(5) Limitation**

Consistent with section 1395y(b) of this title, no payment shall be made under the pilot pro-

<sup>1</sup> So in original. Probably should not be capitalized.

gram under this subsection with respect to benefits, items, or services furnished to an environmental exposure affected individual (as defined in subsection (e)) to the extent that such individual is eligible to receive such benefits, items, or services through any other public or private benefits plan or legal agreement.

**(6) Waiver authority**

The Secretary may waive such provisions of this subchapter and subchapter XI as are necessary to carry out pilot programs under this subsection.

**(7) Funding**

For purposes of carrying out pilot programs under this subsection, the Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1395i of this title and the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, in such proportion as the Secretary determines appropriate, of such sums as the Secretary determines necessary, to the Centers for Medicare & Medicaid Services Program Management Account.

**(8) Waiver of budget neutrality**

The Secretary shall not require that pilot programs under this subsection be budget neutral with respect to expenditures under this subchapter.

**(c) Determinations**

**(1) By the Commissioner of Social Security**

For purposes of this section, the Commissioner of Social Security, in consultation with the Secretary, and using the cost allocation method prescribed in section 401(g) of this title, shall determine whether individuals are environmental exposure affected individuals.

**(2) By the Secretary**

The Secretary shall determine eligibility for pilot programs under subsection (b).

**(d) Emergency declaration defined**

For purposes of this section, the term “emergency declaration” means a declaration of a public health emergency under section 9604(a) of this title.

**(e) Environmental exposure affected individual defined**

**(1) In general**

For purposes of this section, the term “environmental exposure affected individual” means—

- (A) an individual described in paragraph (2); and
- (B) an individual described in paragraph (3).

**(2) Individual described**

**(A) In general**

An individual described in this paragraph is any individual who—

- (i) is diagnosed with 1 or more conditions described in subparagraph (B);
- (ii) as demonstrated in such manner as the Secretary determines appropriate, has been present for an aggregate total of 6

months in the geographic area subject to an emergency declaration specified in subsection (b)(2)(A), during a period ending—

(I) not less than 10 years prior to such diagnosis; and

(II) prior to the implementation of all the remedial and removal actions specified in the Record of Decision for Operating Unit 4 and the Record of Decision for Operating Unit 7;

(iii) files an application for benefits under this subchapter (or has an application filed on behalf of the individual), including pursuant to this section; and

(iv) is determined under this section to meet the criteria in this subparagraph.

**(B) Conditions described**

For purposes of subparagraph (A), the following conditions are described in this subparagraph:

(i) Asbestosis, pleural thickening, or pleural plaques as established by—

(I) interpretation by a “B Reader” qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary; or

(II) such other diagnostic standards as the Secretary specifies,

except that this clause shall not apply to pleural thickening or pleural plaques unless there are symptoms or conditions requiring medical treatment as a result of these diagnoses.

(ii) Mesothelioma, or malignancies of the lung, colon, rectum, larynx, stomach, esophagus, pharynx, or ovary, as established by—

(I) pathologic examination of biopsy tissue;

(II) cytology from bronchioalveolar lavage; or

(III) such other diagnostic standards as the Secretary specifies.

(iii) Any other diagnosis which the Secretary, in consultation with the Commissioner of Social Security, determines is an asbestos-related medical condition, as established by such diagnostic standards as the Secretary specifies.

**(3) Other individual described**

An individual described in this paragraph is any individual who—

(A) is not an individual described in paragraph (2);

(B) is diagnosed with a medical condition caused by the exposure of the individual to a public health hazard to which an emergency declaration applies, based on such medical conditions, diagnostic standards, and other criteria as the Secretary specifies;

(C) as demonstrated in such manner as the Secretary determines appropriate, has been present for an aggregate total of 6 months in the geographic area subject to the emergency declaration involved, during a period determined appropriate by the Secretary;

(D) files an application for benefits under this subchapter (or has an application filed on behalf of the individual), including pursuant to this section; and

(E) is determined under this section to meet the criteria in this paragraph.

