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AUTHORITY: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w-5) and sec. 105, Pub. L. 114-10, 129 Stat. 87.

Subpart A [Reserved]**Subpart B—Confidentiality and Disclosure**

SOURCE: 46 FR 55696, Nov. 12, 1981, unless otherwise noted.

§ 401.101 Purpose and scope.

(a) The regulations in this subpart:

(1) Implement section 1106(a) of the Social Security Act as it applies to the Centers for Medicare & Medicaid Services (CMS). The rules apply to information obtained by officers or employees of CMS in the course of administering title XVIII of the Social Security Act (Medicare), information obtained by Medicare intermediaries or carriers in the course of carrying out agreements under sections 1816 and 1842 of the Social Security Act, and any other information subject to section 1106(a) of the Social Security Act;

(2) Relate to the availability to the public, under 5 U.S.C. 552, of records of CMS and its components. They set out what records are available and how they may be obtained; and

(3) Supplement the regulations of the Department of Health and Human Services relating to availability of information under 5 U.S.C. 552, codified in 45 CFR part 5, and do not replace or restrict them.

(b) Except as authorized by the rules in this subpart, no information described in paragraph (a)(1) of this section shall be disclosed. The procedural rules in this subpart (§§ 401.106 through 401.152) shall be applied to requests for information which is subject to the rules for disclosure in this subpart.

(c) Requests for information which may not be disclosed according to the provisions of this subpart shall be denied under authority of section 1106(a) of the Social Security Act and this subpart, and furthermore, such requests which have been made pursuant to the Freedom of Information Act shall be denied under authority of an appropriate Freedom of Information Act exemption, 5 U.S.C. 552(b).

§ 401.102 Definitions.

For purposes of this subpart:

Act means the Social Security Act.

Freedom of Information Act rules means the substantive mandatory disclosure provisions of the Freedom of Information Act, 5 U.S.C. 552 (including the exemptions from mandatory disclosure, 5 U.S.C. 552(b), as implemented by the Department's public information regulation, 45 CFR part 5, subpart F

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and by §§ 401.106 to 401.152 of this subpart.

Person means a person as defined in the Administrative Procedure Act, 5 U.S.C. 551(2). This includes State or local agencies, but does not include Federal agencies or State or Federal courts.

Record has the same meaning as that provided in 45 CFR 5.5.

Subject individual means an individual whose record is maintained by the Department in a system of records, as the terms “individual,” “record,” and “system of records” are defined in the Privacy Act of 1974, 5 U.S.C. 552a(a).

§ 401.105 Rules for disclosure.

(a) *General rule.* The Freedom of Information Act rules shall be applied to every proposed disclosure of information. If, considering the circumstances of the disclosure, the information would be made available in accordance with the Freedom of Information Act rules, then the information may be disclosed regardless of whether the requester or beneficiary of the information has a statutory right to request the information under the Freedom of Information Act, 5 U.S.C. 552, or whether a request has been made.

(b) *Application of the general rule.* Pursuant to the general rule in paragraph (a) of this section,

(1) Information shall be disclosed—

(i) To a subject individual when required by the access provision of the Privacy Act, 5 U.S.C. 552a(d), as implemented by the Department Privacy Act regulation, 45 CFR part 5b; and

(ii) To a person upon request when required by the Freedom of Information Act, 5 U.S.C. 552;

(2) Unless prohibited by any other statute (e.g., the Privacy Act of 1974, 5 U.S.C. 552a(b), the Tax Reform Act of 1976, 26 U.S.C. 6103, or section 1106(d) and (e) of the Social Security Act), information may be disclosed to any requester or beneficiary of the information, including another Federal agency or a State or Federal court, when the information would not be exempt from mandatory disclosure under Freedom of Information Act rules or when the information nevertheless would be made available under the Department’s public information regulation’s cri-

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teria for disclosures which are in the public interest and consistent with obligations of confidentiality and administrative necessity, 45 CFR part 5, subpart F, as supplemented by §§ 401.106 to 401.152 of this subpart.

