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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 455

Office of Inspector General

42 CFR Part 1007

RIN 0936-AA07

Medicaid; Revisions to State Medicaid Fraud Control Unit Rules

AGENCIES: Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS)

ACTION: Proposed Rule

SUMMARY: This proposed rule would amend the regulation governing State Medicaid Fraud Control Units (MFCUs or Units). The proposed rule would incorporate statutory changes affecting the MFCUs as well as policy and practice changes that have occurred since the regulation was initially issued in 1978. These changes include a codification of OIG's delegated authority, MFCU authority, functions, and responsibilities; disallowances; and issues related to organization, prosecutorial authority, staffing, recertification, and the MFCUs' relationship with Medicaid agencies.

DATES: To ensure consideration, comments must be delivered to the address provided below by no later than 5 p.m. Eastern Standard Time on [INSERT: 60 days from Federal Register publication date].

ADDRESSES: In commenting, please reference file code OIG-406-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. However, you may submit comments using one of two ways (no duplicates, please):

1. Electronically. We strongly encourage you to submit your comments via the Internet. You may submit electronically through the Federal eRulemaking Portal at http://www.regulations.gov. (Attachments should be in Microsoft Word, if possible.)

2. By regular, express, or overnight mail. Because of potential delays in our receipt and processing of mail, we encourage respondents to submit comments electronically to ensure timely receipt. However, you may mail your printed or written submissions to the following address:

Patrice Drew
Office of Inspector General
Department of Health and Human Services
Attention: OIG-406-P
Cohen Building
330 Independence Avenue, SW, Room 5269
Washington, DC 20201

Please allow sufficient time for mailed comments to be received before the close of the comment period. Comments received after the end of the comment period may not be considered.

Inspection of Public Comments: All comments received before the end of the comment period will be posted on http://www.regulations.gov for public viewing. Hard copies will also be available for public inspection at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201, Monday through Friday from 10 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619-1368.

FOR FURTHER INFORMATION CONTACT:

Susan Burbach, (202) 708-9789 or Richard Stern, (202) 205-0572, Office of Inspector General, for questions relating to the proposed rule.

Executive Summary

A. Need for Regulatory Action

We propose to amend this regulation for two reasons. First, we want to incorporate into the rule the statutory changes that have occurred since the 1977 enactment of the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95-142), which amended section 1903(a) of the Social Security Act (the Act) to provide for Federal participation in the costs attributable to establishing and operating a State Medicaid Fraud Control Unit (MFCU or Unit). Second, we want to align the rule with practices and policies that have developed and evolved since the initial version of the rule was issued in 1978, 43 Fed. Reg. 32078 (July 24, 1978), codified at 42 CFR part 1007. Because of the extensive nature of our proposal, we have republished the entirety of part 1007 and incorporated our proposed changes as part of that publication. However, for some sections within part 1007, we are not proposing substantive changes.

B. Legal Authority

The legal authority for this regulatory action is found in the Act as follows:

1007: SSA §§ 1902(a)(61), 1903(a)(6), 1903(b)(3), 1903(q), and 1102.

455: SSA §§ 1902(a)(4), 1903(i)(2), 1909.

C. Summary of Major Provisions

1) Statutory Changes. We propose to incorporate statutory changes that have occurred since 1977, including (1) raising the Federal matching rate for ongoing operating costs from 50 percent to 75 percent, (2) establishing a Medicaid State plan requirement that a State must operate an effective MFCU, (3) establishing standards under which Units must be operated, (4) allowing MFCUs to seek approval from the relevant Inspector General to investigate and prosecute violations of State law related to fraud in any aspect of the provision of health care services and activities of providers of such services under any Federal health care program, including Medicare, as long as the fraud is primarily related to Medicaid, and (5) giving MFCUs the option to investigate and prosecute patient abuse or neglect in board and care facilities, regardless of whether the facilities receive Medicaid payments.