(Aug. 14, 1935, ch. 531, title XVIII, §1881A, as added Pub. L. 111-148, title X, §10323(a), Mar. 23, 2010, 124 Stat. 954.)

REFERENCES IN TEXT

Parts A and B, referred to in subsecs. (a)(3) and (b)(2), are classified to sections 1395c et seq. and 1395j et seq., respectively, of this title.

**§ 1395ss. Certification of medicare supplemental health insurance policies**

**(a) Submission of policy by insurer**

(1) The Secretary shall establish a procedure whereby medicare supplemental policies (as defined in subsection (g)(1) of this section) may be certified by the Secretary as meeting minimum standards and requirements set forth in subsection (c) of this section. Such procedure shall provide an opportunity for any insurer to submit any such policy, and such additional data as the Secretary finds necessary, to the Secretary for his examination and for his certification thereof as meeting the standards and requirements set forth in subsection (c) of this section. Subject to subsections (k)(3), (m), and (n) of this section, such certification shall remain in effect if the insurer files a notarized statement with the Secretary no later than June 30 of each year stating that the policy continues to meet such standards and requirements and if the insurer submits such additional data as the Secretary finds necessary to independently verify the accuracy of such notarized statement. Where the Secretary determines such a policy meets (or continues to meet) such standards and requirements, he shall authorize the insurer to have printed on such policy (but only in accordance with such requirements and conditions as the Secretary may prescribe) an emblem which the Secretary shall cause to be designed for use as an indication that a policy has received the Secretary's certification. The Secretary shall provide each State commissioner or superintendent of insurance with a list of all the policies which have received his certification.

(2) No medicare supplemental policy may be issued in a State on or after the date specified in subsection (p)(1)(C) of this section unless—

(A) the State's regulatory program under subsection (b)(1) of this section provides for the application and enforcement of the standards and requirements set forth in such subsection (including the 1991 NAIC Model Regulation or 1991 Federal Regulation (as the case may be)) by the date specified in subsection (p)(1)(C) of this section; or

(B) if the State's program does not provide for the application and enforcement of such standards and requirements, the policy has been certified by the Secretary under paragraph (1) as meeting the standards and requirements set forth in subsection (c) of this section (including such applicable standards) by such date.

Any person who issues a medicare supplemental policy, on and after the effective date specified in subsection (p)(1)(C) of this section, in violation of this paragraph is subject to a civil money penalty of not to exceed \$25,000 for each such violation. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

**(b) Standards and requirements; periodic review by Secretary**

(1) Any medicare supplemental policy issued in any State which the Secretary determines has established under State law a regulatory program that—

(A) provides for the application and enforcement of standards with respect to such policies equal to or more stringent than the NAIC Model Standards (as defined in subsection (g)(2)(A) of this section), except as otherwise provided by subparagraph (H);

(B) includes requirements equal to or more stringent than the requirements described in paragraphs (2) through (5) of subsection (c) of this section;

(C) provides that—

(i) information with respect to the actual ratio of benefits provided to premiums collected under such policies will be reported to the State on forms conforming to those developed by the National Association of Insurance Commissioners for such purpose, or

(ii) such ratios will be monitored under the program in an alternative manner approved by the Secretary, and that a copy of each such policy, the most recent premium for each such policy, and a listing of the ratio of benefits provided to premiums collected for the most recent 3-year period for each such policy issued or sold in the State is maintained and made available to interested persons;

(D) provides for application and enforcement of the standards and requirements described in subparagraphs (A), (B), and (C) to all medicare supplemental policies (as defined in subsection (g)(1) of this section) issued in such State,

(E) provides the Secretary periodically (but at least annually) with a list containing the name and address of the issuer of each such policy and the name and number of each such policy (including an indication of policies that have been previously approved, newly approved, or withdrawn from approval since the previous list was provided),

(F) reports to the Secretary on the implementation and enforcement of standards and requirements of this paragraph at intervals established by the Secretary,

(G) provides for a process for approving or disapproving proposed premium increases with respect to such policies, and establishes a policy for the holding of public hearings prior to approval of a premium increase, and

(H) in the case of a policy that meets the standards under subparagraph (A) except that benefits under the policy are limited to items