

erage 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)(3) 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.

Amendment by section 204(c)(2), (d)(3) of Pub. L. 100-360 applicable to screening mammography performed on or after Jan. 1, 1990, see section 204(e) of Pub. L. 100-360, set out as a note under section 1395m of this title.

Except as specifically provided in section 411 of Pub. L. 100-360, amendment by section 411(d)(4)(A), (l)(1)(C), (6)(B) 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 OF 1987 AMENDMENT

Pub. L. 100-203, title IV, §4025(c), formerly §4025(b), Dec. 22, 1987, 101 Stat. 1330-74, as redesignated and amended by Pub. L. 100-360, title IV, §411(d)(4)(B)(i), July 1, 1988, 102 Stat. 774, provided that: "The amendment made by this section [amending this section and section 1395bb of this title] shall apply with respect to agreements entered into or renewed on or after the date of enactment of this Act [Dec. 22, 1987]."

For effective date of amendment by section 4072(d) of Pub. L. 100-203, see section 4072(e) of Pub. L. 100-203, set out as a note under section 1395x of this title.

Amendments by sections 4201(a)(2), (d)(4) and 4202(a)(1), (c) of Pub. L. 100-203 applicable to services furnished on or after Oct. 1, 1990, without regard to whether regulations to implement such amendments are promulgated by such date, except as otherwise specifically provided in section 1395i-3 of this title, see section 4204(a) of Pub. L. 100-203, as amended, set out as an Effective Date note under section 1395i-3 of this title.

Amendment by section 4203(a)(1) of Pub. L. 100-203 applicable Jan. 1, 1988, except as otherwise specifically provided in section 1395i-3 of this title, without regard to whether regulations to implement such amendment are promulgated by such date, and in applying amendment by section 4203(a)(1) of Pub. L. 100-203 for services furnished by a skilled nursing facility before Oct. 1, 1990, any reference to a requirement of section 1395i-3(b), (c), or (d) of this title is deemed a reference to section 1395x(j) of this title, see section 4204(b) of Pub. L. 100-203, as added by Pub. L. 100-485, set out as an Effective Date note under section 1395i-3 of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99-509 applicable to services furnished on or after Jan. 1, 1989, with exceptions for hospitals located in rural areas which meet certain requirements related to certified registered nurse anesthetists, see section 9320(i), (k) of Pub. L. 99-509, as amended, set out as notes under section 1395k 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 1982 AMENDMENT

Amendment by Pub. L. 97-248 applicable to hospice care provided on or after Nov. 1, 1983, see section 122(h)(1) of Pub. L. 97-248, as amended, set out as a note under section 1395c of this title.

EFFECTIVE DATE OF 1980 AMENDMENTS

Amendment by Pub. L. 96-611 effective July 1, 1981, and applicable to services furnished on or after that

date, see section 2 of Pub. L. 96-611, set out as a note under section 1395l of this title.

For effective date of amendment by section 933(g) of Pub. L. 96-499, see section 933(h) of Pub. L. 96-499, set out as a note under section 1395k of this title.

EFFECTIVE DATE OF 1977 AMENDMENT

Amendment by Pub. L. 95-210 applicable to services rendered on or after first day of third calendar month which begins after Dec. 31, 1977, see section 1(j) of Pub. L. 95-210, set out as a note under section 1395k of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Pub. L. 92-603, title II, §299D(c), Oct. 30, 1972, 86 Stat. 1462, provided that: "The provisions of this section [amending this section and section 1396a of this title] shall be effective beginning January 1, 1973, or within 6 months following the enactment of this Act [Oct. 30, 1972], whichever is later."

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by section 133(f) of Pub. L. 90-248 applicable with respect to services furnished after June 30, 1968, see section 133(g) of Pub. L. 90-248, set out as a note under section 1395k of this title.

Pub. L. 90-248, title II, §228(b), Jan. 2, 1968, 81 Stat. 904, provided that the amendment made by such section 228(b) is effective July 1, 1969.

