

Services, after consultation with the Physician Payment Review Commission, develop recommendations and guidelines respecting other surgical procedures for which an assistant at surgery was generally not medically necessary and circumstances under which use of an assistant at surgery was generally appropriate but should be subject to prior approval of an appropriate entity and that the Secretary report to Congress, not later than January 1, 1987, on these recommendations and guidelines.

PACEMAKER REIMBURSEMENT REVIEW AND REFORM;  
PROMULGATION OF REGULATIONS; EFFECTIVE DATE OF  
PACEMAKER REGISTRATION

Pub. L. 98-369, div. B, title III, §2304(d), July 18, 1984, 98 Stat. 1069, provided that: "The Secretary of Health and Human Services shall promulgate final regulations to carry out this section and the amendment made by this section [amending this section and enacting provisions set out as a note under section 1395f of this title] prior to January 1, 1985, and the amendment made by subsection (c) [amending this section] shall apply to pacemaker devices and leads implanted or removed on or after the effective date of such regulations."

PAYMENT FOR DEBRIDEMENT OF MYCOTIC TOENAILS

Pub. L. 98-369, div. B, title III, §2325, July 18, 1984, 98 Stat. 1087, provided that: "The Secretary shall provide, pursuant to section 1862(a) of the Social Security Act [42 U.S.C. 1395y(a)], that payment will not be made under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] for a physician's debridement of mycotic toenails to the extent such debridement is performed for a patient more frequently than once every 60 days, unless the medical necessity for more frequent treatment is documented by the billing physician."

INTERIM WAIVER IN CERTAIN CASES OF BILLING RULE  
FOR ITEMS AND SERVICES OTHER THAN PHYSICIANS'  
SERVICES

Pub. L. 98-21, title VI, §602(k), Apr. 20, 1983, 97 Stat. 165, as amended by Pub. L. 99-272, title IX, §9112(a), Apr. 7, 1986, 100 Stat. 163, provided that:

"(1) The Secretary of Health and Human Services may, for any cost reporting period beginning prior to October 1, 1986, waive the requirements of sections 1862(a)(14) and 1866(a)(1)(H) of the Social Security Act [42 U.S.C. 1395y(a)(14), 1395cc(a)(1)(H)] in the case of a hospital which has followed a practice, since prior to October 1, 1982, of allowing direct billing under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] for services (other than physicians' services) so extensively, that immediate compliance with those requirements would threaten the stability of patient care. Any such waiver shall provide that such billing may continue to be made under part B of such title but that the payments to such hospital under part A of such title [42 U.S.C. 1395c et seq.] shall be reduced by the amount of the billings for such services under part B of such title. If such a waiver is granted, at the end of the waiver period the Secretary may provide for such methods of payments under part A as is appropriate, given the organizational structure of the institution.

"(2) In the case of a hospital which is receiving payments pursuant to a waiver under paragraph (1), payment of the adjustment for indirect costs of approved educational activities shall be made as if the hospital were receiving under part A of title XVIII of the Social Security Act all the payments which are made under part B of such title solely by reason of such waiver.

"(3) Any waiver granted under paragraph (1) shall provide that, with respect to those items and services billed under part B of title XVIII of the Social Security Act solely by reason of such waiver—

"(A) payment under such part shall be equal to 100 percent of the reasonable charge or other applicable payment base for the items and services; and

"(B) the entity furnishing the items and services must agree to accept the amount paid pursuant to

subparagraph (A) as the full charge for the items and services."

[Pub. L. 99-272, title IX, §9112(b), Apr. 7, 1986, 100 Stat. 163, provided that:

"(1) Section 602(k)(2) of the Social Security Amendments of 1983 (as added by subsection (a)) [set out above] shall apply to cost reporting periods beginning on or after January 1, 1986.

"(2) Section 602(k)(3) of the Social Security Amendments of 1983 (as added by subsection (a)) [set out above] shall apply to items and services furnished after the end of the 10-day period beginning on the date of the enactment of this Act [Apr. 7, 1986]."

