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\*\*\* Current through PL 113-36, approved 9/18/13 \*\*\*

TITLE 42. THE PUBLIC HEALTH AND WELFARE  
CHAPTER 7. SOCIAL SECURITY ACT  
TITLE XVIII. HEALTH INSURANCE FOR THE AGED AND DISABLED  
PART E. MISCELLANEOUS PROVISIONS

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*42 USCS § 1395hh*

§ 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 *title* [42 USCS §§ 1395 et seq.]. When used in this *title* [42 USCS §§ 1395 et seq.], 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 title 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 Secretary 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, United States Code*, 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 *title [42 USCS §§ 1395 et seq.]*, 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 *title [42 USCS §§ 1395 et seq.]* 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 1816 [*42 USCS § 1395h*] 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 *title [42 USCS §§ 1395 et seq.]*, 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.

[(d)](e) 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 title 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 noncompliance 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 Secretary or by a medicare contractor (as defined in section 1889(g) [42 USCS § 1395zz(g)]) 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 *title* [42 USCS §§ 1395 et seq.] or the provisions of title XI [42 USCS §§ 1301 et seq.] insofar as they relate to this *title* [42 USCS §§ 1395 et seq.] (including interest under a repayment plan under section 1893 [42 USCS § 1395ddd] 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.

[(e)](f) Report on areas of inconsistency or conflict

(1) Not later than 2 years after the date of the enactment of this subsection [enacted Dec. 8, 2003], and every 3 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this *title* [42 USCS §§ 1395 et seq.] 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 [42 USCS §§ 1395c et seq.] or enrolled under part B [42 USCS §§ 1395j et seq.], 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.

#### **HISTORY:**

(Aug. 14, 1935, ch 531, Title XVIII, Part E[D][C], § 1871, as added July 30, 1965, P.L. 89-97, Title I, Part 1, § 102(a), 79 Stat. 331; Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9321(e)(1), 100 Stat. 2016; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpart C, § 4035(b), (c), 101 Stat. 1330-78; Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275; Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), Title IX, Subtitle A, §§ 902(a)(1), (b)(1), 903(a)(1), (b)(1), (c)(1), 904(b), 117 Stat. 2071, 2375, 2376, 2377.)

#### **HISTORY; ANCILLARY LAWS AND DIRECTIVES**

Explanatory notes:

The bracketed subsec. designators "(d)" and "(e)" have been inserted in order to maintain alphabetical continuity, as no subsec. (d) has been enacted.

## Amendments:

1986. Act Oct. 21, 1986 (applicable to notices of proposed rulemaking issued after 10/21/86, as provided by § 9321(e)(3)(A) of such Act, which appears as a note to this section), designated existing matter as subsec. (a) and added subsec. (b).

1987. Act Dec. 22, 1987 (applicable as provided by § 4035(a)(3) of such Act, which appears as *42 USCS § 1395h* note), in subsec. (a), designated the existing provisions as para. (1) and added para. (2); and added subsec. (c).

2003. Act Dec. 8, 2003 (effective on enactment, as provided by § 902(a)(2) of such Act, which appears as a note to this section), in subsec. (a), added para. (3).

Such Act further (applicable to final regulations published on or after 12/8/2003, as provided by § 902(b)(2) of such Act, which appears as a note to this section), in subsec. (a), added para. (4).

Such Act further (applicable to substantive changes issued on or after 12/8/2003, as provided by § 903(a)(2) of such Act, which appears as a note to this section), added subsec. [(d)](e)(1)(A).

Such Act further (applicable to compliance actions undertaken on or after 12/8/2003, as provided by § 903(b)(2) of such Act, which appears as a note to this section), in subsec. [(d)](e)(1), added subparas. (B) and (C).

Such Act further (effective on enactment and applicable as provided by § 903(c)(2) of such Act, which appears as a note to this section), in subsec. [(d)](e), added para. (2).

Such Act further added subsec. [(e)](f).