[42 FR 14704, Mar. 16, 1977. Redesignated at 45 FR 74913, 74914, Nov. 13, 1980, and correctly redesignated at 46 FR 24551, May 1, 1981, as amended at 46 FR 55697, Nov. 12, 1981]

§ 401.106 Publication.

(a) *Methods of publication.* Materials required to be published under the provisions of The Freedom of Information Act, 5 U.S.C. 552 (a)(1) and (2) are published in one of the following ways:

(1) By publication in the FEDERAL REGISTER of CMS regulations, and by their subsequent inclusion in the Code of Federal Regulations;

(2) By publication in the FEDERAL REGISTER of appropriate general notices;

(3) By other forms of publication, when incorporated by reference in the FEDERAL REGISTER with the approval of the Director of the Federal Register; and

(4) By publication of indexes of preceptual orders and opinions issued in the adjudication of claims, statements of policy and interpretations which have been adopted but have not been published in the FEDERAL REGISTER, and of administrative staff manuals and instructions to staff that affect a member of the public.

(b) *Availability for inspection.* Those materials which are published in the FEDERAL REGISTER pursuant to 5 U.S.C. 552(a)(1) shall, to the extent practicable and to further assist the public, be made available for inspection at the places specified in § 401.128.

[46 FR 55696, Nov. 12, 1981, as amended at 48 FR 22924, May 23, 1983]

§ 401.108 CMS rulings.

(a) After September 1981, a precedent final opinion or order or a statement of policy or interpretation that has not been published in the FEDERAL REGISTER as a part of a regulation or of a notice implementing regulations, but which has been adopted by CMS as having precedent, may be published in the FEDERAL REGISTER as a CMS Ruling

and will be made available in the publication entitled *CMS Rulings*.

(b) Precedent final opinions and orders and statements of policy and interpretation that were adopted by CMS before October, 1981, and that have not been published in the FEDERAL REGISTER are available in *CMS Rulings*.

(c) CMS Rulings are published under the authority of the Administrator, CMS. They are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

[48 FR 22924, May 23, 1983, as amended at 70 FR 11472, Mar. 8, 2005; 70 FR 37702, June 30, 2005]

§ 401.109 Precedential Final Decisions of the Secretary.

(a) The Chair of the Department of Health and Human Services Departmental Appeals Board (DAB Chair) may designate a final decision of the Secretary issued by the Medicare Appeals Council in accordance with part 405, subpart I; part 422, subpart M; part 423, subpart U; or part 478, subpart B, of this chapter as precedential. In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.

(b) Precedential decisions are made available to the public, with personally identifiable information of the beneficiary removed, and have precedential effect from the date they are made available to the public. Notice of precedential decisions is published in the FEDERAL REGISTER.

(c) Medicare Appeals Council decisions designated in accordance with paragraph (a) of this section have precedential effect and are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Se-

curity Administration adjudicate matters under the jurisdiction of CMS.

(d) Precedential effect, as used in this section, means that the Medicare Appeals Council's—

(1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and

(2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

[82 FR 5105, Jan. 17, 2017]

§ 401.110 Publications for sale.

The following publications containing information pertaining to the program, organization, functions, and procedures of CMS may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402.

(a) Titles 20, 42, and 45 of the Code of Federal Regulations.

(b) FEDERAL REGISTER issues.

(c) Compilation of the Social Security Laws.

(d) CMS Rulings.

(e) Social Security Handbook. The information in the Handbook is not of precedent or interpretative force.

(f) Medicare/Medicaid Directory of Medical Facilities.

§ 401.112 Availability of administrative staff manuals.

All CMS administrative staff manuals and instructions to staff personnel which contain policies, procedures, or interpretations that affect the public are available for inspection and copying. A complete listing of such materials is published in CMS Rulings. These manuals are generally not printed in a sufficient quantity to permit sale or other general distribution to the public. Selected material is maintained at Social Security Administration district offices and field offices and may be inspected there. See §§ 401.130 and 401.132 for a listing of this material.

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§ 401.116 Availability of records upon request.

