

## EFFECTIVE DATE OF 1972 AMENDMENT

Pub. L. 92-603, title II, §261(b), Oct. 30, 1972, 86 Stat. 1448, provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to waiver actions considered after the date of the enactment of this Act [Oct. 30, 1972]."

Pub. L. 92-603, title II, §281(g), Oct. 30, 1972, 86 Stat. 1456, provided that: "The provisions of subsection (a)(1) [amending this section] shall apply with respect to notices of payment sent to individuals after the date of enactment of this Act [Oct. 30, 1972]. The provisions of subsections (a)(2), (b), (c), and (d) [amending this section and sections 1395u and 1395cc of this title] shall apply in the case of notices sent to individuals after 1968. The provisions of subsections (e) and (f) [amending sections 1395f and 1395n of this title] shall apply in the case of services furnished (or deemed to have been furnished) after 1970."

## WAIVER OF LIABILITY LIMITING RECOUPMENT IN CERTAIN CASES

Pub. L. 101-239, title VI, §6109, Dec. 19, 1989, 103 Stat. 2213, provided that: "In the case where more than the correct amount may have been paid to a physician or individual under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] with respect to services furnished during the period beginning on July 1, 1985, and ending on March 31, 1986, as a result of a carrier's establishing statewide fees for certain procedure codes while the carrier was in the process of implementing the national common procedure coding system of the Health Care Financing Administration, the provisions of section 1870(c) of the Social Security Act [42 U.S.C. 1395gg(c)] shall apply, without the need for affirmative action by such a physician or individual, so as to prevent any recoupment, or other decrease in subsequent payments, to the physician or individual. The previous sentence shall apply to claims for items and services which were reopened by carriers on or after July 31, 1987."

**§ 1395hh. Regulations****(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation**

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Sec-

retary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

**(b) Notice of proposed regulations; public comment**

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

**(c) Publication of certain rules; public inspection; changes in data collection and retrieval**

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which—

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) and have not been previously published in a list under this subsection.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this subchapter shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1395h of this title as are necessary to make easily accessible for the Secretary and other appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this subchapter, including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.

**(e)<sup>1</sup> Retroactivity of substantive changes; reliance upon written guidance**

(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to non-compliance with such a substantive change for items and services furnished before the effective date of such a change.

(2)(A) If—

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Sec-

retary or by a medicare contractor (as defined in section 1395zz(g) of this title) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any penalty or interest under this subchapter or the provisions of subchapter XI insofar as they relate to this subchapter (including interest under a repayment plan under section 1395ddd of this title or otherwise) relating to the provision of such items or service or such claim if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.

**(f) Report on areas of inconsistency or conflict**

(1) Not later than 2 years after December 8, 2003, and every 3 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this subchapter and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect—

(A) information from individuals entitled to benefits under part A or enrolled under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman with respect to such areas of inconsistency and conflict; and

(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

(Aug. 14, 1935, ch. 531, title XVIII, §1871, as added Pub. L. 89-97, title I, §102(a) July 30, 1965, 79 Stat. 331; amended Pub. L. 99-509, title IX, §9321(e)(1), Oct. 21, 1986, 100 Stat. 2017; Pub. L. 100-203, title IV, §4035(b), (c), Dec. 22, 1987, 101 Stat. 1330-78; Pub. L. 108-173, title IX, §§902(a)(1), (b)(1), 903(a)(1), (b)(1), (c)(1), 904(b), Dec. 8, 2003, 117 Stat. 2375-2377.)

**Editorial Notes**

AMENDMENTS

2003—Subsec. (a)(3). Pub. L. 108-173, §902(a)(1), added par. (3).

Subsec. (a)(4). Pub. L. 108-173, §902(b)(1), added par. (4).

<sup>1</sup> So in original. No subsec. (d) has been enacted.

Subsec. (e). Pub. L. 108-173, §903(a)(1), added subsec. (e).

Subsec. (e)(1)(B), (C). Pub. L. 108-173, §903(b)(1), added subpars. (B) and (C).

Subsec. (e)(2). Pub. L. 108-173, §903(c)(1), added par. (2).

Subsec. (f). Pub. L. 108-173, §904(b), added subsec. (f). 1987—Subsec. (a). Pub. L. 100-203, §4035(b), designated existing provisions as par. (1) and added par. (2).

Subsec. (c). Pub. L. 100-203, §4035(c), added subsec. (c). 1986—Pub. L. 99-509 designated existing provisions as subsec. (a) and added subsec. (b).