## Redesignation:

Act Aug. 5, 1997, P.L. 105-33, Title IV, Subtitle A, Ch 1, Subch A, § 4001, 111 Stat. 275, redesignated Part C of Title XVIII of Act Aug. 14, 1935, ch 531, as Part D of such Title.

Act Dec. 8, 2003, P.L. 108-173, Title I, § 101(a)(1), 117 Stat. 2071, redesignated Part D of Title XVIII of Act Aug. 14, 1935, ch 531, as Part E of such Title.

## Other provisions:

**Application and effective date of Oct. 21, 1986 amendments.** Act Oct. 21, 1986, P.L. 99-509, Title IX, Subtitle D, Part 2, § 9321(e)(3)(A), 100 Stat. 2017, provides: "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."

**Use of interim final regulations.** Act Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle A, Part 2, Subpart C, § 4039(g), 101 Stat. 1330-83, provides: "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 [*42 USCS §§ 1395x et seq.*] and the amendments made by this subtitle [*42 USCS §§ 1395x et seq.*]."

**Issuance of regulations implementing Title IV of Act Nov. 5, 1990.** Act Nov. 5, 1990, P.L. 101-508, Title IV, Subtitle A, Part 3, § 4207(j), 104 Stat. 1388-124; Oct. 31, 1994, P.L. 103-432, Title I, Subtitle C, § 160(d)(4), (12), 108 Stat. 4444, provides: "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 of Title IV of Act Nov. 5, 1990, P.L. 101-508, 104 Stat. 1388-30; for full classification, consult USCS Tables volumes]."

**Effective date of amendments made by § 902(a) of Act Dec. 8, 2003.** Act Dec. 8, 2003, P.L. 108-173, Title IX, Subtitle A, § 902(a)(2), 117 Stat. 2375, provides: "The amendment made by paragraph (1) [adding subsec. (a)(3) of this section] shall take effect on the date of the enactment of this Act. The Secretary shall provide for an appropriate transition to take into account the backlog of previously published interim final regulations."

**Applicability of amendments made by § 902(b)(1) of Act Dec. 8, 2003.** Act Dec. 8, 2003, P.L. 108-173, Title IX, Subtitle A, § 902(b)(2), 117 Stat. 2376, provides: "The amendment made by paragraph (1) [adding subsec. (a)(4) of this section] shall apply to final regulations published on or after the date of the enactment of this Act."

**Applicability of amendments made by § 903(a)(1) of Act Dec. 8, 2003.** Act Dec. 8, 2003, P.L. 108-173, Title IX, Subtitle A, § 903(a)(2), 117 Stat. 2376, provides: "The amendment made by paragraph (1) [adding subsec. (e)(1)(A) of this section] shall apply to substantive changes issued on or after the date of the enactment of this Act."

**Applicability of amendments made by § 903(b)(1) of Act Dec. 8, 2003.** Act Dec. 8, 2003, P.L. 108-173, Title IX, Subtitle A, § 903(b)(2), 117 Stat. 2376, provides: "The amendment made by paragraph (1) [adding subsec. (e)(1)(B) and (C) of this section] shall apply to compliance actions undertaken on or after the date of the enactment of this Act."

**Effective date and applicability of amendments made by § 903(c)(1) of Act Dec. 8, 2003.** Act Dec. 8, 2003, P.L. 108-173, Title IX, Subtitle A, § 903(c)(2), 117 Stat. 2377, provides: "The amendment made by paragraph (1) [adding subsec. (e)(2) of this section] shall take effect on the date of the enactment of this Act and shall only apply to a penalty or interest imposed with respect to guidance provided on or after July 24, 2003."

**GAO study on advisory opinion authority.** Act Dec. 8, 2003, P.L. 108-173, Title IX, Subtitle A, § 904(a), 117 Stat. 2377, provides:

"(1) Study. The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary 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 USCS §§ 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."