USE OF STATE OR LOCAL AGENCIES IN EVALUATING LABORATORIES

Pub. L. 103-432, title I, §160(a)(2), Oct. 31, 1994, 108 Stat. 4443, provided that: "An agreement made by the Secretary of Health and Human Services with a State under section 1864(a) of the Social Security Act [42 U.S.C. 1395aa(a)] may include an agreement that the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by the Secretary for the purpose of determining whether a laboratory meets the requirements of section 353 of the Public Health Service Act [42 U.S.C. 263a]."

NURSE AID TRAINING AND COMPETENCY EVALUATION, FAILURE BY STATE TO MEET GUIDELINES

Pub. L. 101-508, title IV, §4008(h)(1)(A), Nov. 5, 1990, 104 Stat. 1388-46, provided that: "The Secretary of Health and Human Services may not refuse to enter into an agreement or cancel an existing agreement with a State under section 1864 of the Social Security Act [42 U.S.C. 1395aa] on the basis that the State failed to meet the requirement of section 1819(e)(1)(A) of such Act [42 U.S.C. 1395i-3(e)(1)(A)] before the effective date of guidelines, issued by the Secretary, establishing requirements under section 1819(f)(2)(A) of such Act, if the State demonstrates to the satisfaction of the Secretary that it has made a good faith effort to meet such requirement before such effective date."

§ 1395bb. Effect of accreditation

(a) Accreditation by American Osteopathic Association or other national accreditation body

(1) If the Secretary finds that accreditation of a provider entity (as defined in paragraph (4)) by the American Osteopathic Association or any other national accreditation body demonstrates that all of the applicable conditions or requirements of this subchapter (other than the requirements of section 1395m(j) of this title or the conditions and requirements under section 1395rr(b) of this title) are met or exceeded—

(A) in the case of a provider entity not described in paragraph (3)(B), the Secretary shall treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding; or

(B) in the case of a provider entity described in paragraph (3)(B), the Secretary may treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding.

(2) In making such a finding, the Secretary shall consider, among other factors with respect to a national accreditation body, its requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation.

(3)(A) Except as provided in subparagraph (B), not later than 60 days after the date of receipt of a written request for a finding under paragraph (1) (with any documentation necessary to make a determination on the request), the Secretary shall publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing a period of at least 30 days for the public to comment on the request. The Secretary shall approve or deny a request for such a finding, and shall publish notice of such approval or denial, not later than 210 days after the date of receipt of the request (with such documentation). Such an approval shall be effective with respect to accreditation determinations made on or after such effective date (which may not be later than the date of publication of the approval) as the Secretary specifies in the publication notice.

(B) The 210-day and 60-day deadlines specified in subparagraph (A) shall not apply in the case of any request for a finding with respect to accreditation of a provider entity to which the conditions and requirements of sections 1395i-3 and 1395x(j) of this title apply.

(4) For purposes of this section, the term “provider entity” means a provider of services, supplier, facility, clinic, agency, or laboratory.

(b) Disclosure of accreditation survey

The Secretary may not disclose any accreditation survey (other than a survey with respect to a home health agency) made and released to the Secretary by the American Osteopathic Association or any other national accreditation body, of an entity accredited by such body, except that the Secretary may disclose such a survey and information related to such a survey to the extent such survey and information relate to an enforcement action taken by the Secretary.

(c) Deficiencies

Notwithstanding any other provision of this subchapter, if the Secretary finds that a provider entity has significant deficiencies (as defined in regulations pertaining to health and safety), the entity shall, after the date of notice of such finding to the entity and for such period as may be prescribed in regulations, be deemed not to meet the conditions or requirements the entity has been treated as meeting pursuant to subsection (a)(1).

