might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to the objection.

(f) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the OIG may seek enforcement of the subpoena under § 1006.5.

(g)(1) The proceedings will be recorded and transcribed.

(2) The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(3)(i) The transcript will be submitted to the witness for signature.

(ii) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the OIG written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(iii) Where, as provided in paragraph (g)(2) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(iv) The OIG's proposed corrections the record of transcript will be attached to the transcript.

(h) Testimony and other evidence obtained in an investigational inquiry may be used by the OIG or DHHS in any of its activities, and may be used or offered into evidence in any administrative or judicial proceeding.

[57 FR 3354, Jan. 29, 1992, as amended at 65 FR 24419, Apr. 26, 2000]

§ 1006.5 Enforcement of a subpoena.

A subpoena to appear at an investigational inquiry is enforceable through the District Court of the United States and the district where the subpoenaed person is found, resides or transacts business.

PART 1007—STATE MEDICAID FRAUD CONTROL UNITS

Subpart A—General Provisions and Definitions

Sec.

Subpart B—Requirements for Certification

Subpart C—Federal Financial Participation (FFP)

Subpart D—Other Provisions

AUTHORITY: 42 U.S.C. 1302, 1396a(a)(61), 1396b(a)(6), 1396b(b)(3), and 1396b(q).

SOURCE: 84 FR 10713, Mar. 22, 2019, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 1007.1 Definitions.

As used in this part, unless otherwise indicated by the context:

Abuse of patients or residents means any act that constitutes abuse of a patient or resident of a health care facility or board and care facility under applicable State law. Such conduct may include the infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical or financial harm, pain, or mental anguish.

Board and care facility means a residential setting that receives payment (regardless of whether such payment is made under Title XIX of the Social Security Act) from or on behalf of two or more unrelated adults who reside in such facility, and for whom one or both of the following is provided:

(1) Nursing care services provided by, or under the supervision of, a registered nurse, licensed practical nurse, or licensed nursing assistant.

(2) A substantial amount of personal care services that assist residents with the activities of daily living, including personal hygiene, dressing, bathing, eating, toileting, ambulation, transfer, positioning, self-medication, body care, travel to medical services, essential shopping, meal preparation, laundry, and housework.

Data mining means the practice of electronically sorting Medicaid or other relevant data, including, but not limited to, the use of statistical models and intelligent technologies, to uncover patterns and relationships within that data to identify aberrant utilization, billing, or other practices that are potentially fraudulent.

Director means a professional employee of the Unit who supervises all Unit employees, either directly or through other Unit managers.

Exclusive effort means that a Unit's professional employees, except as otherwise permitted in §1007.13, dedicate their efforts ''exclusively'' to the functions and responsibilities of a Unit as described in this part. Exclusive effort requires that duty with the Unit be intended to last for at least one (1) year and includes an arrangement in which an employee is on detail or assignment from another government agency, but only if the detail or arrangement is intended to last for at least one (1) year.

Fraud means any act that constitutes criminal or civil fraud under applicable State law. Such conduct may include deception, concealment of material fact, or misrepresentation made intentionally, in deliberate ignorance of the truth, or in reckless disregard of the truth.

Full-time employee means an employee of the Unit who has full-time status as defined by the State.

Health care facility means a provider that receives payments under Medicaid and furnishes food, shelter, and some treatment or services to four or more persons unrelated to the proprietor in an inpatient setting.

Misappropriation of patient or resident funds means the wrongful taking or use, as defined under applicable State law, of funds or property of a patient or resident of a health care facility or board and care facility.

Neglect of patients or residents means any act that constitutes neglect of a patient or resident of a health care facility or board and care facility under applicable State law. Such conduct may include the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

Part-time employee means an employee of the Unit who has part-time status as defined by the State.

Professional employee means an investigator, attorney, or auditor.

Program abuse means provider practices that do not meet the definition of civil or criminal fraud under applicable State law, but nonetheless are inconsistent with sound fiscal, business, or medical practices.