2) Office of Inspector General Authority. We propose to amend the regulation to codify that the authority for certification and recertification of the MFCUs as well as the administration of the grant award was transferred from the predecessor agency of CMS (Health Care Financing Administration) to OIG on July 27, 1979. 44 Fed. Reg. 47811 (August 15, 1979).

3) Unit Authority. We propose to add definitions to clarify key issues related to Unit authority under the grant to conduct fraud investigations as well as patient abuse and neglect and misappropriation of patient funds investigations. Specifically, we propose to add definitions for fraud, abuse of patients, board and care facility, health care facility, misappropriation of patient funds, neglect of patients, and program abuse. We also propose to modify the definition of provider.

4) Organizational Requirements. We propose to clarify what it means to be considered a single identifiable entity of State government.

5) Prosecutorial Authority Requirements. We propose to make technical amendments to the prosecutorial authority requirement options to include the prosecution of patient abuse and neglect and to include referrals to other offices with statewide prosecutorial authority, in addition to the State Attorney General.

6) Agreement with Medicaid agency. We propose that the agreement with the Medicaid agency must include establishing regular communication, procedures for coordination, including those involving payment suspension and acceptance or declination of cases. We also propose that the parties review and, if needed, update the agreement no less frequently than every 5 years.

7) Functions and Responsibilities. In addition to the proposed statutory amendments that expand the Units' functions and responsibilities, we propose to require that Units submit all convictions to OIG for purposes of program exclusion within 30 days of sentencing or

as soon as practicable if a Unit encounters delays from the courts. We propose to further clarify the requirement that a Unit make information available to, and coordinate with, OIG investigators and attorneys, other Federal investigators, and Federal prosecutors on Medicaid fraud information and investigations involving the same suspects or allegations.

8) Staffing Requirements. We propose to clarify that Units may choose to employ professional employees as full- or part-time employees so long as they devote their "exclusive effort" to MFCU functions. We also propose that a Unit must employ a director and that all MFCU employees must be under the direction and supervision of the Unit director. We propose that MFCU professional employees may also obtain outside employment with some restriction and may perform temporary assignments that are not a required function of the Unit so long as the grant is not charged for those duties. We also propose to clarify that Units may employ employees or consultants with specialized knowledge and skills, as well as administrative and support staff, on a full- or part-time basis. We further propose to clarify that investigation and prosecution functions may not be outsourced through consultant agreements or other contracts. We propose to require that Units provide training for professional employees on Medicaid fraud and patient abuse and neglect matters. Finally, we propose to add definitions for full- and part-time employee, professional employee, director, and exclusive effort.

9) Recertification Requirements. We propose to amend the regulation to reflect the Unit recertification process. This includes describing what is required annually by OIG as part of recertification, including submission of a reapplication, including certain requested information, as well as a statistical report. We also propose to modify the annual report

requirements. We also propose to clarify the factors, such as performance standards, that OIG considers when recertifying a MFCU. We also propose to notify the Unit of approval or denial of recertification and to create procedures for reconsideration should OIG deny recertification.

10) Federal Financial Participation (FFP). We propose to clarify that, except for Units with OIG approval to conduct data mining under this part, the prohibition of FFP for data mining activities extends only to the cost of activities that duplicate surveillance and utilization review responsibilities of State Medicaid agencies. We also propose to clarify that efforts to increase referrals through program outreach activities are eligible for FFP.

11) Disallowance Procedures. We propose to amend the regulations to set forth procedures for OIG disallowances of FFP and for Unit requests for reconsideration and appeal of disallowances.

12) CMS Companion Regulation. To ensure that both the MFCU and the State Medicaid agency are required to have an agreement with each other, we are including amendments to the CMS regulation at 42 CFR § 455.21 of this section to require that the State Medicaid agency have an agreement with the MFCU. The regulations at 42 CFR § 455.21 are enforced by CMS. However, we are including amendments to part 455 here to ensure a comprehensive regulatory package that sets forth in one location the Department's regulations related to MFCUs.