(d) State or local accreditation

For provisions relating to validation surveys of entities that are treated as meeting applica-

ble conditions or requirements of this subchapter pursuant to subsection (a)(1), see section 1395aa(c) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1865, as added Pub. L. 89-97, title I, § 102(a), July 30, 1965, 79 Stat. 326; amended Pub. L. 92-603, title II, §§ 234(h), 244(b), Oct. 30, 1972, 86 Stat. 1413, 1423; Pub. L. 97-248, title I, §§ 122(g)(4), 128(d)(3), Sept. 3, 1982, 96 Stat. 362, 367; Pub. L. 98-369, div. B, title III, §§ 2345(a), 2346(a), July 18, 1984, 98 Stat. 1096; Pub. L. 99-509, title IX, §§ 9305(c)(3), 9320(h)(3), Oct. 21, 1986, 100 Stat. 1990, 2016; Pub. L. 100-203, title IV, §§ 4025(b), 4072(d), Dec. 22, 1987, 101 Stat. 1330-117, as amended Pub. L. 100-360, title IV, § 411(d)(4)(B)(ii), July 1, 1988, 102 Stat. 774; Pub. L. 100-360, title II, §§ 204(c)(3), (d)(3), July 1, 1988, 102 Stat. 728, 729; Pub. L. 100-485, title VI, § 608(d)(20)(D), Oct. 13, 1988, 102 Stat. 2420; Pub. L. 101-234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 101-239, title VI, §§ 6003(g)(3)(C)(iv), 6019(a)-(c), 6115(c), Dec. 19, 1989, 103 Stat. 2153, 2165, 2166, 2219; Pub. L. 101-508, title IV, § 4163(c)(3), Nov. 5, 1990, 104 Stat. 1388-100; Pub. L. 103-432, title I, § 145(c)(4), Oct. 31, 1994, 108 Stat. 4427; Pub. L. 104-134, title I, § 101(d) [title V, § 516(b), (c)(2)], Apr. 26, 1996, 110 Stat. 1321-211, 1321-246, 1321-247; renumbered title I, Pub. L. 104-140, § 1(a), May 2, 1996, 110 Stat. 1327; Pub. L. 108-173, title VII, § 736(a)(12), Dec. 8, 2003, 117 Stat. 2355; Pub. L. 110-275, title I, § 125(a), (b)(1), July 15, 2008, 122 Stat. 2519.)

AMENDMENTS

2008—Subsec. (a). Pub. L. 110-275, § 125(a), redesignated subsec. (b) as (a) and struck out former subsec. (a) which provided criteria necessary for an institution to meet certain requirements enumerated in section 1395x(e) of this title.

Subsec. (a)(1). Pub. L. 110-275, § 125(b)(1)(A), substituted “If” for “In addition, if”.

Subsec. (b). Pub. L. 110-275, § 125(a), (b)(1)(B), redesignated subsec. (c) as (b), substituted “released to the Secretary by” for “released to him by the Joint Commission on Accreditation of Hospitals,” and struck out the comma after “Osteopathic Association”. Former subsec. (b) redesignated (a).

Subsecs. (c), (d). Pub. L. 110-275, § 125(a), (b)(1)(C), (D), redesignated subsecs. (d) and (e) as (c) and (d), respectively, and substituted “pursuant to subsection (a)(1)” for “pursuant to subsection (a) or (b)(1)”. Former subsec. (c) redesignated (b).

Subsec. (e). Pub. L. 110-275, § 125(a), redesignated subsec. (e) as (d).

2003—Subsec. (b)(3)(B). Pub. L. 108-173 substituted “sections” for “section”.

1996—Subsec. (a). Pub. L. 104-134, § 101(d) [title V, § 516(b)(2), (3)], struck out after second sentence: “In addition, if the Secretary finds that accreditation of an entity by the American Osteopathic Association or any other national accreditation body provides reasonable assurance that any or all of the conditions of section 1395k(a)(2)(F)(i), 1395x(e), 1395x(f), 1395x(j), 1395x(o), 1395x(p)(4)(A) or (B), paragraphs (15) and (16) of section 1395x(s), section 1395x(aa)(2), 1395x(cc)(2), 1395x(dd)(2), or 1395x(mm)(1) of this title, as the case may be, are met, he may, to the extent he deems it appropriate, treat such entity as meeting the condition or conditions with respect to which he made such finding.” and redesignated fourth sentence as subsec. (c).

