§ 1395bbb. Conditions of participation for home health agencies; home health quality

(a) Conditions of participation; protection of individual rights; notification of State entities; use of home health aides; medical equipment; individual’s plan of care; compliance with Federal, State, and local laws and regulations

The conditions of participation that a home health agency is required to meet under this subsection are as follows:

(1) The agency protects and promotes the rights of each individual under its care, including each of the following rights:

(A) The right to be fully informed in advance about the care and treatment to be provided by the agency, to be fully informed in advance of any changes in the care or treatment to be provided by the agency that may affect the individual’s well-being, and (except with respect to an individual adjudged incompetent) to participate in planning care and treatment or changes in care or treatment.

(B) The right to voice grievances with respect to treatment or care that is (or fails to be) furnished without discrimination or reprisal for voicing grievances.

(C) The right to confidentiality of the clinical records described in section 1395x (o)(3) of this title.

(D) The right to have one’s property treated with respect.

(E) The right to be fully informed orally and in writing (in advance of coming under the care of the agency) of—

(i) all items and services furnished by (or under arrangements with) the agency for which payment may be made under this subchapter,

(ii) the coverage available for such items and services under this subchapter, subchapter XIX of this chapter, and any other Federal program of which the agency is reasonably aware,

(iii) any charges for items and services not covered under this subchapter and any charges the individual may have to pay with respect to items and services furnished by (or under arrangements with) the agency, and

(iv) any changes in the charges or items and services described in clause (i), (ii), or (iii).

(F) The right to be fully informed in writing (in advance of coming under the care of the agency) of the individual’s rights and obligations under this subchapter.

(G) The right to be informed of the availability of the State home health agency hot-line established under section 1395aa (a) of this title.

(2) The agency notifies the State entity responsible for the licensing or certification of the agency of a change in—

(A) the persons with an ownership or control interest (as defined in section 1320a–3 (a)(3) of this title) in the agency,

(B) the persons who are officers, directors, agents, or managing employees (as defined in section 1320a–5 (b) of this title) of the agency, and

(C) the corporation, association, or other company responsible for the management of the agency.

Such notice shall be given at the time of the change and shall include the identity of each new person or company described in the previous sentence.
(3) (A) The agency must not use as a home health aide (on a full-time, temporary, per diem, or other basis), any individual to provide items or services described in section 1395x (m) of this title on or after January 1, 1990, unless the individual—

(i) has completed a training and competency evaluation program, or a competency evaluation program, that meets the minimum standards established by the Secretary under subparagraph (D), and

(ii) is competent to provide such items and services.

For purposes of clause (i), an individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual’s most recent completion of such a program, there has been a continuous period of 24 consecutive months during none of which the individual provided items and services described in section 1395x (m) of this title for compensation.

(B) (i) The agency must provide, with respect to individuals used as a home health aide by the agency as of July 1, 1989, for a competency evaluation program (as described in subparagraph (A)(i)) and such preparation as may be necessary for the individual to complete such a program by January 1, 1990.

(ii) The agency must provide such regular performance review and regular in-service education as assures that individuals used to provide items and services described in section 1395x (m) of this title are competent to provide those items and services.

(C) The agency must not permit an individual, other than in a training and competency evaluation program that meets the minimum standards established by the Secretary under subparagraph (D), to provide items or services of a type for which the individual has not demonstrated competency.

(D) (i) The Secretary shall establish minimum standards for the programs described in subparagraph (A) by not later than October 1, 1988.

(ii) Such standards shall include the content of the curriculum, minimum hours of training, qualification of instructors, and procedures for determination of competency.

(iii) Such standards may permit approval of programs offered by or in home health agencies, as well as outside agencies (including employee organizations), and of programs in effect on December 22, 1987; except that they may not provide for the approval of a program offered by or in a home health agency which, within the previous 2 years—

(I) has been determined to be out of compliance with subparagraph (A), (B), or (C);

(II) has been subject to an extended (or partial extended) survey under subsection (c)(2)(D) of this section;

(III) has been assessed a civil money penalty described in subsection (f)(2)(A)(i) of this section of not less than $5,000; or

(IV) has been subject to the remedies described in subsection (e)(1) of this section or in clauses (ii) or (iii) of subsection (f)(2)(A) of this section.