(a) *General.* In addition to the records made available pursuant to §§ 401.106, 401.108, 401.110 and 401.112, CMS will, upon request made in accordance with this subpart, make identified records available to any person, unless they are exempt from disclosure under the provisions of section 552(b) of title 5, United States Code (see § 401.126), or any other provision of law.

(b) *Misappropriation, alteration, or destruction of records.* No person may remove any record made available to him for inspection or copying under this part, from the place where it is made available. In addition, no person may steal, alter, mutilate, obliterate, or destroy in whole or in part, such a record. See sections 641 and 2071 of title 18 of the United States Code.

§ 401.118 Deletion of identifying details.

When CMS publishes or otherwise makes available an opinion or order, statement of policy, or other record which relates to a private party or parties, the name or names or other identifying details will be deleted.

§ 401.120 Creation of records.

Records will not be created by compiling selected items from the files, and records will not be created to provide the requester with such data as ratios, proportions, percentages, per capita, frequency distributions, trends, correlations, and comparisons. If such data have been compiled and are available in the form of a record, the record shall be made available as provided in this subpart.

§ 401.126 Information or records that are not available.

(a) *Specific exemptions from disclosure.* Pursuant to paragraph (b) of 5 U.S.C. 552, certain classes of records are exempt from disclosure. For some examples of the kinds of materials which are exempt, see subpart F of the public information regulation of the Department of Health and Human Services (45 CFR part 5) and the appendix to that regulation.

(b) *Materials exempt from disclosure by statute.* Pursuant to paragraph (b)(3) of

5 U.S.C. 552, as amended, which exempts from the requirement for disclosure matters that are exempted from disclosure by statute, provided that such statute requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or establishes particular criteria for withholding or refers to particular types of matter to be withheld:

(1) Reports described in sections 1106 (d) and (e) of the Social Security Act shall not be disclosed, except in accordance with the provisions of sections 1106 (d) and (e). Sections 1106 (d) and (e) provide for public inspection of certain official reports dealing with the operation of the health programs established by titles XVIII and XIX of the Social Security Act (Medicare and Medicaid), but require that program validation survey reports and other formal evaluations of providers of services shall not identify individual patients, individual health care practitioners, or other individuals. Section 1106(e) further requires that none of the reports shall be made public until the contractor or provider whose performance is being evaluated has had a reasonable opportunity to review that report and to offer comments. See § 401.133 (b) and (c);

(2)(i) Except as specified in paragraph (b)(2)(ii) of this section, CMS may not disclose any accreditation survey or any information directly related to the survey (including corrective action plans) made by and released to it by the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association or any other national accreditation organization that meets the requirements of § 488.5 or § 493.506 of this chapter. Materials that are confidential include accreditation letters and accompanying recommendations and comments prepared by an accreditation organization concerning the entities it surveys.

(ii) *Exceptions.* (A) CMS may release the accreditation survey of any home health agency; and

(B) CMS may release the accreditation survey and other information directly related to the survey (including corrective action plans) to the extent the survey and information relate to an enforcement action (for example,

denial of payment for new admissions, civil money penalties, temporary management and termination) taken by CMS; and

(3) Tax returns and return information defined in section 6103 of the Internal Revenue Code, as amended by the Tax Reform Act of 1976, shall not be disclosed except as authorized by the Internal Revenue Code.

(c) *Effect of exemption.* Neither 5 U.S.C. 552 nor this regulation directs the withholding of any record or information, except to the extent of the prohibitions in paragraph (b) of this section. Except for material required to be withheld under the statutory provisions incorporated in paragraph (b) of this section or under another statute which meets the standards in 5 U.S.C. 552(b)(3), materials exempt from mandatory disclosure will nevertheless be made available when this can be done consistently with obligations of confidentiality and administrative necessity. The disclosure of materials or records under these circumstances in response to a specific request, however, is of no precedent force with respect to any other request.

[46 FR 55696, Nov. 12, 1981, as amended at 58 FR 61837, Nov. 23, 1993; 80 FR 29834, May 22, 2015]

§ 401.128 Where requests for records may be made.