Subsec. (b). Pub. L. 104-134, § 101(d) [title V, § 516(b)(3)], added subsec. (b). Former subsec. (b) redesignated (d).

Subsec. (c). Pub. L. 104-134, § 101(d) [title V, § 516(b)(2)], redesignated fourth sentence of subsec. (a) as subsec. (c).

Subsec. (d). Pub. L. 104-134, § 101(d) [title V, § 516(b)(1), (c)(2)(A)], redesignated subsec. (b) as (d) and substituted “a provider entity” for “a hospital”, “the entity” for “the hospital” in two places, and “the conditions or requirements the entity has been treated as meeting pursuant to subsection (a) or (b)(1) of this section” for “the requirements of the numbered paragraphs of section 1395x(e) of this title”.

Subsec. (e). Pub. L. 104-134, § 101(d) [title V, § 516(c)(2)(B)], added subsec. (e).

1994—Subsec. (a). Pub. L. 103-432 struck out “1395m(c)(3),” after “conditions of section 1395k(a)(2)(F)(i),” in closing provisions.

1990—Subsec. (a). Pub. L. 101-508 inserted “1395m(c)(3),” after “1395k(a)(2)(F)(i),” in second sentence.

1989—Subsec. (a). Pub. L. 101-239, § 6115(c), substituted “paragraphs (15) and (16)” for “paragraphs (14) and (15)”.

Pub. L. 101-239, § 6019(b), inserted before period at end “, except that the Secretary may disclose such a survey and information related to such a survey to the extent such survey and information relate to an enforcement action taken by the Secretary”.

Pub. L. 101-239, § 6003(g)(3)(C)(iv), substituted “1395x(dd)(2), or 1395x(mm)(1) of this title” for “or 1395x(dd)(2) of this title” in third sentence.

Pub. L. 101-234 repealed Pub. L. 100-360, § 204(c)(3), (d)(3), 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 and 1989 Amendment notes.

Subsec. (a)(2). Pub. L. 101-239, § 6019(a), designated existing provisions as subpar. (A), struck out “(if it is included within a survey described in section 1395aa(c) of this title)” after “such institution”, inserted “, together with any other information directly related to the survey as the Secretary may require (including corrective action plans)” after “by such Commission”, and added subpar. (B).

Subsec. (b). Pub. L. 101-239, § 6019(c), struck out “following a survey made pursuant to section 1395aa(c) of this title” after “if the Secretary finds”.

1988—Subsec. (a). Pub. L. 100-360, § 411(d)(4)(B)(ii), as amended by Pub. L. 100-485, § 608(d)(20)(D), added Pub. L. 100-203, § 4025(b), see 1987 Amendment note below.

Pub. L. 100-360, § 204(d)(3), substituted “paragraphs (14) and (15)” for “paragraphs (13) and (14)” in third sentence.

Pub. L. 100-360, § 204(c)(3), inserted “1395m(e)(3),” after “1395k(a)(2)(F)(i),” in third sentence.

1987—Subsec. (a). Pub. L. 100-203, § 4072(d), substituted “paragraphs (13) and (14)” for “paragraphs (12) and (13)” in penultimate sentence.

Pub. L. 100-203, § 4025(b), as added by Pub. L. 100-360, § 411(d)(4)(B)(ii), as amended by Pub. L. 100-485, § 608(d)(20)(D), inserted “(other than a survey with respect to a home health agency)” after “survey” in last sentence.

1986—Subsec. (a). Pub. L. 99-509, § 9305(c)(3), inserted “, requires a discharge planning process (or imposes another requirement which serves substantially the same purpose)” after “the same purpose”, and “clause (A) or (B) of” after “comply also with” in second sentence.

Pub. L. 99-509, § 9320(h)(3), substituted “paragraphs (12) and (13)” for “paragraphs (11) and (12)” in third sentence.

