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 Reconcili-

ation Act of 1989, Pub. L. 101–239, see section 4154(e)(5) of Pub. L. 101–508, set out as a note under section 1395*l* 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 competitive acquisition programs under this section—

(I) the contracts awarded under this section before July 15, 2008, are terminated, no payment shall be made under this subchapter on or after July 15, 2008, based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title;

(II) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV);

(III) the Secretary shall exclude Puerto Rico so that such round of competition covers 9, instead of 10, of the largest metropolitan statistical areas; and

(IV) there shall be excluded negative pressure wound therapy items and services.

Nothing in subclause (I) shall be construed to provide an independent cause of action or right to administrative or judicial review with regard to the termination provided under such subclause.

**(ii) Round 2 of competitive acquisition program**

In implementing the second round of the competitive acquisition programs under this section described in subparagraph (B)(i)(II)—

(I) the metropolitan statistical areas to be included shall be those metropolitan statistical areas selected by the Secretary for such round as of June 1, 2008;

(II) the Secretary shall include the next 21 largest metropolitan statistical areas by total population (after those selected under subclause (I)) for such round; and

(III) the Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes.

**(iii) Exclusion of certain areas in subsequent rounds of competitive acquisition programs**

In implementing subsequent rounds of the competitive acquisition programs