(a) *General.* Any request for any record may be made to—

(1) Any CMS component;

(2) Director, Office of Public Affairs, CMS 313-H, Hubert H. Humphrey Building, 200 Independence Avenue, Washington, DC 20201; or

(3) Director of Public Affairs in any Regional Office of the Department of Health and Human Services.

The locations and service areas of these offices are as follows:

Region I—John F. Kennedy Federal Building, Boston, MA 02203. Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.

Region II—26 Federal Plaza, New York, NY 10007. New York, New Jersey, Puerto Rico, Virgin Islands.

Region III—Gateway Building, 3535 Market Street, Philadelphia, PA 19101. Delaware, Maryland, Pennsylvania, Virginia, West Virginia, District of Columbia.

Region IV—101 Marietta Street, Atlanta, GA 30323. Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee.

Region V—300 South Wacker Drive, Chicago, IL 60606. Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin.

Region VI—1200 Main Tower Building, Dallas, TX 75202. Arkansas, Louisiana, New Mexico, Oklahoma, Texas.

Region VII—601 East 12th Street, Kansas City, MO 64106. Iowa, Kansas, Missouri, Nebraska.

Region VIII—Federal Office Building, 19th and Stout Streets, Denver, CO 80294. Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming.

Region IX—Federal Office Building, 50 United Nations Plaza, San Francisco, CA 94102. Arizona, California, Hawaii, Nevada, Guam, Trust Territory of Pacific Islands, American Samoa.

Region X—Arcade Plaza Building, 1321 Second Avenue, Seattle, WA 98101. Alaska, Idaho, Oregon, Washington.

(b) *Records pertaining to individuals.* CMS maintains some records pertaining to individuals. Disclosure of such records is generally prohibited by section 1106 of the Social Security Act (42 U.S.C. 1306), except as prescribed in § 401.105 (See also § 401.126(b)). Requests for records pertaining to individuals may be addressed to:

Director, Office of Research, Demonstrations and Statistics, CMS, Baltimore, Maryland 21235, when information is sought from the record of a person who has participated in a research survey conducted by or for CMS, Office of Research, Demonstrations and Statistics; or whose records have been included by statistical sampling techniques in research and statistical studies authorized by the Social Security Act in the field of health care financing.

(c) *Requests for materials listed in § 401.130 or § 401.132 or indexed in the CMS Rulings.* A request to inspect and copy materials listed in § 401.130 or § 401.132 or indexed in CMS Rulings may be made to any district or branch office of the Social Security Administration. If the specific material requested is not available in the office receiving the request, the material will be obtained and made available promptly.

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§ 401.130 Materials available at social security district offices and branch offices.

(a) *Materials available for inspection.* The following are available or will be made available for inspection at the social security district offices and branch offices:

(1) Compilation of the Social Security Laws.

(2) The Public Information Regulation of the Department of Health and Human Services (45 CFR part 5).

(3) Medicare Program regulations issued by the Centers for Medicare & Medicaid Services, 42 CFR chapter IV.

(4) CMS Rulings.

(5) Social Security Handbook.

(b) *Materials available for inspection and copying.* The following materials are available or will be made available for inspection and copying at the social security district offices and branch offices:

(1) Claims Manual of the Social Security Administration.

(2) Department Staff Manual on Organization, Department of Health and Human Services, Part F, CMS.

(3) Parts 2 and 3 of the Part A

Intermediary Manual (Provider Services under Medicare CMS Pub. 13–2 and 13–3).

(4) Parts 2 and 3 of the Part B Intermediary Manual (Physician and Supplier Services).

(5) Intermediary Letters Related to Parts 2 and 3 of the Part A and Part B Intermediary Manuals.

(6) State Buy-In Handbook (State Enrollment of Eligible Individuals under the Supplementary Medical Insurance Program) and Letters.

(7) Group Practice Prepayment Plan Manual (HIM–8) and Letters.

(8) State Operations Manual (HIM–7).

(9) CMS Letters to State Agencies on Medicare.

(10) Skilled Nursing Facility Manual (CMS Pub. 12).