Provider means:

(1) An individual or entity that furnishes or arranges for the furnishing of items or services for which payment is claimed under Medicaid, including an individual or entity in a managed care network;

(2) An individual or entity that is required to enroll in a State Medicaid program, such as an ordering, prescribing, or referring physician; or

(3) Any individual or entity that may operate as a health care provider under applicable State law.

Unit means State Medicaid Fraud Control Unit.

§ 1007.3 Statutory basis and organization of rule.

(a) *Statutory basis.* This part codifies sections 1903(a)(6) and 1903(b)(3) of the Social Security Act (the Act), which establish the amounts and conditions of Federal matching payments for expenditures incurred in establishing and operating a State MFCU. This part also implements section 1903(q) of the Act, which establishes the basic requirements and standards that Units must meet to demonstrate that they are effectively carrying out the functions of the Unit in order to be certified by OIG as eligible for FFP under Title XIX of the Act. Section 1902(a)(61) of the Act requires a State to provide in its Medicaid State plan that it operates a Unit that effectively carries out the functions and requirements described in this part, as determined in accordance with standards established by OIG, unless the State demonstrates that a Unit would not be cost effective because of minimal Medicaid fraud in the covered services under the plan and that beneficiaries under the plan will be protected from abuse and neglect in connection with the provision of medical assistance under the plan without the existence of such a Unit. CMS retains the authority to determine a State's compliance with Medicaid State plan requirements in accordance with section 1902(a) of the Act.

(b) *Organization of this part.* Subpart A of this part defines terms used in this part and sets forth the statutory basis and organization of this part. Subpart B specifies the certification requirements that a Unit must meet to be eligible for FFP, including requirements for applying and reapplying for certification. Subpart C specifies FFP rates, costs eligible and not eligible for FFP, and FFP disallowance procedures. Subpart D specifies other HHS regulations applicable to the MFCU grants.

Subpart B—Requirements for Certification

§ 1007.5 Single, identifiable entity requirements of Unit.

(a) A Unit must be a single, identifiable entity of the State government.

(b) To be considered a single, identifiable entity of the State government, the Unit must:

(1) Be a single organization reporting to the Unit director;

(2) Operate under a budget that is separate from that of its parent agency; and

(3) Have the headquarters office and any field offices each in their own contiguous space, unless the Unit demonstrates to OIG that circumstances warrant a different arrangement for certain employees.

§ 1007.7 Prosecutorial authority requirements of Unit.

A Unit must be organized according to one of the following three options related to a Unit's prosecutorial authority:

(a) The Unit is in the office of the State Attorney General or another department of State government that has statewide authority to prosecute individuals for violations of criminal laws with respect to fraud and patient or resident abuse or neglect in the provision or administration of medical assistance under a State plan implementing Title XIX of the Act.

(b) If there is no State agency with statewide authority and capability for criminal fraud or patient or resident abuse or neglect prosecutions, the Unit has established formal written procedures ensuring that the Unit refers suspected cases of criminal fraud in the State Medicaid program or of patient or resident abuse and neglect to the appropriate prosecuting authority or authorities, and coordinates with and assists such authority or authorities in the prosecution of such cases.

(c) The Unit has a formal working relationship with the office of the State Attorney General, or another office with statewide prosecutorial authority, and has formal written procedures for referring to the State Attorney General or other office suspected criminal violations and for effective coordination of the activities of both entities relating to the detection, investigation, and prosecution of those violations relating to the State Medicaid program. Under this working relationship, the office of the State Attorney General, or other office, must agree to

assume responsibility for prosecuting alleged criminal violations referred to it by the Unit. However, if the State Attorney General finds that another prosecuting authority has the demonstrated capacity, experience, and willingness to prosecute an alleged violation, he or she may refer a case to that prosecuting authority, as long as the office of the State Attorney General maintains oversight responsibility for the prosecution and for coordination between the Unit and the prosecuting authority.

§ 1007.9 Relationship and agreement between Unit and Medicaid agency.

(a) The Unit must be separate and distinct from the Medicaid agency.

(b) No official of the Medicaid agency will have authority to review the activities of the Unit or to review or overrule the referral of a suspected criminal violation to an appropriate prosecuting authority.