PROHIBITION OF PAYMENT FOR INEFFECTIVE DRUGS

Pub. L. 97-248, title I, §115(b), Sept. 3, 1982, 96 Stat. 353, provided that: "No provision of law limiting the use of funds for purposes of enforcing or implementing section 1862(c) [42 U.S.C. 1395y(c)] or section 1903(i)(5) [42 U.S.C. 1396b(i)(5)] of the Social Security Act, section 2103 of the Omnibus Budget Reconciliation Act of 1981 [section 2103 of Pub. L. 97-35, amending sections 1395y and 1396b of this title and enacting provisions set out as notes under sections 1395y and 1396b of this title], or any rule or regulation issued pursuant to any such section (including any provision contained in, or incorporated by reference into, any appropriation Act or resolution making continuing appropriations) shall apply to any period after September 30, 1982, unless such provision of law is enacted after the date of the enactment of this Act [Sept. 3, 1982] and specifically states that such provision is to supersede this section."

ESTABLISHMENT AND IMPLEMENTATION OF GUIDELINES

Pub. L. 97-35, title XXI, §2152(b), Aug. 13, 1981, 95 Stat. 802, directed the Secretary of Health and Human Services to establish, and provide for the implementation of, the guidelines described in subsec. (f) of this section not later than Oct. 1, 1981.

REPORT TO CONGRESSIONAL COMMITTEES ON IMPLEMENTATION OF CERTIFICATION REQUIREMENTS RELATING TO MODIFICATION OF HEALTH BENEFITS PLAN OR PROGRAM; FAILURE TO SUBMIT REPORT

Pub. L. 93-480, §4(b), Oct. 26, 1974, 88 Stat. 1454, provided that the Civil Service Commission and the Secretary of Health, Education, and Welfare submit a report on or before Mar. 1, 1975, on the steps which have been taken, and the steps which are planned, to enable the Secretary to make the determination and certification referred to in former subsec. (c) of this section and that if such report is not submitted by Mar. 1, 1975, the date specified in former subsec. (c) shall be deemed to be July 1, 1975, rather than Jan. 1, 1976.

**§ 1395z. Consultation with State agencies and other organizations to develop conditions of participation for providers of services**

In carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15),<sup>1</sup> (o)(6), (cc)(2)(I), and<sup>2</sup> (dd)(2), and (mm)(1) of section 1395x of this title, or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) of this title, the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies. Such conditions prescribed under any of such subsections may be varied for different areas or different classes of institutions or agencies and may, at the request of a State, provide higher requirements for such State than for

<sup>1</sup> See References in Text note below.

<sup>2</sup> So in original. The word "and" probably should not appear.

other States; except that, in the case of any State or political subdivision of a State which imposes higher requirements on institutions as a condition to the purchase of services (or of certain specified services) in such institutions under a State plan approved under subchapter I, XVI, or XIX of this chapter, the Secretary shall impose like requirements as a condition to the payment for services (or for the services specified by the State or subdivision) in such institutions in such State or subdivision.

(Aug. 14, 1935, ch. 531, title XVIII, § 1863, as added Pub. L. 89-97, title I, § 102(a), July 30, 1965, 79 Stat. 325; amended Pub. L. 92-603, title II, § 234(g)(2), Oct. 30, 1972, 86 Stat. 1413; Pub. L. 96-499, title IX, §§ 933(f), 934(c)(1), Dec. 5, 1980, 94 Stat. 2636, 2639; Pub. L. 97-248, title I, § 122(g)(2), Sept. 3, 1982, 96 Stat. 362; Pub. L. 98-369, div. B, title III, §§ 2335(c), 2349(b)(1), 2354(b)(32), July 18, 1984, 98 Stat. 1090, 1097, 1102; Pub. L. 100-360, title II, §§ 203(e)(2), 204(c)(1), July 1, 1988, 102 Stat. 725, 728; Pub. L. 101-234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981; Pub. L. 101-239, title VI, § 6003(g)(3)(C)(ii), Dec. 19, 1989, 103 Stat. 2152; Pub. L. 101-508, title IV, § 4163(c)(1), Nov. 5, 1990, 104 Stat. 1388-99; Pub. L. 103-432, title I, § 145(c)(2), Oct. 31, 1994, 108 Stat. 4427.)