#### NOTES:

Code of Federal Regulations:

Public Health Service, Department of Health and Human Services--Organ procurement and transplantation network, 42 CFR 121.1 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Introduction; definitions, 42 CFR 400.200 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--General administrative requirements, 42 CFR 401.101 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Special programs and projects, 42 CFR 403.200 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Federal health insurance for the aged and disabled, 42 CFR 405.201 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Hospital insurance eligibility and entitlement, 42 CFR 406.1 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Supplementary medical insurance (SMI) enrollment and entitlement, 42 CFR 407.1 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Premiums for supplementary medical insurance, 42 CFR 408.1 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Hospital insurance benefits, 42 CFR 409.1 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Supplementary medical insurance (SMI) benefits, 42 CFR 410.1 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Principles of reasonable cost reimbursement; payment for end-stage renal disease services; prospectively determined payment rates for skilled nursing facilities, 42 CFR 413.1 et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Payment for Part B medical and other health services, *42 CFR 414.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Health maintenance organizations, competitive medical plans, and health care prepayment plans, *42 CFR 417.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Hospice care, *42 CFR 418.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Prospective payment system for hospital outpatient department services, *42 CFR 419.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Program integrity: Medicare, *42 CFR 420.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Medicare contracting, *42 CFR 421.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Medicare Advantage program, *42 CFR 422.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Voluntary Medicare prescription drug benefit, *42 CFR 423.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Conditions for Medicare payment, *42 CFR 424.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Reviews of local and national coverage determinations, *42 CFR 426.100* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Quality improvement organizations, *42 CFR 475.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Quality improvement organizations, *42 CFR 475.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Utilization and quality control review, *42 CFR 476.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Reconsiderations and appeals, *42 CFR 478.10* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Acquisition, protection, and disclosure of quality improvement organization review information, *42 CFR 480.101* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Conditions of participation for hospitals, *42 CFR 482.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Requirements for States and long term care facilities, *42 CFR 483.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Conditions for coverage of specialized services furnished by suppliers, *42 CFR 486.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Survey, certification, and enforcement procedures, *42 CFR 488.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Provider agreements and supplier approval, *42 CFR 489.1* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Standards for the electronic health record technology incentive program, *42 CFR 495.2* et seq.

Centers for Medicare & Medicaid Services, Department of Health and Human Services--Establishment of the Healthcare Infrastructure Improvement Program, *42 CFR 505.1* et seq.

Office of Inspector General-Health Care, Department of Health and Human Services--Introduction: General definitions, *42 CFR 1000.10* et seq.

Office of Inspector General-Health Care, Department of Health and Human Services--Program integrity-Medicare and State health care programs, *42 CFR 1001.1* et seq.

**Related Statutes & Rules:**

This section is referred to in *26 USCS § 223*; *42 USCS § 1395ff*.

**Research Guide:****Criminal Law and Practice:**

4 Criminal Defense Techniques (Matthew Bender), ch 85, Essentials for the Prosecution and Defense of Federal Program Fraud § 85.10.

**Law Review Articles:**

Weeks. After the Catastrophe: Disaster Relief for Hospitals. *85 NC L Rev* 223, December 2006.

**Interpretive Notes and Decisions:**

1. Generally 2. Retroactivity 3. Substantive or interpretive rule 4. Reasonable costs 5. Covered items or services 6. Professional standards

**1. Generally**

Deference to decision of Secretary of HHS that hospital "maxicare unit" did not meet regulation's requirements for "special care unit" is especially appropriate, since complex scheme of reimbursement for sizable number of medical procedures is involved, and Congress assigned primary responsibility for assessment of reasonable costs to Secretary. *Butler County Memorial Hospital v Heckler* (1985, CA3 Pa) 780 F2d 352.