(iv) Such standards shall permit a determination that an individual who has completed (before July 1, 1989) a training and competency evaluation program or a competency evaluation program shall be deemed for purposes of subparagraph (A) to have completed a program that is approved by the Secretary under the standards established under this subparagraph if the Secretary determines that, at the time the program was offered, the program met such standards.

(E) In this paragraph, the term “home health aide” means any individual who provides the items and services described in section 1395x (m) of this title, but does not include an individual—

(i) who is a licensed health professional (as defined in subparagraph (F)), or
who volunteers to provide such services without monetary compensation.

(F) In this paragraph, the term “licensed health professional” means a physician, physician assistant, nurse practitioner, physical, speech, or occupational therapist, physical or occupational therapy assistant, registered professional nurse, licensed practical nurse, or licensed or certified social worker.

(4) The agency includes an individual’s plan of care required under section 1395x (m) of this title as part of the clinical records described in section 1395x (o)(3) of this title.

(5) The agency operates and provides services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of section 1320a–3 of this title) and with accepted professional standards and principles which apply to professionals providing items and services in such an agency.

(6) The agency complies with the requirement of section 1395cc (f) of this title (relating to maintaining written policies and procedures respecting advance directives).

(b) Duty of Secretary

It is the duty and responsibility of the Secretary to assure that the conditions of participation and requirements specified in or pursuant to section 1395x (o) of this title and subsection (a) of this section and the enforcement of such conditions and requirements are adequate to protect the health and safety of individuals under the care of a home health agency and to promote the effective and efficient use of public moneys.

(c) Surveys of home health agencies

(1) Any agreement entered into or renewed by the Secretary pursuant to section 1395aa of this title relating to home health agencies shall provide that the appropriate State or local agency shall conduct, without any prior notice, a standard survey of each home health agency. Any individual who notifies (or causes to be notified) a home health agency of the time or date on which such a survey is scheduled to be conducted is subject to a civil money penalty of not to exceed $2,000. The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a of this title. The Secretary shall review each State’s or local agency’s procedures for scheduling and conduct of standard surveys to assure that the State or agency has taken all reasonable steps to avoid giving notice of such a survey through the scheduling procedures and the conduct of the surveys themselves.

(2) (A) Except as provided in subparagraph (B), each home health agency shall be subject to a standard survey not later than 36 months after the date of the previous standard survey conducted under this paragraph. The Secretary shall establish a frequency for surveys of home health agencies within this 36-month interval commensurate with the need to assure the delivery of quality home health services.

(B) If not otherwise conducted under subparagraph (A), a standard survey (or an abbreviated standard survey) of an agency—

(i) may be conducted within 2 months of any change of ownership, administration, or management of the agency to determine whether the change has resulted in any decline in the quality of care furnished by the agency, and

(ii) shall be conducted within 2 months of when a significant number of complaints have been reported with respect to the agency to the Secretary, the State, the entity responsible for the licensing of the agency, the State or local agency responsible for maintaining a toll-free hotline and investigative unit (under section 1395aa (a) of this title), or any other appropriate Federal, State, or local agency.

(C) A standard survey conducted under this paragraph with respect to a home health agency—

(i) shall include (to the extent practicable), for a case-mix stratified sample of individuals furnished items or services by the agency—
(I) visits to the homes of such individuals, but only with the consent of such individuals, for the purpose of evaluating (in accordance with a standardized reproducible assessment instrument (or instruments) approved by the Secretary under subsection (d) of this section) the extent to which the quality and scope of items and services furnished by the agency attained and maintained the highest practicable functional capacity of each such individual as reflected in such individual’s written plan of care required under section 1395x(m) of this title and clinical records required under section 1395x(o)(3) of this title; and

(II) a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care;

(ii) shall be based upon a protocol that is developed, tested, and validated by the Secretary not later than January 1, 1989; and

(iii) shall be conducted by an individual—

(I) who meets minimum qualifications established by the Secretary not later than July 1, 1989,

(II) who is not serving (or has not served within the previous 2 years) as a member of the staff of, or as a consultant to, the home health agency surveyed respecting compliance with the conditions of participation specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section, and

(III) who has no personal or familial financial interest in the home health agency surveyed.