(c) The Unit will not receive funds paid under this part either from or through the Medicaid agency.

(d) The Unit must enter into a written agreement with the Medicaid agency under which:

(1) The Medicaid agency will agree to comply with all requirements of § 455.21(a) of this title;

(2) The Unit will agree to comply with the requirements of § 1007.11(c) of this title; and

(3) The Medicaid agency and the Unit will agree to:

(i) Establish a practice of regular meetings or communication between the two entities;

(ii) Establish procedures for how they will coordinate their efforts;

(iii) Establish procedures for §§ 1007.9(e) through 1007.9(h) of this title;

(iv) Establish procedures by which the Unit will receive referrals of potential fraud from managed care organizations, if applicable, either directly or through the Medicaid agency, as required at § 438.608(a)(7) of this title; and

(v) Review and, as necessary, update the agreement no less frequently than every five (5) years to ensure that the agreement reflects current law and practice.

(e)(1) The Unit may refer any provider with respect to which there is pending an investigation of a credible allegation of fraud under the Medicaid program to the Medicaid agency for payment suspension in whole or part under § 455.23 of this title.

(2) Referrals may be brief but must be in writing and include sufficient information to allow the Medicaid agency to identify the provider and to explain the credible allegations forming the grounds for the payment suspension.

(f) Any request by the Unit to the Medicaid agency to delay notification to the provider of a payment suspension under § 455.23 of this title must be made promptly in writing.

(g) The Unit should reach a decision on whether to accept a case referred by the Medicaid agency in a timely fashion. When the Unit accepts or declines a case referred by the Medicaid agency, the Unit promptly notifies the Medicaid agency in writing of the acceptance or declination of the case.

(h) Upon request from the Medicaid agency on a quarterly basis under § 455.23(d)(3)(ii), the Unit will certify that any matter accepted on the basis of a referral continues to be under investigation, thus warranting continuation of the payment suspension.

§ 1007.11 Duties and responsibilities of Unit.

(a) The Unit will conduct a statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws, including criminal statutes as well as civil false claims statutes or other civil authorities, pertaining to the following:

(1) Fraud in the administration of the Medicaid program, the provision of medical assistance, or the activities of providers.

(2) Fraud in any aspect of the provision of health care services and activities of providers of such services under any Federal health care program (as defined in section 1128B(f)(1)of the Act), if the Unit obtains the written approval of the Inspector General of the relevant agency and the suspected fraud or violation of law in such case

or investigation is primarily related to the State Medicaid program.

(b)(1) The Unit will also review complaints alleging abuse or neglect of patients or residents in health care facilities receiving payments under Medicaid and may review complaints of the misappropriation of funds or property of patients or residents of such facilities.

(2) At the option of the Unit, it may review complaints of abuse or neglect, including misappropriation of funds or property, of patients or residents of board and care facilities, regardless of whether payment to such facilities is made under Medicaid.

(3) If the initial review of the complaint indicates substantial potential for criminal prosecution, the Unit will investigate the complaint or refer it to an appropriate criminal investigative or prosecutorial authority.

(4) If the initial review does not indicate a substantial potential for criminal prosecution, the Unit will, if appropriate, refer the complaint to the proper Federal, State, or local agency.

(c) If the Unit, in carrying out its duties and responsibilities under paragraphs (a) and (b) of this section, discovers that overpayments have been made to a health care facility or other provider, the Unit will either recover such overpayment as part of its resolution of a fraud case or refer the matter to the appropriate State agency for collection.

(d) Where a prosecuting authority other than the Unit is to assume responsibility for the prosecution of a case investigated by the Unit, the Unit will ensure that those responsible for the prosecutorial decision and the preparation of the case for trial have the fullest possible opportunity to participate in the investigation from its inception and will provide all necessary assistance to the prosecuting authority throughout all resulting prosecutions.

(e)(1) The Unit, if requested, will make available to OIG investigators and attorneys, or to other Federal investigators and prosecutors, all information in the Unit's possession concerning investigations or prosecutions conducted by the Unit.