Secretary of Department of Health and Human Services had not abused his discretion under *5 USCS § 706(2)(A)* and (E), in finding that plaintiff hospital was not operator of affiliated nursing school for Medicare reimbursement purposes, nor provider under *42 USCS § 1395x(u)*. *Baptist Health v Thompson* (2006, CA8 Ark) 458 F3d 768.

*42 USCS § 1395w-3(b)(10)(E)* precluded judicial review of Department of Health and Human Service's (HHS's) selection of items and services for competitive acquisition under Medicare Part B because HHS had discretion to discriminate by delivery method by virtue of *42 USCS § 1395hh(a)(1)*, part of Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), which authorized Secretary to prescribe necessary regulations to carry out MMA's purpose. *Carolina Med. Sales, Inc. v Leavitt* (2008, DC Dist Col) 559 F Supp 2d 69.

In case for reimbursement following merger in which hospital filed motion for leave to amend complaint, asserting that Secretary of Health and Human Services violated *42 USCS § 1395hh(c)(1)* by failing to timely list Program Memorandum A-00-76 in Federal Register, amendment would be futile; hospital failed to show that it suffered any prejudice from publication of Program Memorandum A-00-76 in June 2002, as opposed to October 2000. *Cent. Iowa Hosp. Corp. v Sebelius* (2011, DC Dist Col) 762 F Supp 2d 49.

Centers for Medicare and Medicaid Services did not violate notice and comment requirements of Administrative Procedure Act and Medicare Act when it published correcting amendment to *42 CFR § 412.534* without additional notice and comment because contents of correcting amendment were logical outgrowth of previous public comments; both proposed rule and preamble to final rule addressing commenters' concerns demonstrated that public had opportunity during comment period to present to agency its contentions to proposed rule, and as transition period was merely implementing mechanism for 25 percent rule--already subject of extensive public comment after defendant

issued notice of proposed rulemaking--an additional notice and comment period before correcting amendment was issued would not have provided commentators with their first occasion to offer new and different criticisms which agency might find convincing. *Select Specialty Hosp.--Akron, LLC v Sebelius* (2011, DC Dist Col) 820 F Supp 2d 13.

## 2. Retroactivity

Section of Medicare Act (42 USCS § 1395hh(a)(2)) under which rule establishing "substantive legal standard" must be published as regulation, with notice and opportunity for public comment, is not retroactively applicable. *Cedars-Sinai Medical Ctr. v Shalala* (1996, CD Cal) 939 F Supp 1457, 52 Soc Sec Rep Serv 26, remanded (1997, CA9 Cal) 125 F3d 765, 97 CDOS 7269, 97 Daily Journal DAR 11753, 38 FR Serv 3d 1532.

Radiologists' challenge to Health Care Financing Administration policy applying comparability provision of Medicare reimbursement statute and implementing regulation to Medicare reimbursement rates for their radiology services must fail, even though policy is interpretive rule they allege is invalid for failure to publish it in Federal Register as required by 42 USCS § 1395hh(c)(1), because rule articulated in letter dated June 1977 predated enactment of § 1395hh(c)(1) by more than one decade, and that section does not apply retroactively. *Abbott Radiology Assocs. v Shalala* (1997, WD NY) 992 F Supp 212, 55 Soc Sec Rep Serv 991, affd (1998, CA2 NY) 160 F3d 137, 59 Soc Sec Rep Serv 13.

As correcting amendment was not issued retroactively, nor did plaintiff hospitals suffer any harm as result of its issuance, Center for Medicare and Medicaid Service (CMS) did not act in arbitrary and capricious manner when it issued correcting amendment to 42 CFR § 412.534. *Select Specialty Hosp.--Akron, LLC v Sebelius* (2011, DC Dist Col) 820 F Supp 2d 13.

## 3. Substantive or interpretive rule

Whether administrative ruling is substantive or interpretive is question of law that court of appeals reviews *de novo*. *Warder v Shalala* (1998, CA1 Mass) 149 F3d 73, 57 Soc Sec Rep Serv 847, cert den (1999) 526 US 1064, 143 L Ed 2d 541, 119 S Ct 1455.