(D) Each home health agency that is found, under a standard survey, to have provided substandard care shall be subject to an extended survey to review and identify the policies and procedures which produced such substandard care and to determine whether the agency has complied with the conditions of participation specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section. Any other agency may, at the Secretary’s or State’s discretion, be subject to such an extended survey (or a partial extended survey). The extended survey shall be conducted immediately after the standard survey (or, if not practical, not later than 2 weeks after the date of completion of the standard survey).

(E) Nothing in this paragraph shall be construed as requiring an extended (or partial extended) survey as a prerequisite to imposing a sanction against an agency under subsection (e) of this section on the basis of the findings of a standard survey.

(d) Assessment process; reports to Congress

(1) Not later than January 1, 1989, the Secretary shall designate an assessment instrument (or instruments) for use by an agency in complying with subsection (c)(2)(C)(i)(I) of this section.

(2) (A) Not later than January 1, 1992, the Secretary shall—

(i) evaluate the assessment process,

(ii) report to Congress on the results of such evaluation, and

(iii) based on such evaluation, make such modifications in the assessment process as the Secretary determines are appropriate.

(B) The Secretary shall periodically update the evaluation conducted under subparagraph (A), report the results of such update to Congress, and, based on such update, make such modifications in the assessment process as the Secretary determines are appropriate.

(3) The Secretary shall provide for the comprehensive training of State and Federal surveyors in matters relating to the performance of standard and extended surveys under this section, including the use of any assessment instrument (or instruments) designated under paragraph (1).

(e) Enforcement
(1) If the Secretary determines on the basis of a standard, extended, or partial extended survey or otherwise, that a home health agency that is certified for participation under this subchapter is no longer in compliance with the requirements specified in or pursuant to section 1395x (o) of this title or subsection (a) of this section and determines that the deficiencies involved immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subsection (f)(2)(A)(iii) of this section or terminate the certification of the agency, and may provide, in addition, for 1 or more of the other remedies described in subsection (f)(2)(A) of this section.

(2) If the Secretary determines on the basis of a standard, extended, or partial extended survey or otherwise, that a home health agency that is certified for participation under this subchapter is no longer in compliance with the requirements specified in or pursuant to section 1395x (o) of this title or subsection (a) of this section and determines that the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, the Secretary may (for a period not to exceed 6 months) impose intermediate sanctions developed pursuant to subsection (f) of this section, in lieu of terminating the certification of the agency. If, after such a period of intermediate sanctions, the agency is still no longer in compliance with the requirements specified in or pursuant to section 1395x (o) of this title or subsection (a) of this section, the Secretary shall terminate the certification of the agency.

(3) If the Secretary determines that a home health agency that is certified for participation under this subchapter is in compliance with the requirements specified in or pursuant to section 1395x (o) of this title or subsection (a) of this section but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty under subsection (f)(2)(A)(i) of this section for the days in which it finds that the agency was not in compliance with such requirements.

(4) The Secretary may continue payments under this subchapter with respect to a home health agency not in compliance with the requirements specified in or pursuant to section 1395x (o) of this title or subsection (a) of this section over a period of not longer than 6 months, if—

(A) the State or local survey agency finds that it is more appropriate to take alternative action to assure compliance of the agency with the requirements than to terminate the certification of the agency,

(B) the agency has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and

(C) the agency agrees to repay to the Federal Government payments received under this subparagraph if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by home health agencies under this subparagraph.