(2) The Unit will coordinate with OIG investigators and attorneys, or with other Federal investigators and prosecutors, on any Unit cases involving the same suspects or allegations that are also under investigation or prosecution by OIG or other Federal investigators or prosecutors.

(3) The Unit will establish a practice of regular Unit meetings or communication with OIG investigators and Federal prosecutors.

(4) When the Unit lacks the authority or resources to pursue a case, including for allegations of Medicare fraud and for civil false claims actions in a State without a civil false claims act or other State authority, the Unit will make appropriate referrals to OIG investigators and attorneys or other Federal investigators or prosecutors.

(5) The Unit will establish written policy consistent with paragraphs (e)(1) through (4) of this section.

(f) The Unit will guard the privacy rights of all beneficiaries and other individuals whose data is under the Unit's control and will provide adequate safeguards to protect sensitive information and data under the Unit's control.

(g)(1) The Unit will transmit to OIG pertinent information on all convictions, including charging documents, plea agreements, and sentencing orders, for purposes of program exclusion under section 1128 of the Act.

(2) Convictions include those obtained either by Unit prosecutors or non-Unit prosecutors in any case investigated by the Unit.

(3) Such information will be transmitted to OIG within 30 days of sentencing, or as soon as practicable if the Unit encounters delays in receiving the necessary information from the court.

§ 1007.13 Staffing requirements of Unit.

(a) The Unit will employ sufficient professional, administrative, and support staff to carry out its duties and responsibilities in an effective and efficient manner.

(b) The Unit will employ individuals from each of the following categories of professional employees, whose exclusive effort, as defined in § 1007.1, is devoted to the work of the Unit:

(1) One or more attorneys capable of prosecuting the Unit's health care fraud or criminal cases and capable of giving informed advice on applicable law and procedures and providing effective prosecution or liaison with other prosecutors;

(2) One or more experienced auditors capable of reviewing financial records and advising or assisting in the investigation of alleged health care fraud and patient or resident abuse and neglect; and

(3) One or more investigators capable of conducting investigations of health care fraud and patient or resident abuse and neglect matters, including a senior investigator who is capable of supervising and directing the investigative activities of the Unit.

(c) The Unit will employ a director, as defined in §1007.1, who supervises all Unit employees.

(d) Professional employees:

(1) Will devote their exclusive effort to the work of the Unit, as defined in §1007.1 and except as provided in paragraphs (d)(2) and (3) of this section;

(2) May be employed outside the Unit during nonduty hours, only if the employee is not:

(i) Employed with a State agency (other than the Unit itself) or its contractors; or

(ii) Employed with an entity whose mission poses a conflict of interest with Unit function and duties;

(3) May perform non-Unit assignments for the State government only to the extent that such duties are limited in duration; and

(4) Will be under the direction and supervision of the Unit director.

(e) The Unit may employ administrative and support staff, such as paralegals, information technology personnel, interns, and secretaries, who may be full-time or part-time employees and must report to the Unit director or other Unit supervisor.

(f) The Unit will employ, or have available to it, individuals who are knowledgeable about the provision of medical assistance under Title XIX of the Act and about the operations of health care providers.

(g)(1) The Unit may employ, or have available through consultant agreements or other contractual arrangements, individuals who have forensic or other specialized skills that support the investigation and prosecution of cases.

(2) The Unit may not, through consultant agreements or other contractual arrangements, rely on individuals not employed directly by the Unit for the investigation or prosecution of cases.

(h) The Unit will provide training for its professional employees for the purpose of establishing and maintaining proficiency in Medicaid fraud and patient or resident abuse and neglect matters.

§ 1007.15 Establishment and certification of Unit.