(11) Hearing Officers Handbook (Supplementary Medical Insurance Program—HIM–21).

(12) Hospital Manual (HIM–10).

(13) Home Health Agency Manual (HIM–11).

(14) Outpatient Physical Therapy Provider Manual (HIM–9).

(15) Provider Reimbursement Manual (HIM–15).

(16) Audit Program Manuals for Hospital (HIM–16), Home Health Agency (HIM–17), and Extended Care Facilities (HIM–18).

(17) Statements of deficiencies based upon survey reports of health care institutions or facilities prepared after January 31, 1973, by a State agency, and such reports (including pertinent written statements furnished by such institution or facility on such statements of deficiencies), as set forth in § 401.133(a). Except as otherwise provided for at §§ 401.133 and 488.325 of this chapter for SNFs, such statements of deficiencies, reports, and pertinent written statements shall be available or made available only at the social security district office and regional office servicing the area in which the institution or facility is located, except that such statements of deficiencies and pertinent written statements shall also be available at the local public assistance offices servicing such area.

(18) Indexes to the materials listed in paragraph (a) of this section and in this paragraph (b) and an index to the Bureau of Hearings and Appeals Handbook.

[46 FR 55696, Nov. 12, 1981, as amended at 59 FR 56232, Nov. 10, 1994]

§ 401.132 Materials in field offices of the Office of Hearings and Appeals, SSA.

(a) *Materials available for inspection.* The following materials are available for inspection in the field offices of the Office of Hearings and Appeals, SSA.

(1) Title 45 of the Code of Federal Regulations (including the public information regulation of the Department of Health and Human Services).

(2) Regulations of the Social Security Administration and CMS.

(3) Title 5, United States Code.

(4) Compilation of the Social Security Laws.

(5) CMS Rulings.

(6) Social Security Handbook.

(b) *Handbook available for inspection and copying.* The Office of Hearings and Appeals Handbook is available for inspection and copying in the field offices of the Office of Hearings and Appeals.

§ 401.133 Availability of official reports on providers and suppliers of services, State agencies, intermediaries, and carriers under Medicare.

Except as otherwise provided for in § 488.325 of this chapter for SNFs, the following must be made available to the public under the conditions specified:

(a) *Statements of deficiencies and survey reports on providers of services prepared by State agencies.* (1) Statements of deficiencies based upon official survey reports prepared after January 31, 1973, by a State agency pursuant to its agreement entered into under section 1864 of the Social Security Act and furnished to CMS, which relate to a State agency's findings on the compliance of a health care institution or facility with the applicable provisions in section 1861 of the Act and with the regulations, promulgated pursuant to those provisions, dealing with health and safety of patients in those institutions and facilities; and (2) State agency survey reports. The statement of deficiencies or report and any pertinent written statements furnished by the institution or facility on the statement of deficiencies shall be disclosed within 90 days following the completion of the survey by the State agency, but not to exceed 30 days following the receipt of the report by CMS. (See § 401.130(b)(17)) for places where statements of deficiencies, reports, and pertinent written statements will be available.)

(b) *CMS reports on providers of services.* Upon request in writing, official reports and other formal evaluations (including followup reviews), excluding references to internal tolerance rules and practices contained therein, internal working papers or other informal memoranda, prepared and completed after January 31, 1973, which relate to the performance of providers of services under Medicare: *Provided*, That no information identifying individual patients, physicians, or other practitioners, or other individuals shall be disclosed under this paragraph. Those reports and other evaluations shall be disclosed within 30 days following the final preparation thereof by CMS during which time the providers of services shall be afforded a reasonable opportunity to offer comments, and there

shall be disclosed with those reports and evaluations any pertinent written statements furnished CMS by those providers on those reports and evaluations.