(f) Intermediate sanctions

(1) The Secretary shall develop and implement, by not later than April 1, 1989—

(A) a range of intermediate sanctions to apply to home health agencies under the conditions described in subsection (e) of this section, 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) civil money penalties in an amount not to exceed $10,000 for each day of noncompliance,

(ii) suspension of all or part of the payments to which a home health agency would otherwise be entitled under this subchapter with respect to items and services furnished
by a home health agency on or after the date on which the Secretary determines that intermediate sanctions should be imposed pursuant to subsection (e)(2) of this section, and

(iii) the appointment of temporary management to oversee the operation of the home health agency and to protect and assure the health and safety of the individuals under the care of the agency while improvements are made in order to bring the agency into compliance with all the requirements specified in or pursuant to section 1395x (o) of this title or 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 (i) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a (a) of this title. The temporary management under clause (iii) shall not be terminated until the Secretary has determined that the agency has the management capability to ensure continued compliance with all the requirements referred to in that clause.

(B) The sanctions specified in subparagraph (A) are in addition to sanctions otherwise available under State or Federal law and shall not be construed as limiting other remedies, including any remedy available to an individual at common law.

(C) A finding to suspend payment under subparagraph (A)(ii) shall terminate when the Secretary finds that the home health agency is in substantial compliance with all the requirements specified in or pursuant to section 1395x (o) of this title and subsection (a) of this section.

(3) The Secretary shall develop and implement, by not later than April 1, 1989, specific procedures with respect to the conditions under which each of the intermediate sanctions developed under paragraph (1) is to be applied, including the amount of any fines and the severity of each of these sanctions. Such procedures shall be designed so as to minimize the time between identification of deficiencies and imposition of these sanctions and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies.

(g) Payment on basis of location of service

A home health agency shall submit claims for payment for home health services under this subchapter only on the basis of the geographic location at which the service is furnished, as determined by the Secretary.


Amendments


1996—Subsec. (c)(2)(A). Pub. L. 104–134 substituted “36 months” for “15 months” in first sentence and amended last sentence generally. Prior to amendment, last sentence read as follows: “The statewide average interval between standard surveys of any home health agency shall not exceed 12 months.”
1990—Subsec. (a)(3)(D)(iii). Pub. L. 101–508, § 4207(i)(1), formerly § 4027(i)(1), as renumbered by Pub. L. 103–432, substituted “which, within the previous 2 years—” and subcls. (I) to (IV) for “which has been determined to be out of compliance with the requirements specified in or pursuant to section 1395x (o) of this title or subsection (a) of this section within the previous 2 years.”


Subsec. (a)(4) to (6). Pub. L. 100–360, § 411(d)(1)(A)(iii), redesignated pars. (5) and (6) as (4) and (5), respectively, and struck out former par. (4) which read as follows: “With respect to durable medical equipment furnished to individuals for whom the agency provides items and services, suppliers of such equipment do not use (on a full-time, temporary, per diem, or other basis) any individual who does not meet minimum training standards (established by the Secretary by October 1, 1988) for the demonstration and use of any such equipment furnished to individuals with respect to whom payments may be made under this subchapter.”

Subsec. (c)(1). Pub. L. 100–360, § 411(d)(2)(A), as amended by Pub. L. 100–485, § 608(d)(20)(A), amended third sentence generally. Prior to amendment, third sentence read as follows: “The Secretary shall provide for imposition of civil money penalties under this clause in a manner similar to that for the imposition of civil money penalties under section 1320a–7a of this title.”


Subsec. (f)(2)(A). Pub. L. 100–360, § 411(d)(3)(B)(i), inserted before last sentence “The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a (a) of this title.”

Pub. L. 100–360, § 411(d)(3)(B)(ii), realigned the margins of cls. (i) to (iii) and concluding provisions.

Subsec. (f)(2)(A)(i). Pub. L. 100–360, § 411(d)(3)(B)(iii), substituted “in an amount not to exceed $10,000 for each day of noncompliance” for “for each day of noncompliance”.

1987—Subsecs. (c), (d). Pub. L. 100–203, § 4022(a), added subsecs. (c) and (d).


Effective Date of 1997 Amendment

Amendment by Pub. L. 105–33 applicable to cost reporting periods beginning on or after Oct. 1, 1997, see section 4604(c) of Pub. L. 105–33, set out as a note under section 1395x of this title.