(a) *Initial application.* In order to demonstrate that it meets the requirements for certification, the State or territory must submit to OIG an application approved by the Governor or chief executive, containing the following:

(1) A description of the applicant's organization, structure, and location within State government, and a statement of whether it seeks certification under §1007.7(a), (b), or (c);

(2) A statement from the State Attorney General that the applicant has authority to carry out the functions and responsibilities set forth in Subpart B. If the applicant seeks certification under §1007.7(b), the statement must also specify either that:

(i) There is no State agency with the authority to exercise statewide prosecuting authority for the violations with which the Unit is concerned, or

(ii) Although the State Attorney General may have common law authority for statewide criminal prosecutions, he or she has not exercised that authority;

(3) A copy of whatever memorandum of agreement, regulation, or other document sets forth the formal procedures required under §1007.7(b), or the formal working relationship and procedures required under §1007.7(c);

(4) A copy of the agreement with the Medicaid agency required under §§1007.9 and 455.21(c);

(5) A statement of the procedures to be followed in carrying out the functions and responsibilities of this part;

(6) A proposed budget for the 12-month period for which certification is sought; and

(7) Current and projected staffing, including the names, education, and experience of all senior professional employees already employed and job descriptions, with minimum qualifications, for all professional positions.

(b) *Basis for, and notification of, certification.* (1) OIG will make a determination as to whether the initial application under paragraph (a) of this section meets the requirements of §§1007.5 through 1007.13 and whether a Unit will be effective in using its resources in investigating Medicaid fraud and patient or resident abuse and neglect.

(2) OIG will certify a Unit only if OIG specifically approves the applicant's formal written procedures under §1007.7(b) or (c), if either of those provisions is applicable.

(3) If the application is not approved, the applicant may submit a revised application at any time.

(4) OIG will certify a Unit that meets the requirements of this Subpart B for 12 months.

§1007.17 Annual recertification of Unit.

(a) *Information required annually for recertification.* To continue receiving payments under this part, a Unit must submit to OIG:

(1) *Reapplication for recertification.* Reapplication is due at least 60 days prior to the expiration of the 12-month certification period. A reapplication must include:

(i) A brief narrative that evaluates the Unit's performance, describes any specific problems it has had in connection with the procedures and agreements required under this part, and discusses any other matters that have impaired its effectiveness. The narrative should include any extended investigative authority approvals obtained pursuant to §1007.11(a)(2).

(ii) For those Units approved to conduct data mining under §1007.20, all costs expended by the Unit attributed to data mining activities; the amount of staff time devoted to data mining activities; the number of cases generated from those activities; the outcome and status of those cases, including the expected and actual monetary recoveries (both Federal and non-Federal share); and any other relevant indicia of return on investment from such activities.

(iii) Information requested by OIG to assess compliance with this part and adherence to MFCU performance standards, including any significant changes in the information or documentation provided to OIG in the previous reporting period.

(2) *Statistical reporting.* By November 30 of each year, the Unit will submit statistical reporting for the Federal fiscal year that ended on the prior September 30 containing the following statistics:

(i) *Unit staffing.* The number of Unit employees, categorized by attorneys, investigators, auditors, and other employees, on board, and total number of approved Unit positions;

(ii) *Caseload.* The number of open, new, and closed cases categorized by type of case and the number of open criminal and civil cases categorized by type of provider;

(iii) *Criminal case outcomes.* The number of criminal convictions and indictments categorized by type of case and by type of provider; the number of acquittals, dismissals, referrals for prosecution, sentences, and other nonmonetary penalties categorized by type of case; and the amount of total ordered criminal recoveries categorized by type of provider; the amount of ordered Medicaid restitution, fines ordered, investigative costs ordered, and other monetary payment ordered categorized by type of case;

(iv) *Civil case outcomes.* The number of civil settlements and judgments and recoveries categorized by type of provider; the number of global (coordinated among a group of States) civil settlements and successful judgments; the amount of global civil recoveries to the Medicaid program; the amount of other global civil monetary recoveries; the number of other civil cases opened, filed, or referred for filing; the number of other civil case settlements and successful judgments; the amount of other civil case recoveries to the Medicaid program; the amount of other monetary recoveries; and the number of other civil cases declined or closed

without successful settlement or judgment;

(v) *Collections.* The monies actually collected on criminal and civil cases categorized by type of case; and

(vi) *Referrals.* The number of referrals received categorized by source of referral and type of case; the number of cases opened categorized by source of referral and type of case; and the number of referrals made to other agencies categorized by type of case.