1984—Subsec. (a). Pub. L. 98-369, § 2346(a), in provisions following par. (4), substituted “section 1395k(a)(2)(F)(i), 1395x(e), 1395x(f), 1395x(j), 1395x(o), 1395x(p)(4)(A) or (B), paragraphs (11) and (12) of section 1395x(s), section 1395x(aa)(2), 1395x(cc)(2), or 1395x(dd)(2) of this title” for “section 1395x(e), (j), (o), or (dd) of this title”, and substituted “entity” for “institution or agency” in two places.

Pub. L. 98-369, § 2345(a), struck out “(on a confidential basis)” after “release to the Secretary” in par. (2), and inserted provision that the Secretary may not disclose any accreditation survey made and released to him by

the Joint Commission on Accreditation of Hospitals, the American Osteopathic Association, or any other national accreditation body, of an entity accredited by such body, in provisions following par. (4).

1982—Subsec. (a). Pub. L. 97-248, § 122(g)(4), substituted “(o), or (dd)” for “or (o)”.

Subsec. (b). Pub. L. 97-248, § 128(d)(3), substituted “a hospital” for “an institution” and “the hospital” for “such institution”.

1972—Pub. L. 92-603 designated existing provisions as subsec. (a), inserted reference to subsec. (b) of this section in opening provisions, redesignated existing provisions as pars. (1) and (3) and added pars. (2) and (4) and in provisions following par. (4) inserted provisions for the imposition of a standard which the Secretary determines is at least equivalent to the standard promulgated by the Secretary as described in par. (4), and added subsec. (b).

EFFECTIVE DATE OF 2008 AMENDMENT; TRANSITION RULE

Pub. L. 110-275, title I, § 125(d), July 15, 2008, 122 Stat. 2520, provided that:

“(1) Subject to paragraph (2), the amendments made by this section [amending this section and sections 1395m, 1395w-22, 1395x, 1395aa, and 1395l of this title] shall apply with respect to accreditations of hospitals granted on or after the date that is 24 months after the date of the enactment of this Act [July 15, 2008].

“(2) For purposes of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the amendments made by this section shall not effect [sic] the accreditation of a hospital by the Joint Commission, or under accreditation or comparable approval standards found to be essentially equivalent to accreditation or approval standards of the Joint Commission, for the period of time applicable under such accreditation.”

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-432 applicable to mammography furnished by a facility on and after the first date that the certificate requirements of section 263b(b) of this title apply to such mammography conducted by such facility, see section 145(d) of Pub. L. 103-432, set out as a note under section 1395m of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-508 applicable to screening mammography performed on or after Jan. 1, 1991, see section 4163(e) of Pub. L. 101-508, set out as a note under section 1395l of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Pub. L. 101-239, title VI, § 6019(d), Dec. 19, 1989, 103 Stat. 2166, provided that:

“(1) Except as provided in paragraph (2), the amendments made by this section [amending this section] shall take effect on the date of the enactment of this Act [Dec. 19, 1989].

“(2) The amendments made by subsection (a) [amending this section] shall take effect 6 months after the date of the enactment of this Act.”

Amendment by section 6115(c) of Pub. L. 101-239 applicable to screening pap smears performed on or after July 1, 1990, see section 6115(d) of Pub. L. 101-239, set out as a note under section 1395x of this title.

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 AMENDMENT

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 204(c)(3), (d)(3) of Pub. L. 100-360 applicable to screening mammography performed on or after Jan. 1, 1990, see section 204(e) of Pub.

L. 100-360, set out as a note under section 1395m of this title.

Except as specifically provided in section 411 of Pub. L. 100-360, amendment by section 411(d)(4)(B)(ii) 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 OF 1987 AMENDMENT

Amendment by section 4025(b) of Pub. L. 100-203 applicable with respect to agreements entered into or renewed on or after Dec. 22, 1987, see section 4025(c) of Pub. L. 100-203, as amended, set out as a note under section 1395aa of this title.

For effective date of amendment by section 4072(d) of Pub. L. 100-203, see section 4072(e) of Pub. L. 100-203, set out as a note under section 1395x of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by section 9305(c)(3) of Pub. L. 99-509 applicable to hospitals as of one year after Oct. 21, 1986, see section 9305(c)(4) of Pub. L. 99-509, set out as a note under section 1395x of this title.