D. Costs and Benefits

There are no significant costs associated with the proposed regulatory revisions that would impose any mandates on State, local, or tribal governments or on the private sector.

I. Background

A. Statutory Changes Since 1977 Implemented by this Rulemaking

1) Omnibus Reconciliation Act of 1980 (Pub. L. 96-499). In order to provide a continuing incentive for operation of State MFCUs, the Omnibus Reconciliation Act (OBRA) of 1980, amended section 1903(a)(6) of the Act and raised the Federal matching rate for ongoing operating costs (i.e., for all years after the initial 3 years of operations) from 50 percent to 75 percent.

2) Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66). The Omnibus Budget Reconciliation Act of 1993 added § 1902(a)(61) to the Act, establishing a Medicaid State plan requirement that a State must operate an effective MFCU, unless the State demonstrates that effective operation of a Unit would not be cost effective and that, in the absence of a Unit, beneficiaries will be protected from abuse and neglect. The statute further requires that the Units be operated in accordance with standards established by the Secretary.

3) Ticket to Work and Work Incentives Improvement Act of 1999 (Pub. L. 106-170). In the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA), Congress

amended section 1903(q) of the Act to extend the authority of MFCUs in two ways. First, the Units may now seek approval from the relevant Inspector General (in most circumstances the Inspector General of the Department of Health and Human Services (HHS) to investigate and prosecute violations of State law related to any aspect of fraud in connection with "the provision of health care services and activities of providers of such services under any Federal health care program," including Medicare, "if the suspected fraud or violation of State law is primarily related to" Medicaid. Second, the law gives Units the option to investigate and prosecute patient abuse or neglect in board and care facilities, regardless of whether those facilities receive Medicaid payments.

B. Regulatory, Practice, and Policy Changes to the MFCU Program Since 1978

The regulation has been amended on two occasions. First, the regulation was amended at § 1007.9(e)-(g) to implement payment suspension provisions found in the Affordable Care Act (76 Fed. Reg. 5970 (February 2, 2011)). Second, the regulation was modified at § 1007.20 to allow FFP for data mining under certain circumstances (78 FR 29055 (May 17, 2013)). With the exception of these two revisions, the regulation has not received a wholesale revision since it was originally published in 1978. In the ensuing years, growth of the MFCU program to 50 Units (49 States and the District of Columbia) as well as changes in MFCU practice, health care, and the workplace have led to the need for many amendments to the regulation. Further, in 1994, pursuant to section 1902(a)(61) of the Act, OIG, in consultation with the MFCUs, developed 12 performance standards to be used in assessing the operations of MFCUs. These performance standards have since been revised and republished at 77 Fed. Reg. 32645 (June 1, 2012). OIG

uses the performance standards in annually recertifying each Unit and in determining if a Unit is effectively and efficiently carrying out its duties and responsibilities.

I. Provisions of the Proposed Rule

Subpart A--General Provisions and Definitions.

We propose to add a new subpart A of this part entitled "General Provisions and Definitions" which includes § 1007.1, "Definitions," and § 1007.3, "What is the statutory basis and organization of this rule?"

1007.1 Definitions

Current § 1007.1 defines four terms: "data mining," "employ or employee," "provider," and "Unit." We propose to modify the current definition of "provider," eliminate the definition of "employ or employee," and add definitions for "full-time employee," "part-time employee," "professional employee" and "exclusive effort." We propose to add a definition of the term "director." We also propose to add several additional terms to clarify the scope of the Units' duties and responsibilities: "fraud," "abuse of patients," "board and care facility," "health care facility," "misappropriation of patient funds," "neglect of patients," and "program abuse."

1. <u>Full-Time Employee, Part-Time Employee, and Exclusive Effort</u>

Existing regulations at § 1007.19 preclude FFP in expenditures for any management function for the Unit, any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution that is not performed by a "full time employee of the Unit." As a matter of policy and practice, OIG has permitted professional employees (attorneys, auditors, and investigators) to work on a part-time basis, provided that the part-time employee work exclusively on MFCU matters while on duty for the Unit. Consistent with this policy, we propose to replace the term "employ or employee" with definitions for the terms "full-time employee," "part-time employee," and "exclusive effort" to help clarify the staffing requirements for MFCUs. We also propose to define professional employee to mean an investigator, attorney, or auditor.