(b) *Other information reviewed for recertification.* In addition to reviewing information required at § 1007.17(a), OIG will review, as appropriate, the following information when considering recertification of a Unit:

(1) Information obtained through onsite reviews and

(2) Other information OIG deems necessary or warranted.

(c) *Basis for recertification.* In reviewing the information described at § 1007.17(a) and (b), OIG will evaluate whether the Unit has demonstrated that it effectively carries out the functions and requirements described in section 1903(q) of the Act as implemented by this part. In making that determination, OIG will take into consideration the following factors:

(1) Unit's compliance with this part and other Federal regulations, including those specified in § 1007.23;

(2) Unit's compliance with OIG policy transmittals;

(3) Unit's adherence to MFCU performance standards as published in the FEDERAL REGISTER;

(4) Unit's effectiveness in using its resources in investigating cases of possible fraud in the administration of the Medicaid program, the provision of medical assistance, or the activities of providers of medical assistance under the State Medicaid plan, and in prosecuting cases or cooperating with the prosecuting authorities; and

(5) Unit's effectiveness in using its resources in reviewing and investigating, referring for investigation or prosecution, or criminally prosecuting complaints alleging abuse or neglect of patients or residents in health care facilities receiving payments under the State Medicaid plan and, at the Unit's option, in board and care facilities.

(d) *Notification.* OIG will notify the Unit by the Unit's recertification date of approval or denial of the recertification reapplication.

(1) *Approval subject to conditions.* OIG may impose special conditions or restrictions and may require corrective action, as provided in 45 CFR 75.207, before approving a reapplication for recertification.

(2) *Written explanation for denials.* If the reapplication is denied, OIG will provide a written explanation of the findings on which the denial was based.

(e) *Reconsideration of denial of recertification.* (1) A Unit may request that OIG reconsider a decision to deny recertification by providing written information contesting the findings on which the denial was based.

(2) Within 30 days of receipt of the request for reconsideration, OIG will provide a final decision in writing, explaining its basis for approving or denying the reconsideration of recertification.

Subpart C—Federal Financial Participation (FFP)

§ 1007.19 FFP rate and eligible FFP costs.

(a) *Rate of FFP.* (1) Subject to the limitation of this section, the Secretary of Health and Human Services must reimburse each State by an amount equal to 90 percent of the allowable costs incurred by a certified Unit during the first 12 quarters of operation that are attributable to carrying out its functions and responsibilities under this part. Each quarter of operation must be counted in determining when the Unit has accumulated 12 quarters of operation and is, therefore, no longer eligible for a 90-percent matching rate. Quarters of operation do not have to be consecutive to accumulate.

(2) Beginning with the 13th quarter of operation, the Secretary must reimburse 75 percent of allowable costs incurred by a certified Unit.

(b) *Retroactive certification.* OIG may grant certification retroactive to the date on which the Unit first met all the requirements of section 1903(q) of the Act and of this part. For any quarter

with respect to which the Unit is certified, the Secretary will provide reimbursement for the entire quarter.

(c) *Total amount of FFP.* FFP for any quarter must not exceed the higher of $125,000 or one-quarter of 1 percent of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State Medicaid program.

(d) *Costs eligible for FFP.* (1) FFP is allowable under this part for the expenditures attributable to the establishment and operation of the Unit, including the cost of training personnel employed by the Unit and efforts to increase referrals to the Unit through program outreach. Reimbursement is allowable only for costs attributable to the specific responsibilities and functions set forth in this part and if the Unit has been certified and recertified by OIG.

(2) Establishment costs are limited to clearly identifiable costs of personnel that meet the requirements of §1007.13 of this part.

(e) *Costs not eligible for FFP.* FFP is not allowable under this part for expenditures attributable to:

(1) The investigation of cases involving program abuse or other failures to comply with applicable laws and regulations, if these cases do not involve substantial allegations or other indications of fraud, as described in §1007.11(a) of this part;

(2) Routine verification with beneficiaries of whether services billed by providers were actually received, or, except as provided in §1007.20, efforts to identify situations in which a question of fraud may exist by the screening of claims and analysis of patterns and practice that involve data mining as defined in §1007.1.