(c) *Contractor performance review reports.* Upon request in writing, official contractor performance review reports and other formal evaluations (including followup reviews), excluding references to internal tolerance rules and practices contained therein, internal working papers or other informal memoranda, prepared and completed after January 31, 1973, which relate to the evaluation of the performance of (1) intermediaries and carriers under their agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act and (2) State agencies under their agreements entered into pursuant to section 1864 of the Act (including comparative evaluations of the performance of those intermediaries, carriers, and State agencies). The latest Contract Performance Review Report pertaining to a particular intermediary or carrier, prepared prior to February 1, 1973, may also be disclosed to any person upon request in writing. Those reports and evaluations shall be disclosed within 30 days following their final preparation by CMS (or 30 days following the request therefor, in the case of the contract performance review report prepared prior to February 1, 1973), during which time those intermediaries, carriers, and State agencies, as the case may be, shall be afforded a reasonable opportunity to offer comments, and there shall be disclosed with those reports and evaluations any pertinent written statements furnished CMS by those intermediaries, carriers, on State agencies or those reports and evaluations.

(d) *Accreditation surveys.* Upon written request, CMS will release the accreditation survey and related information from an accreditation organization meeting the requirements of § 488.5 or § 493.506 of this chapter to the extent the survey and information relate to an enforcement action taken (for example, denial of payment for new admission, civil money penalties, temporary management and termination) by CMS;

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(e) Upon written request, CMS will release the accreditation survey of any home health agency.

[46 FR 55696, Nov. 12, 1981; 46 FR 59249, Dec. 4, 1981, as amended at 58 FR 61838, Nov. 23, 1993; 59 FR 56232, Nov. 10, 1994; 80 FR 29834, May 22, 2015]

§ 401.134 Release of Medicare information to State and Federal agencies.

(a) Except as provided in paragraph (b) of this section, the following information may be released to an officer or employee of an agency of the Federal or a State government lawfully charged with the administration of a program receiving grants-in-aid under title V and XIX of the Social Security Act for the purpose of administration of those titles, or to any officer or employee of the Department of Army, Department of Defense, solely for the administration of its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS):

(1) Information, including the identification number, concerning charges made by physicians, other practitioners, or suppliers, and amounts paid under Medicare for services furnished to beneficiaries by such physicians, other practitioners, or suppliers, to enable the agency to determine the proper amount of benefits payable for medical services performed in accordance with those programs; or

(2) Information as to physicians or other practitioners that has been disclosed under § 401.105.

(3) Information relating to the qualifications and certification status of hospitals and other health care facilities obtained in the process of determining whether, and certifying as to whether, institutions or agencies meet or continue to meet the conditions of participation of providers of services or whether other entities meet or continue to meet the conditions for coverage of services they furnish.

(b) The release of such information shall not be authorized by a fiscal intermediary or carrier.

(c) The following information may be released to any officer or employee of an agency of the Federal or a State government lawfully charged with the duty of conducting an investigation or prosecution with respect to possible

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fraud or abuse against a program receiving grants-in-aid under Medicaid, but only for the purpose of conducting such an investigation or prosecution, or to any officer or employee of the Department of the Army, Department of Defense, solely for the administration of its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), provided that the agency has filed an agreement with CMS that the information will be released only to the agency's enforcement branch and that the agency will preserve the confidentiality of the information received and will not disclose that information for other than program purposes:

(1) The name and address of any provider of medical services, organization, or other person being actively investigated for possible fraud in connection with Medicare, and the nature of such suspected fraud. An active investigation exists when there is significant evidence supporting an initial complaint but there is need for further investigation.

(2) The name and address of any provider of medical services, organization, or other person found, after consultation with an appropriate professional association or a program review team, to have provided unnecessary services, or of any physician or other individual found to have violated the assignment agreement on at least three occasions.

(3) The name and address of any provider of medical services, organization or other person released under paragraph (c)(1) or (2) of this section concerning which an active investigation is concluded with a finding that there is no fraud or other prosecutable offense.

§ 401.135 Release of Medicare information to the public.

The following shall be made available to the public under the conditions specified:

(a) Information as to amounts paid to providers and other organizations and facilities for services to beneficiaries under title XVIII of the Act: *Provided*, That no information identifying any particular beneficiaries shall be disclosed under this paragraph.