Effective Date of 1990 Amendment

Amendment by section 4206(d)(2) of Pub. L. 101–508 applicable with respect to services furnished on or after the first day of the first month beginning more than 1 year after Nov. 5, 1990, see section 4206(e)(1) of Pub. L. 101–508, set out as a note under section 1395i–3 of this title.


Section 4207 (i)(2), formerly 4207(ii)(2), of Pub. L. 101–508, as renumbered and amended by Pub. L. 103–432, title I, § 160(d)(4), (11), Oct. 31, 1994, 108 Stat. 4444, provided that: “The amendments made by paragraph (1) [amending this section] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203], except that the Secretary may not permit approval of a training and competency evaluation program or a competency evaluation program offered by or in a home health agency which, pursuant to any Federal or State law within the 2-year period beginning on October 1, 1988—

“(i) had its participation terminated under title XVIII of the Social Security Act [this subchapter];

“(ii) was assessed a civil money penalty not less than $5,000 for deficiencies in applicable quality standards for home health agencies;
“(iii) was subject to suspension by the Secretary of all or part of the payments to which it would otherwise be entitled under such title;

“(iv) operated under a temporary management appointed to oversee the operation of the agency and to ensure the health and safety of the agency’s patients; or

“(v) pursuant to State action, was closed or had its patients transferred.”

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.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by 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

Section 4022(b) of Pub. L. 100–203 provided that: “Except as otherwise specifically provided in section 1891(d) of the Social Security Act [subsec. (d) of this section] (as added by subsection (a)), the amendment made by subsection (a) [amending this section] shall become effective on the first day of the 18th calendar month to begin after the date of the enactment of this Act [Dec. 22, 1987].”

Section 4023(b) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, § 411(d)(3)(C), July 1, 1988, 102 Stat. 774, provided that: “Except as otherwise specifically provided in subsections (e) and (f) of section 1891 of the Social Security Act [subsecs. (e) and (f) of this section] (as added by subsection (a)), the amendment made by subsection (a) [amending this section] shall become effective on the first day of the 18th calendar month to begin after the date of the enactment of this Act [Dec. 22, 1987], and no intermediate sanction described in section 1891(f)(2)(A) of such Act [subsec. (f)(2)(A) of this section] shall be imposed for violations occurring before such effective date.”

Effective Date

Section applicable to home health agencies as of the first day of the 18th calendar month that begins after Dec. 22, 1987, except as otherwise provided, see section 4021(c) of Pub. L. 100–203, set out as an Effective Date of 1987 Amendment note under section 1395x of this title.

Treatment of Branch Offices; GAO Study on Supervision of Home Health Care Provided in Isolated Rural Areas

Pub. L. 106–554, § 1(a)(6) [title V, § 506], Dec. 21, 2000, 114 Stat. 2763, 2763A–531, provided that:

“(a) Treatment of Branch Offices.—

“(1) In general.—Notwithstanding any other provision of law, in determining for purposes of title XVIII of the Social Security Act [this subchapter] whether an office of a home health agency constitutes a branch office or a separate home health agency, neither the time nor distance between a parent office of the home health agency and a branch office shall be the sole determinant of a home health agency’s branch office status.

“(2) Consideration of forms of technology in definition of supervision.—The Secretary of Health and Human Services may include forms of technology in determining what constitutes ‘supervision’ for purposes of determining a home health agency’s branch office status under paragraph (1).

“(b) GAO Study.—

“(1) Study.—The Comptroller General of the United States shall conduct a study of the provision of adequate supervision to maintain quality of home health services delivered under the medicare program under title XVIII of the Social Security Act [this subchapter] in isolated rural areas. The study shall evaluate the methods that home health agency branches and subunits use to maintain adequate supervision in the delivery of services to clients residing in those areas, how these methods of supervision compare to requirements that subunits independently meet medicare conditions of participation, and the resources utilized by subunits to meet such conditions.

“(2) Report.—Not later than January 1, 2002, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). The report shall include recommendations on whether exceptions are needed for subunits and branches of home health agencies under the medicare program to maintain access to the home health benefit or whether alternative policies should be developed to assure adequate supervision and access and recommendations on whether a national standard for supervision is appropriate.”