Amendment by section 9320(h)(3) of Pub. L. 99-509 applicable to services furnished on or after Jan. 1, 1989, with exceptions for hospitals located in rural areas which meet certain requirements related to certified registered nurse anesthetists, see section 9320(i), (k) of Pub. L. 99-509, as amended, set out as notes under section 1395k of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

Pub. L. 98-369, div. B, title III, §2345(b), July 18, 1984, 98 Stat. 1096, provided that: "The amendments made by this section [amending this section] shall become effective on the date of the enactment of this Act [July 18, 1984], and shall apply with respect to surveys released to the Secretary on, before, or after such date."

Pub. L. 98-369, div. B, title III, §2346(b), July 18, 1984, 98 Stat. 1096, provided that: "The amendments made by this section [amending this section] shall become effective on the date of the enactment of this Act [July 18, 1984]."

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by section 122(g)(4) of Pub. L. 97-248 applicable to hospice care provided on or after Nov. 1, 1983, see section 122(h)(1) of Pub. L. 97-248, as amended, set out as a note under section 1395c of this title.

Amendment by section 128(d)(3) of Pub. L. 97-248 effective Sept. 3, 1982, see section 128(e)(3) of Pub. L. 97-248, set out as a note under section 1395x of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by section 234(h) of Pub. L. 92-603 applicable with respect to providers of services for fiscal years beginning after the fifth month following October 1972, see section 234(i) of Pub. L. 92-603, set out as a note under section 1395x of this title.

AUTHORITY TO RECOGNIZE THE JOINT COMMISSION AS A NATIONAL ACCREDITATION BODY

Pub. L. 110-275, title I, §125(c), July 15, 2008, 122 Stat. 2519, provided that: "The Secretary of Health and Human Services may recognize the Joint Commission as a national accreditation body under section 1865 of the Social Security Act (42 U.S.C. 1395bb), as amended by this section, upon such terms and conditions, and upon submission of such information, as the Secretary may require."

§ 1395cc. Agreements with providers of services; enrollment processes

(a) Filing of agreements; eligibility for payment; charges with respect to items and services

(1) Any provider of services (except a fund designated for purposes of section 1395f(g) and sec-

tion 1395n(e) of this title) shall be qualified to participate under this subchapter and shall be eligible for payments under this subchapter if it files with the Secretary an agreement—

(A)(i) not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this subchapter (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this subchapter or for which such provider is paid pursuant to the provisions of section 1395f(e) of this title), and (ii) not to impose any charge that is prohibited under section 1396a(n)(3) of this title,

(B) not to charge any individual or any other person for items or services for which such individual is not entitled to have payment made under this subchapter because payment for expenses incurred for such items or services may not be made by reason of the provisions of paragraph (1) or (9) of section 1395y(a) of this title, but only if (i) such individual was without fault in incurring such expenses and (ii) the Secretary's determination that such payment may not be made for such items and services was made after the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this subchapter,

(C) to make adequate provision for return (or other disposition, in accordance with regulations) of any moneys incorrectly collected from such individual or other person,

(D) to promptly notify the Secretary of its employment of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity (as determined by the Secretary by regulation) by an agency or organization which serves as a fiscal intermediary or carrier (for purposes of part A or part B, or both, of this subchapter) with respect to the provider,

(E) to release data with respect to patients of such provider upon request to an organization having a contract with the Secretary under part B of subchapter XI of this chapter as may be necessary (i) to allow such organization to carry out its functions under such contract, or (ii) to allow such organization to carry out similar review functions under any contract the organization may have with a private or public agency paying for health care in the same area with respect to patients who authorize release of such data for such purposes,

(F)(i) in the case of hospitals which provide inpatient hospital services for which payment may be made under subsection (b), (c), or (d) of section 1395ww of this title, to maintain an agreement with a professional standards review organization (if there is such an organization in existence in the area in which the hospital is located) or with a quality improvement organization which has a contract with the Secretary under part B of subchapter XI of