(b) The name of any provider of services or other person furnishing services to Medicare beneficiaries who—

(1) Has been found by a Federal court to have been guilty of submitting false claims in connection with Medicare; or

(2) Has been found by a carrier or intermediary, after consultation with a professional medical association functioning external to program administration or, if appropriate, the State medical authority, to have been engaged in a pattern of furnishing services to beneficiaries which are substantially in excess of their medical needs; except that the name of any provider or other person shall not be disclosed pursuant to a finding under this paragraph (b)(2) of this section, unless that provider or other person has first been afforded a reasonable opportunity to offer evidence on his behalf.

(c) Upon request in writing, cost reports submitted by providers of services pursuant to section 1815 of the Act to enable the Secretary to determine amounts due the providers.

§ 401.136 Requests for information or records.

(a) A request should reasonably identify the requested record by brief description. Requesters who have detailed information which would assist in identifying the records requested are urged to provide such information in order to expedite the handling of the request. Envelopes in which written requests are submitted should be clearly identified as Freedom of Information requests. The request should include the fee or request determination of the fee. When necessary, a written request will be promptly forwarded to the proper office, and the requester will be advised of the date of the receipt and identification and address of the proper office.

(b) Determinations of whether records will be released or withheld will be made within 10 working days from date of receipt of the request in the office listed in § 401.128 except where CMS extends this time and sends notice of such extension to the requester. Such extension may not exceed 10 additional working days and shall apply only where the following unusual circumstances exist:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the requests;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are requested in a single request; or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the request or among two or more components of CMS having a substantial interest in the subject matter of the request.

(c) If an extension is made, the requester will be notified in writing before the expiration of 10 working days from receipt of the request and will be given an explanation of why the extension was necessary and the date on which a determination will be made.

(d) Authority to extend the time limit with respect to any request for information or records is granted to the Director, Office of Public Affairs, CMS and to the Director of Public Affairs in any HHS Regional Office. Those officers and employees of CMS who are listed in § 401.144(a) as having authority to deny requests for information from records maintained on individuals are granted authority to extend the time limit for responding to requests for information from such records.

§ 401.140 Fees and charges.

(a) *Statement of policy.* It is CMS's policy to comply with certain requests for information services without charge. Except as otherwise determined pursuant to paragraph (c) of this section, fees will be charged for the following services with respect to all other requests for information from records which are reasonably identified by the requesters:

(1) Reproduction, duplication, or copying of records;

(2) Searches for records; and

(3) Certification or authentication of records.

(b) *Fee schedules.* The fee schedule is as follows:

(1) *Search for records.* Three dollars per hour: *Provided, however, That no*

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charge will be made for the first half hour.

(2) *Reproduction, duplication, or copying of records.* Ten cents per page where such reproduction can be made by commonly available photocopying machines. The cost of reproducing records which cannot be so photocopied will be determined on an individual basis at actual cost.

(3) *Certification or authentication of records.* Three dollars per certification or authentication.

(4) *Forwarding materials to destination.* Any special arrangements for forwarding which are requested shall be charged at actual cost; however, no charge will be made for postage.

(5) No charge will be made when the total amount does not exceed five dollars.

(c) *Waiver or reduction of fees.* Waiver or reduction of the fees in paragraph (b) of this section may be made upon a determination that such waiver or reduction is in the public interest because furnishing the information can be considered as primarily benefiting the general public. Such determination may be made by the appropriate officer or employee identified in § 401.144.

(d) *Sale of documents.* On occasion, a previously printed document may be available for sale to the public; the cost of supplying the document is one cent per page unless the document is available for sale from the Superintendent of Documents, in which case the price shall be that determined by the Superintendent.

§ 401.144 Denial of requests.

(a) *General authority.* Only the Director, Office of Public Affairs, CMS, and the Regional Directors of Public Affairs, HHS, are authorized to deny written requests to obtain, inspect or copy any CMS information or record.

(b) *Forms of denials.* (1) Oral requests may be dealt with orally, but the requester should be advised that the oral response is not an official determination and that an official determination may be obtained only by submitting the request in writing. Appropriate available assistance will be offered.