Administrative rule is exempt from notice and comment requirements as interpretive rule if it does not effect substantive change in regulations. *Warder v Shalala* (1998, CA1 Mass) 149 F3d 73, 57 Soc Sec Rep Serv 847, cert den (1999) 526 US 1064, 143 L Ed 2d 541, 119 S Ct 1455.

Interpretive rule binds agency's employees, including its ALJs, but it does not bind agency itself. *Warder v Shalala* (1998, CA1 Mass) 149 F3d 73, 57 Soc Sec Rep Serv 847, cert den (1999) 526 US 1064, 143 L Ed 2d 541, 119 S Ct 1455.

U.S. Dep't Health & Human Serv., Health Care Fin. Admin., Program Integrity Manual ch. 13, §§ 5.1 and 5.4, which were unpublished guidelines issued by Secretary of Health and Human Services for Medicare contractors to follow in creating local coverage determinations for review of certain payment claims, were interpretive and not legislative rules; even if 42 USCS § 1395hh(a) created broader promulgation requirement than Administrative Procedure Act, 5 USCS § 553(b) and (d), those provisions were not substantive rules and, thus, they did not have to be promulgated in accordance with notice and comment provisions of § 553(b) and (c). *Erringer v Thompson* (2004, CA9 Ariz) 371 F3d 625.

Reimbursement calculation by Center for Medicare and Medicaid Services (CMS) for psychiatric services by acute-care hospital providers by using capped rate under 42 USCS § 1395ww(b)(3)(A) and 42 CFR § 413.40 after caps had expired was not entitled to deference because regulation enacted pursuant to 42 USCS § 1395hh(a)(1) was unambiguous and CMS ignored its own regulation. *Hardy Wilson Mem. Hosp. v Sebelius* (2010, CA5 Miss) 616 F3d 449.



Secretary of Health and Human Services' 1995 interpretation of Medicare cost-reporting rules do not impose "new duties" on home health care providers or other institutions, but simply restates that providers are required to adhere to limitations contained in other sections of Medicare regulations in preparing their cost reports; as result, Medicare Provider Reimbursement Manual § 3205 is interpretive rule that is exempt under 42 USCS § 1395hh(b)(2)(C) from Administrative Procedure Act's notice and comment provisions under 5 USCS § 553(b)(3)(A), rather than legislative rule. *Visiting Nurse Ass'n v Thompson* (2004, ED NY) 378 F Supp 2d 75.

Plaintiffs failed to state claim under 5 USCS § 553(b)(3) or 42 USCS § 1395hh(b)(1) where United States Secretary of Health and Human Services' choice of general description of applicable financial standards under durable medical equipment bidding program was consistent with text of Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003), promoted purposes behind program, and had been affirmed by Congress. *Tex. Alliance for Home Care Servs. v Sebelius* (2011, DC Dist Col) 811 F Supp 2d 76.

In case in which Medicare provider argued that even if Secretary of U.S. Department of Health and Human Services' subdelegation to outside entity was permissible, it had to be effected through notice-and-comment rulemaking; since Secretary's subdelegation of her authority to make sustained or high level of payment error determination did not establish or change substantive legal standard governing scope of benefits, payment for services, or eligibility of individuals, entities or organizations to furnish or receive services, subdelegation was not required under 42 USCS § 1395hh(a)(2) to be effected via notice-and-comment rulemaking. *Gentiva Healthcare Corp. v Sebelius* (2012, DC Dist Col) 857 F Supp 2d 1.

#### Unpublished Opinions

Unpublished: Rules issued by Secretary of Health and Human Services in Medicare Carrier's Manual (MCM) that related to 42 USCS § 1395x(s)(1) and (2)(A) were not incorrectly promulgate because statute did not define "incident to," so it was ambiguous on meaning of phrase, and MCM provided meaning for phrase; therefore, MCM rule was interpretation, which did not require notice and comment under 42 USCS § 1395hh(a)(2), and it was reasonable interpretation of statute. *Gary Gibbon, M.D., Inc. v Thompson* (2005, CA9 Cal) 121 Fed Appx 703.