(3) The routine notification of providers that fraudulent claims may be punished under Federal or State law;

(4) The performance of any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution of suspected providers by a person who does not meet the professional employee requirements in §1007.13(d);

(5) The investigation or prosecution of fraud cases involving a beneficiary's eligibility for benefits, unless the suspected fraud cases also involve conspiracy with a provider;

(6) Any payment, direct or indirect, from the Unit to the Medicaid agency, other than payments for the salaries of employees on detail to the Unit; or

(7) Temporary duties performed by professional employees that are not required functions and responsibilities of the Unit, as described at §1007.13(d)(3).

§1007.20 Circumstances of permissible data mining.

(a) Notwithstanding §1007.19(e)(2), a Unit may engage in data mining as defined in this part and receive FFP only under the following conditions:

(1) The Unit identifies the methods of coordination between the Unit and the Medicaid agency, the individuals serving as primary points of contact for data mining, as well as the contact information, title, and office of such individuals;

(2) Unit employees engaged in data mining receive specialized training in data mining techniques;

(3) The Unit describes how it will comply with paragraphs (a)(1) and (2) of this section as part of the agreement required by §1007.9(d); and

(4) OIG, in consultation with CMS, approves in advance the provisions of the agreement as defined in paragraph (a)(3) of this section.

(i) OIG will act on a request from a Unit for review and approval of the agreement within 90 days after receipt of a written request, or the request shall be considered approved if OIG fails to respond within 90 days after receipt of the written request.

(ii) If OIG requests additional information in writing, the 90-day period for OIG action on the request begins on the day OIG receives the information from the Unit.

(iii) The approval is for 3 years.

(iv) A Unit may request renewal of its data-mining approval for additional 3-year periods by submitting a written request for renewal to OIG, along with an updated agreement with the Medicaid agency.

§ 1007.21 Disallowance of claims for FFP.

(a) *Notice of disallowance and of right to reconsideration.* When OIG determines that a Unit's claim or portion of a claim for FFP is not allowable, OIG shall promptly send to the Unit notification that meets the requirements listed at 42 CFR 430.42(a).

(b) *Reconsideration of disallowance.* (1) The Principal Deputy Inspector General will reconsider Unit disallowance determinations made by OIG.

(2) To request a reconsideration from the Principal Deputy Inspector General, the Unit must follow the requirements in 42 CFR 430.42(b)(2) and submit all required information to the Principal Deputy Inspector General. Copies should be sent via registered or certified mail to the Principal Deputy Inspector General.

(3) The Unit may request to retain FFP during the reconsideration of the disallowance under section 1116(e) of the Act, in accordance with 42 CFR 433.38.

(4) The Unit is not required to request reconsideration before seeking review from the Departmental Appeals Board.

(5) The Unit may also seek reconsideration, and following the reconsideration decision, request a review from the Departmental Appeals Board.

(6) If the Unit elects reconsideration, the reconsideration process must be completed or withdrawn before requesting review by the Departmental Appeals Board.

(c) *Procedures for reconsideration of a disallowance.* (1) Within 60 days after receipt of the disallowance letter, the Unit shall, in accordance with paragraph (b)(2) of this section, submit in writing to the Principal Deputy Inspector General any relevant evidence, documentation, or explanation.

(2) After consideration of the policies and factual matters pertinent to the issues in question, the Principal Deputy Inspector General shall, within 60 days from the date of receipt of the request for reconsideration, issue a written decision or a request for additional information as described in paragraph (c)(3) of this section.

(3) At the Principal Deputy Inspector General's option, OIG may request from the Unit any additional information or documents necessary to make a decision. The request for additional information must be sent via registered or certified mail to establish the date the request was sent by OIG and received by the Unit.

(4) Within 30 days after receipt of the request for additional information, the Unit must submit to the Principal Deputy Inspector General all requested documents and materials.