(2) *Written Requests—Denials of* written requests will be in writing and will contain the reasons for the denial

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including, as appropriate, a statement that a document requested is non-existent or not reasonably described or is subject to one or more clearly described exemption(s). Denials will also provide the requester with appropriate information on how to exercise the right of appeal.

§ 401.148 Administrative review.

(a) *Review by the Administrator.* A person whose request has been denied may initiate a review by filing a request for review with the Administrator of CMS, 700 East High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235, within 30 days of receipt of the determination to deny or within 30 days of receipt of records which are in partial response to his request if a portion of a request is granted and a portion denied, whichever is later. Upon receipt of a timely request for review, the Administrator will review the decision in question and the findings upon which it was based. Upon the basis of the data considered in connection with the decision and whatever other evidence and written argument is submitted by the person requesting the review or which is otherwise obtained, the Administrator or his designee will affirm or revise in whole or in part the findings and decision in question. A decision to affirm the denial will be made only upon concurrence of the Assistant Secretary for Public Affairs, or his designee, after consultation with the General Counsel or his or her designee, and the appropriate program policy official. Written notice of the decision of the Administrator will be mailed to the person who requested the review. A written decision will be made within 20 working days from receipt of the request for review. Extension of the time limit may be granted under the circumstances listed in § 401.136(b) to the extent that the maximum 10 days limit on extensions has not been exhausted on the initial determination. The decision will include the basis for it and will advise the requester of his right to judicial review.

(b) *Failure of the Administrator to comply with the time limits.* Failure of the Administrator to comply with the time

limits set forth in § 401.136 and this section constitutes an exhaustion of the requester's administrative remedies.

§ 401.152 Court review.

Where the Administrator upon review affirms the denial of a request for records, in whole or in part, the requester may seek court review in the district court of the United States pursuant to 5 U.S.C. 552(a)(4)(B).

Subpart C [Reserved]

Subpart D—Reporting and Returning of Overpayments

SOURCE: 81 FR 7683, Feb. 12, 2016, unless otherwise noted.

§ 401.301 Basis and scope.

This subpart sets forth the policies and procedures for reporting and returning overpayments to the Medicare program for providers and suppliers of services under Parts A and B of title XVIII of the Act as required by section 1128J(d) of the Act.

§ 401.303 Definitions.

For purposes of this subpart—

Medicare contractor means a Part A/Part B Medicare Administrative Contractor (A/B MAC) or a Durable Medical Equipment Medicare Administrative Contractor (DME MAC).

Overpayment means any funds that a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title.

Person means a provider (as defined in § 400.202 of this chapter) or a supplier (as defined in § 400.202 of this chapter).

§ 401.305 Requirements for reporting and returning of overpayments.

(a) *General.* (1) A person that has received an overpayment must report and return the overpayment in the form and manner set forth in this section.

(2) A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the

overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

(b) *Deadline for reporting and returning overpayments.* (1) A person who has received an overpayment must report and return the overpayment by the later of either of the following:

(i) The date which is 60 days after the date on which the overpayment was identified.

(ii) The date any corresponding cost report is due, if applicable.

(2) The deadline for returning overpayments will be suspended when the following occurs:

(i) OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the OIG Self-Disclosure Protocol, or the person is removed from the OIG Self-Disclosure Protocol.

(ii) CMS acknowledges receipt of a submission to the CMS Voluntary Self-Referral Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the CMS Voluntary Self-Referral Disclosure Protocol, or the person is removed from the CMS Voluntary Self-Referral Disclosure Protocol.

(iii) A person requests an extended repayment schedule as defined in § 401.603 and will remain suspended until such time as CMS or one of its contractors rejects the extended repayment schedule request or the provider or supplier fails to comply with the terms of the extended repayment schedule.

(c) *Applicable reconciliation.* (1) The applicable reconciliation occurs when a cost report is filed; and

(2) In instances when the provider—

(i) Receives more recent CMS information on the SSI ratio, the provider is not required to return any overpayment resulting from the updated information until the final reconciliation of the provider's cost report occurs; or

(ii) Knows that an outlier reconciliation will be performed, the provider is