#### 4. Reasonable costs

Secretary of Department of Health and Human Services violated Medicare Act, 42 USCS § 1395hh(c)(1), by failing to publish in Federal Register its 3.0 hour per treatment national standard for reimbursing providers for kidney dialysis treatment because standard was guideline under which requests for exceptions under 42 CFR §§ 413.180, .182, and .184 were measured. *Chippewa Dialysis Servs. v Leavitt* (2007, App DC) 379 US App DC 143, 511 F3d 172.

Reasonable costs regulation embodied at 20 CFR § 405.427 was validly promulgated and did not violate due process or equal protection of law. *Schroeder Nursing Care, Inc. v Mutual of Omaha Ins. Co.* (1970, ED Wis) 311 F Supp 405.

Reasonable cost regulations, as applied to ambulance Medicare provider, were presumptively not to be applied retroactively, under 42 USCS § 1395hh(e)(1)(A). *Lifestar Ambulance Serv. v United States* (2009, MD Ga) 604 F Supp 2d 1372.

#### 5. Covered items or services

Administrator of Centers for Medicare & Medicaid Services determined that transaction met neither of requirements for reimbursement of depreciation losses: statutory merger between two corporations did not constitute bona fide sale; and parties to transaction were related; in support of his conclusion there was no bona fide sale, Administrator reasoned that corporation one did not receive reasonable consideration for sale of its assets and it did not engage in arm's length bargaining with corporation two; given figures before Administrator and appellants' failure to identify any evidence tending to contradict accuracy of those figures, Administrator's determination was neither

unsupported by substantial evidence nor arbitrary and capricious--he did not act inappropriately in finding vast disparity between corporation one's assets and liabilities did not support finding that merger between two corporations was consummated for reasonable consideration. *Forsyth Mem. Hosp., Inc. v Sebelius* (2011, App DC) 639 F3d 534.

20 CFR §§ 405.480-405.488, issued pursuant to authority granted in 42 USCS § 1395hh, did not require Medicare to pay fee earned and retained by physician-specialist and share of hospital's operating expense as well as additional sum paid by doctors to hospital for privilege of having monopoly there within areas of specialty. *Faith Hospital Asso. v United States* (1978) 218 Ct Cl 255, 585 F2d 474.

Provision of 42 USCS § 1395hh(a) authorizing HHS Secretary to promulgate regulations for administering Part B of Medicare program, allows Secretary great discretion in determining what items or services are covered under Part B; since Congress did not mandate that Part B provide for coverage of all medically necessary procedures, Secretary is authorized to exclude items or services, and reimbursement may be denied for item or service which is excluded at time it is provided, even though Secretary subsequently changes Medicare rules to provide for coverage of that item or service. *Goodman v Sullivan* (1989, SD NY) 712 F Supp 334, affd (1989, CA2 NY) 891 F2d 449.

Secretary of Health and Human Services had discretion to require only mail-order diabetic suppliers, but not storefront suppliers, to submit to phased-in competitive bidding scheme under 42 USCS § 1395w-3(a)(1)(B)(ii) for durable medical equipment for Medicare Part B patients because 42 USCS § 1395hh(a)(1) permitted Secretary to discriminate by delivery method in order to eliminate wasteful purchasing practices. *Carolina Med. Sales, Inc. v Leavitt* (2008, DC Dist Col) 559 F Supp 2d 69.

## **6. Professional standards**

Regulation [20 CFR § 405.1126(c)] establishing professional standards which physical therapists must meet in order to qualify for reimbursements under Medicare Program is within Secretary's rule making power. *Rasulis v Weinberger* (1974, CA7 Ill) 502 F2d 1006.