#### REFERENCES IN TEXT

Subsection (j) of section 1395x of this title, referred to in text, was amended generally by Pub. L. 100-203, title IV, § 4201(a)(1), Dec. 22, 1987, 101 Stat. 1330-160, and, as so amended, does not contain a par. (15).

#### AMENDMENTS

1994—Pub. L. 103-432 struck out “or whether screening mammography meets the standards established under section 1395m(c)(3) of this title,” before “the Secretary shall consult”.

1990—Pub. L. 101-508 inserted “or whether screening mammography meets the standards established under section 1395m(c)(3) of this title,” after “section 1395k(a)(2)(F)(i) of this title.”

1989—Pub. L. 101-239 substituted “(jj)(3), and (mm)(1)” for “and (jj)(3)”.

Pub. L. 101-234 repealed Pub. L. 100-360, §§ 203(e)(2), 204(c)(1), and provided that the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted. In the case of the amendment by Pub. L. 100-360, § 203(e)(2), Pub. L. 101-234 was given effect by substituting “and (dd)(2)” for “(dd)(2), (jj)(3)” because of the intervening amendment by Pub. L. 101-239, see note above and 1988 Amendment note below.

1988—Pub. L. 100-360, § 204(c)(1), inserted “or whether screening mammography meets the standards established under section 1395m(e)(3) of this title,” after “1395k(a)(2)(F)(i) of this title.”

Pub. L. 100-360, § 203(e)(2), substituted “(dd)(2), and (jj)(3)” for “and (dd)(2)”.

1984—Pub. L. 98-369, § 2335(c), struck out “(g)(4),” after “(e)(9), (f)(4).”

Pub. L. 98-369, § 2354(b)(32), substituted “(j)(15)” for “(j)(11)”.

Pub. L. 98-369, § 2349(b)(1), substituted “appropriate State agencies” for “the Health Insurance Benefits Advisory Council established by section 1395dd of this title, appropriate State agencies.”

1982—Pub. L. 97-248 substituted “(cc)(2)(I), and (dd)(2)” for “and (cc)(2)(I)”.

1980—Pub. L. 96-499, § 933(f), substituted “(o)(6), and (cc)(2)(I) of section 1395x” for “and (o)(6) of section 1395x”.

Pub. L. 96-499, § 934(c)(1), inserted “or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) of this title.”

1972—Pub. L. 92-603 substituted “subsections (e)(9), (f)(4), (g)(4), (j)(11), and (o)(6) of section 1395x of this title” for “subsections (e)(8), (f)(4), (g)(4), (j)(10), and (o)(5) of section 1395x of this title”.

#### 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

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 section 203(e)(2) 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)(1) 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.

#### EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by section 2335(c) of Pub. L. 98-369 effective July 18, 1984, see section 2335(g) of Pub. L. 98-369, set out as a note under section 1395f of this title.

Amendment by section 2349(b)(1) of Pub. L. 98-369 effective July 18, 1984, see section 2349(c) of Pub. L. 98-369, set out as a note under section 907a of this title.

Amendment by section 2354(b)(32) of 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, set out as a note under section 1395c of this title.

#### EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by section 933(f) of Pub. L. 96-499 effective with respect to a comprehensive outpatient rehabilitation facility's first accounting period beginning on or after July 1, 1981, see section 933(h) of Pub. L. 96-499, set out as a note under section 1395k of this title.

#### EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by 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.

#### TERMINATION OF ADVISORY COUNCILS

Advisory councils in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by the Con-

gress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

#### § 1395aa. Agreements with States

##### (a) Use of State agencies to determine compliance by providers of services with conditions of participation

The Secretary shall make an agreement with any State which is able and willing to do so under which the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by him for the purpose of determining whether an institution therein is a hospital or skilled nursing facility, or whether an agency therein is a home health agency, or whether an agency is a hospice program or whether a facility therein is a rural health clinic as defined in section 1395x(aa)(2) of this title, a critical access hospital, as defined in section 1395x(mm)(1) of this title, or a comprehensive outpatient rehabilitation facility as defined in section 1395x(cc)(2) of this title, or whether a laboratory meets the requirements of paragraphs (16) and (17) of section 1395x(s) of this title, or whether a clinic, rehabilitation agency or public health agency meets the requirements of subparagraph (A) or (B), as the case may be, of section 1395x(p)(4) of this title, or whether an ambulatory surgical center meets the standards specified under section 1395k(a)(2)(F)(i) of this title. To the extent that the Secretary finds it appropriate, an institution or agency which such a State (or local) agency certifies is a hospital, skilled nursing facility, rural health clinic, comprehensive outpatient rehabilitation facility, home health agency, or hospice program (as those terms are defined in section 1395x of this title) may be treated as such by the Secretary. Any State agency which has such an agreement may (subject to approval of the Secretary) furnish to a skilled nursing facility, after proper request by such facility, such specialized consultative services (which such agency is able and willing to furnish in a manner satisfactory to the Secretary) as such facility may need to meet one or more of the conditions specified in section 1395i-3(a) of this title. Any such services furnished by a State agency shall be deemed to have been furnished pursuant to such agreement. Within 90 days following the completion of each survey of any health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization by the appropriate State or local agency described in the first sentence of this subsection, the Secretary shall make public in readily available form and place, and require (in the case of skilled nursing facilities) the posting in a place readily accessible to patients (and patients' representatives), the pertinent findings of each such survey relating to the compliance of each such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization with (1) the statutory conditions of participation imposed under this subchapter and (2) the major additional

conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinic, agency, or organization. Any agreement under this subsection shall provide for the appropriate State or local agency to maintain a toll-free hotline (1) to collect, maintain, and continually update information on home health agencies located in the State or locality that are certified to participate in the program established under this subchapter (which information shall include any significant deficiencies found with respect to patient care in the most recent certification survey conducted by a State agency or accreditation survey conducted by a private accreditation agency under section 1395bb of this title with respect to the home health agency, when that survey was completed, whether corrective actions have been taken or are planned, and the sanctions, if any, imposed under this subchapter with respect to the agency) and (2) to receive complaints (and answer questions) with respect to home health agencies in the State or locality. Any such agreement shall provide for such State or local agency to maintain a unit for investigating such complaints that possesses enforcement authority and has access to survey and certification reports, information gathered by any private accreditation agency utilized by the Secretary under section 1395bb of this title, and consumer medical records (but only with the consent of the consumer or his or her legal representative).

##### (b) Payment in advance or by way of reimbursement to State for performance of functions of subsection (a)

The Secretary shall pay any such State, in advance or by way of reimbursement, as may be provided in the agreement with it (and may make adjustments in such payments on account of overpayments or underpayments previously made), for the reasonable cost of performing the functions specified in subsection (a) of this section, and for the Federal Hospital Insurance Trust Fund's fair share of the costs attributable to the planning and other efforts directed toward coordination of activities in carrying out its agreement and other activities related to the provision of services similar to those for which payment may be made under part A of this subchapter, or related to the facilities and personnel required for the provision of such services, or related to improving the quality of such services.

##### (c) Use of State or local agencies to survey hospitals

The Secretary is authorized to enter into an agreement with any State under which the appropriate State or local agency which performs the certification function described in subsection (a) of this section will survey, on a selective sample basis (or where the Secretary finds that a survey is appropriate because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients), provider entities that, pursuant to