

## EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 222(l)(2)(C) of Pub. L. 108-173 applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 223(a) of Pub. L. 108-173, set out as a note under section 1395w-21 of this title.

## EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by Pub. L. 106-554 applicable to years beginning with 2003, see section 1(a)(6) [title VI, §606(b)] of Pub. L. 106-554, set out as a note under section 1395r of this title.

## EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101-234 effective Jan. 1, 1990, and applicable to premiums for months beginning after Dec. 31, 1989, see section 202(b) of Pub. L. 101-234, set out as a note under section 401 of this title.

## EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-360 applicable, except as otherwise specified in such amendment, to monthly premiums for months beginning with January 1989, see section 211(d) of Pub. L. 100-360, set out as a note under section 1395r of this title.

## EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98-369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98-369, set out as a note under section 1320a-1 of this title.

## EFFECTIVE DATE OF 1983 AMENDMENT; TRANSITIONAL RULE

Amendment by Pub. L. 98-21 applicable to premiums for months beginning with January 1984, but for months after June 1983 and before January 1984, the amount of Government contributions under subsection (a)(1) of this section shall be computed with the actuarially adequate rate which would have been in effect but for the amendments made by this section and using the amount of the premium in effect for June 1983, see section 606(c) of Pub. L. 98-21, set out as a note under section 1395r of this title.

## EFFECTIVE DATE OF 1972 AMENDMENT

Pub. L. 92-603, title II, §203(e), Oct. 30, 1972, 86 Stat. 1377, provided that the amendment made by that section is effective with respect to enrollee premiums payable for months after June 1973.

## CONSTRUCTION OF 2015 AMENDMENT; CONDITIONAL APPLICATION TO 2017

For provisions relating to construction and application of amendment by Pub. L. 114-74, see sections 601(d) and 601(e) of Pub. L. 114-74, set out as notes under section 1395r of this title.

**§ 1395w-1. Repealed. Pub. L. 105-33, title IV, § 4022(b)(2)(A), Aug. 5, 1997, 111 Stat. 354**

Section, act Aug. 14, 1935, ch. 531, title XVIII, §1845, as added and amended Apr. 7, 1986, Pub. L. 99-272, title IX, §9305, 100 Stat. 190; Oct. 21, 1986, Pub. L. 99-509, title IX, §§9331(e), 9344(a)(1), 100 Stat. 2021, 2042; Dec. 22, 1987, Pub. L. 100-203, title IV, §§4045(b), 4083(a)(1), (c)(1), 4085(a), (i)(8), 101 Stat. 1330-87, 1330-129, 1330-130, 1330-132; July 1, 1988, Pub. L. 100-360, title IV, §411(i)(4)(A), 102 Stat. 788; Nov. 10, 1988, Pub. L. 100-647, title VIII, §8425(a), 102 Stat. 3803; Nov. 5, 1990, Pub. L. 101-508, title IV, §§4002(g)(3), 4118(j)(1), 104 Stat. 1388-37, 1388-70; Oct. 31, 1994, Pub. L. 103-432, title I, §126(g)(8), 108 Stat. 4416, related to Physician Payment Review Commission.

## EFFECTIVE DATE OF REPEAL

Repeal effective Nov. 1, 1997, the date of termination of the Prospective Payment Assessment Commission

and the Physician Payment Review Commission, see section 4022(c)(2) of Pub. L. 105-33 set out as an Effective Date; Transition; Transfer of Functions note under section 1395b-6 of this title.

**§ 1395w-2. Intermediate sanctions for providers or suppliers of clinical diagnostic laboratory tests**

(a) If the Secretary determines that any provider or clinical laboratory approved for participation under this subchapter no longer substantially meets the conditions of participation or for coverage specified under this subchapter with respect to the provision of clinical diagnostic laboratory tests under this part, the Secretary may (for a period not to exceed one year) impose intermediate sanctions developed pursuant to subsection (b) of this section, in lieu of terminating immediately the provider agreement or cancelling immediately approval of the clinical laboratory.

(b)(1) The Secretary shall develop and implement—

(A) a range of intermediate sanctions to apply to providers or clinical laboratories under the conditions described in subsection (a), and

(B) appropriate procedures for appealing determinations relating to the imposition of such sanctions.

(2)(A) The intermediate sanctions developed under paragraph (1) shall include—

(i) directed plans of correction,

(ii) civil money penalties in an amount not to exceed \$10,000 for each day of substantial noncompliance,

(iii) payment for the costs of onsite monitoring by an agency responsible for conducting surveys, and

(iv) suspension of all or part of the payments to which a provider or clinical laboratory would otherwise be entitled under this subchapter with respect to clinical diagnostic laboratory tests furnished on or after the date on which the Secretary determines that intermediate sanctions should be imposed pursuant to subsection (a) of this section.

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (ii) in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(B) The sanctions specified in subparagraph (A) are in addition to sanctions otherwise available under State or Federal law.

(3) The Secretary shall develop and implement specific procedures with respect to when and how each of the intermediate sanctions developed under paragraph (1) is to be applied, the amounts of any penalties, and the severity of each of these penalties. Such procedures shall be designed so as to minimize the time between identification of violations and imposition of these sanctions and shall provide for the imposition of incrementally more severe penalties for repeated or uncorrected deficiencies.