#### Statutory Notes and Related Subsidiaries

##### EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108-173, title IX, §902(a)(2), Dec. 8, 2003, 117 Stat. 2375, provided that: “The amendment made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 8, 2003]. The Secretary [of Health and Human Services] shall provide for an appropriate transition to take into account the backlog of previously published interim final regulations.”

Pub. L. 108-173, title IX, §902(b)(2), Dec. 8, 2003, 117 Stat. 2376, provided that: “The amendment made by paragraph (1) [amending this section] shall apply to final regulations published on or after the date of the enactment of this Act [Dec. 8, 2003].”

Pub. L. 108-173, title IX, §903(a)(2), Dec. 8, 2003, 117 Stat. 2376, provided that: “The amendment made by paragraph (1) [amending this section] shall apply to substantive changes issued on or after the date of the enactment of this Act [Dec. 8, 2003].”

Pub. L. 108-173, title IX, §903(b)(2), Dec. 8, 2003, 117 Stat. 2376, provided that: “The amendment made by paragraph (1) [amending this section] shall apply to compliance actions undertaken on or after the date of the enactment of this Act [Dec. 8, 2003].”

Pub. L. 108-173, title IX, §903(c)(2), Dec. 8, 2003, 117 Stat. 2377, provided that: “The amendment made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 8, 2003] and shall only apply to a penalty or interest imposed with respect to guidance provided on or after July 24, 2003.”

##### EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by Pub. L. 100-203 effective Dec. 22, 1987, and applicable to budgets for fiscal years beginning with fiscal year 1989, see section 4035(a)(3) of Pub. L. 100-203, set out as a note under section 1395h of this title.

##### EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99-509, title IX, §9321(e)(3)(A), Oct. 21, 1986, 100 Stat. 2018, provided that: “The amendments made by paragraph (1) [amending this section] shall apply to notices of proposed rulemaking issued after the date of the enactment of this Act [Oct. 21, 1986].”

##### REGULATIONS

Pub. L. 101-508, title IV, §4207(j), formerly §4027(j), Nov. 5, 1990, 104 Stat. 1388-124, as renumbered and amended by Pub. L. 103-432, title I, §160(d)(4), (12), Oct. 31, 1994, 108 Stat. 4444, provided that: “The Secretary of Health and Human Services shall issue such regulations (on an interim or other basis) as may be necessary to implement this subtitle [subtitle A (§§4000-4361) of title IV of Pub. L. 101-508, see Tables for classification] and the amendments made by this subtitle.”

Section 4039(g) of title IV of Pub. L. 100-203 provided that: “The Secretary of Health and Human Services shall issue such regulations (on an interim or other basis) as may be necessary to implement this subtitle and the amendments made by this subtitle [subtitle A

(§§4001-4097) of title IV of Pub. L. 100-203, see Tables for classification].”

##### REQUIRING THE POSTING AND PERIODIC UPDATE OF OPIOID PRESCRIBING GUIDANCE FOR MEDICARE BENEFICIARIES

Pub. L. 115-271, title VI, §6095, Oct. 24, 2018, 132 Stat. 4003, provided that:

“(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act [Oct. 24, 2018], the Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall post on the public website of the Centers for Medicare & Medicaid Services all guidance published by the Department of Health and Human Services on or after January 1, 2016, relating to the prescribing of opioids and applicable to opioid prescriptions for individuals entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) or enrolled under part B of such title of such Act (42 U.S.C. 1395j et seq.).

“(b) UPDATE OF GUIDANCE.—

“(1) PERIODIC UPDATE.—The Secretary shall, in consultation with the entities specified in paragraph (2), periodically (as determined appropriate by the Secretary) update guidance described in subsection (a) and revise the posting of such guidance on the website described in such subsection.

“(2) CONSULTATION.—The entities specified in this paragraph are the following:

“(A) Medical professional organizations.

“(B) Providers and suppliers of services (as such terms are defined in section 1861 of the Social Security Act (42 U.S.C. 1395x)).

“(C) Health care consumers or groups representing such consumers.

“(D) Other entities determined appropriate by the Secretary.”

##### GAO STUDY ON ADVISORY OPINION AUTHORITY

Pub. L. 108-173, title IX, §904(a), Dec. 8, 2003, 117 Stat. 2377, provided that:

“(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary [of Health and Human Services] authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

“(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003].”

#### § 1395ii. Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(Aug. 14, 1935, ch. 531, title XVIII, §1872, as added Pub. L. 89-97, title I, §102(a), July 30, 1965, 79 Stat. 332; amended Pub. L. 92-603, title II, §242(a), Oct. 30, 1972, 86 Stat. 1419; Pub. L. 98-369, div. B, title III, §2354(b)(36), July 18, 1984, 98