(i) If the Principal Deputy Inspector General finds that the materials are not in readily reviewable form or that additional information is needed, he or she shall notify the Unit via registered or certified mail that it has 15 business days from the date of receipt of the notice to submit the readily reviewable or additional materials.

(ii) If the Unit does not provide the necessary materials within 15 business days from the date of receipt of such notice, the Principal Deputy Inspector General shall affirm the disallowance in a final reconsideration decision issued within 15 days from the due date of additional information from the Unit.

(5) If additional documentation is provided in readily reviewable form under paragraph (c)(4) of this section, the Principal Deputy Inspector General shall issue a written decision within 60 days from the due date of such information.

(6) The final written decision shall constitute final OIG administrative action on the reconsideration and shall be (within 15 business days of the decision) mailed to the Unit via registered or certified mail to establish the date the reconsideration decision was received by the Unit.

(7) If the Principal Deputy Inspector General does not issue a decision within 60 days from the date of receipt of the request for reconsideration or the date of receipt of the requested additional information, the disallowance shall be deemed to be affirmed.

(8) No section of this regulation shall be interpreted as waiving OIG's right to assert any provision or exemption under the Freedom of Information Act.

(d) *Withdrawal of a request for reconsideration of a disallowance.* (1) A Unit

may withdraw the request for reconsideration at any time before the notice of the reconsideration decision is received by the Unit without affecting its right to submit a notice of appeal to the Departmental Appeals Board. The request for withdrawal must be in writing and sent to the Principal Deputy Inspector General via registered or certified mail.

(2) Within 60 days after OIG's receipt of a Unit's withdrawal request, a Unit may, in accordance with (f)(2) of this section, submit a notice of appeal to the Departmental Appeals Board.

(e) *Implementation of decisions for reconsideration of a disallowance.* (1) After undertaking a reconsideration, the Principal Deputy Inspector General may affirm, reverse, or revise the disallowance and shall issue a final written reconsideration decision to the Unit in accordance with paragraphs (c)(4) and (5) of this section.

(2) If the reconsideration decision requires an adjustment of FFP, either upward or downward, a subsequent grant action will be made in the amount of such increase or decrease.

(3) Within 60 days after receipt of a reconsideration decision from OIG, a Unit may, in accordance with paragraph (f) of this section, submit a notice of appeal to the Departmental Appeals Board.

(f) *Appeal of disallowance.* (1) The Departmental Appeals Board reviews disallowances of FFP under Title XIX of the Act, including disallowances issued by OIG to the Units.

(2) A Unit that wishes to appeal a disallowance to the Departmental Appeals Board must follow the requirements in 42 CFR 430.42(f)(2).

(3) The appeals procedures are those set forth in 45 CFR part 16 for Medicaid and for many other programs, including the Units, administered by the Department.

(4) The Departmental Appeals Board may affirm the disallowance, reverse the disallowance, modify the disallowance, or remand the disallowance to OIG for further consideration.

(5) The Departmental Appeals Board will issue a final written decision to the Unit consistent with 45 CFR part 16.

(6) If the appeal decision requires an adjustment of FFP, either upward or downward, a subsequent grant action will be made in the amount of such increase or decrease.

Subpart D—Other Provisions

§ 1007.23 Other applicable HHS regulations.

The following regulations from 45 CFR, subtitle A, apply to grants under this part:

(a) Part 16—Procedures of the Departmental Grant Appeals Board.

(b) Part 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.

(c) Part 80—Nondiscrimination under Programs Receiving Federal Assistance through HHS, Effectuation of Title VI of the Civil Rights Act of 1964.

(d) Part 81—Practice and Procedure for Hearings under 45 CFR part 80.

(e) Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance.

(f) Part 91—Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance from HHS.

PART 1008—ADVISORY OPINIONS BY THE OIG

Subpart A—General Provisions

Sec.

Subpart B—Preliminary Obligations and Responsibilities of the Requesting Party

Subpart C—Advisory Opinion Fees

Subpart D—Submission of a Formal Request for an Advisory Opinion