(Aug. 14, 1935, ch. 531, title XVIII, §1846, as added Pub. L. 100-203, title IV, §4064(d)(1), Dec. 22, 1987, 101 Stat. 1330-111; amended Pub. L. 100-360, title

II, § 203(e)(4), title IV, § 411(g)(3)(G), July 1, 1988, 102 Stat. 725, 784; Pub. L. 100-485, title VI, § 608(d)(22)(C), Oct. 13, 1988, 102 Stat. 2421; Pub. L. 101-234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 101-508, title IV, § 4154(e)(2), Nov. 5, 1990, 104 Stat. 1388-86.)

#### AMENDMENTS

1990—Pub. L. 101-508 substituted “providers or suppliers of” for “providers of” in section catchline.

1989—Pub. L. 101-234 repealed Pub. L. 100-360, § 203(e)(4), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment notes below.

1988—Pub. L. 100-360, § 203(e)(4)(A), inserted “and for qualified home intravenous drug therapy providers” at end of section catchline.

Subsec. (a). Pub. L. 100-360, § 411(g)(3)(G)(i)(I), as amended by Pub. L. 100-485, substituted “approved” for “certified”.

Pub. L. 100-360, § 411(g)(3)(G)(i)(II), inserted “or for coverage” after “conditions of participation”.

Pub. L. 100-360, § 411(g)(3)(G)(i)(III), which directed amendment of subsec. (a) by substituting “terminating immediately the provider agreement or cancelling immediately approval of the clinical laboratory” for “cancelling immediately the certification of the provider or clinical laboratory”, was executed by making the substitution for “canceling immediately the certification of the provider or clinical laboratory” to reflect the probable intent of Congress.

Pub. L. 100-360, § 203(e)(4)(B), inserted “or that a qualified home intravenous drug therapy provider that is certified for participation under this subchapter no longer substantially meets the requirements of section 1395x(jj)(3) of this title” after “under this part”.

Subsec. (b)(1)(A). Pub. L. 100-360, § 411(g)(3)(G)(ii), struck out “certified” before “clinical laboratories”.

Subsec. (b)(2)(A). Pub. L. 100-360, § 411(g)(3)(G)(iv), inserted at end “The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (ii) in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.”

Subsec. (b)(2)(A)(ii). Pub. L. 100-360, § 411(g)(3)(G)(iii), substituted “civil money penalties in an amount not to exceed \$10,000 for each day of substantial noncompliance” for “civil fines and penalties”.

Subsec. (b)(2)(A)(iii). Pub. L. 100-360, § 411(g)(3)(G)(v), struck out “certification” before “surveys”.

Subsec. (b)(2)(A)(iv). Pub. L. 100-360, § 411(g)(3)(G)(ii), (vi), struck out “certified” before “clinical laboratory” and substituted “furnished on or after the date on” for “provided on or after the date in”.

Pub. L. 100-360, § 203(e)(4)(C), inserted “or home intravenous drug therapy services” after “clinical diagnostic laboratory tests”.

Subsec. (b)(3). Pub. L. 100-360, § 411(g)(3)(G)(vii), substituted “any penalties” for “any fines” and “severe penalties” for “severe fines”.

#### EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-508 effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-239, see section 4154(e)(5) of Pub. L. 101-508, set out as a note under section 1395f of this title.

#### EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101-234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101-234, set out as a note under section 1320a-7a of this title.

#### EFFECTIVE DATE OF 1988 AMENDMENTS

Amendment by Pub. L. 100-485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100-360, see section 608(g)(1) of

Pub. L. 100-485, set out as a note under section 704 of this title.

Amendment by section 203(e)(4) of Pub. L. 100-360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100-360, set out as a note under section 1320c-3 of this title.

Except as specifically provided in section 411 of Pub. L. 100-360, amendment by section 411(g)(3)(G) of Pub. L. 100-360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100-203, effective as if included in the enactment of that provision in Pub. L. 100-203, see section 411(a) of Pub. L. 100-360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

#### EFFECTIVE DATE

Pub. L. 100-203, title IV, § 4064(d)(2), Dec. 22, 1987, 101 Stat. 1330-111, provided that: “The amendment made by paragraph (1) [enacting this section] shall become effective on January 1, 1990.”

### § 1395w-3. Competitive acquisition of certain items and services

#### (a) Establishment of competitive acquisition programs

##### (1) Implementation of programs

##### (A) In general

The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

##### (B) Phased-in implementation

The programs—

(i) shall be phased in among competitive acquisition areas in a manner consistent with subparagraph (D) so that the competition under the programs occurs in—

(I) 10 of the largest metropolitan statistical areas in 2007;

(II) an additional 91 of the largest metropolitan statistical areas in 2011; and

(III) additional areas after 2011 (or, in the case of national mail order for items and services, after 2010); and

(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

##### (C) Waiver of certain provisions

In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

#### (D) Changes in competitive acquisition programs

##### (i) Round 1 of competitive acquisition program

Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the