In § 1007.1, we propose to define "full-time employee" to mean an employee of the Unit who has full-time status as defined by the State. Similarly, we propose to define "part-time employee" to mean an employee of the Unit who has part-time status as defined by the State. In § 1007.13(d), we propose to require that professional employees, whether full time or part time, devote "exclusive effort" to the work of the Unit, consistent with OIG's longstanding policy. We therefore also propose to add a definition of "exclusive effort" to mean that professional employees devote their efforts exclusively to the functions and responsibilities of a Unit, as described in this part. As under the current definition of "employee," the proposed definition for "exclusive effort" requires that duty with the Unit be intended to last for at least one year and would include arrangements 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 year. An employee detailed to the Unit from another government agency would need to work

exclusively for the Unit on MFCU matters and would not be able to allocate time to both the home agency and the Unit. As discussed more fully in 1007.13 Staffing Requirements, OIG believes that "exclusive effort" should ensure that professional employees do not engage in outside employment that might jeopardize the distinct nature and specialized skills of the Unit.

These proposed definitions are consistent with OIG existing policy as found in State Fraud Policy Transmittal 2014-1 (March 14, 2014).

We also discuss these proposed definitions in section 1007.13 Staffing.

2. Director

Under proposed § 1007.13 paragraph (c), we specify that each Unit must employ a director who supervises all Unit employees. We propose to add the term "director" to § 1007.1 to mean an employee of the MFCU who supervises the operations of the Unit, either directly or through other MFCU managers.

3. Fraud

We propose to add a definition of fraud at § 1007.1 to clarify that the scope of MFCU authority to investigate "any and all aspects of fraud" encompasses any action for which civil or criminal penalties may be imposed under State law. This definition is similar to the definition of fraud contained in CMS program integrity regulations at 42 CFR § 455.2, but, consistent with the

MFCUs' responsibility for both criminal and civil fraud, incorporates the definition of intent that applies in a civil case.

The primary mission for MFCUs has been the investigation and prosecution (or referral for prosecution) of criminal violations related to the operation of a Medicaid program and of patient abuse and neglect in Medicaid-funded facilities and in board and care facilities. However, State and Federal health care prosecutors commonly use both criminal and civil remedies, and OIG attorneys use administrative remedies, to achieve a full resolution of provider fraud cases. The Deficit Reduction Act of 2005 (Pub. L. 109-171) added § 1909 to the Act to provide a financial incentive for States to enact their own false claims acts establishing liability to the State for the submission of false or fraudulent claims to the State's Medicaid program.

Further, OIG has issued policy guidance that civil actions, including imposition of penalties and damages, are an appropriate outcome of investigations by MFCUs, particularly when providers lack the specific intent required for prosecution under criminal fraud statutes. (State Fraud Policy Transmittal No. 99-01, December 9, 1999). Specifically, OIG stated that meritorious civil cases that are declined criminally should be tried under State law or referred to the U.S. Department of Justice or the U.S. Attorney's Office, as well as the OIG Office of Investigations. As discussed in section 1007.11 Functions and Responsibilities of the Unit, we propose to require at new § 1007.11(e)(4) that appropriate referrals of civil actions be made to Federal investigators or prosecutors, or OIG attorneys.

4. Program Abuse

We propose to define the term "program abuse" at § 1007.1 to make clear that, for purposes of FFP in MFCU expenditures, program abuse includes only improper provider practices that fall short of acts for which civil or criminal penalties are warranted. Current regulations at § 1007.19(e)(1) prohibit FFP in MFCU expenditures for 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."

Congress has expanded the range of Federal civil and administrative sanctions available when false and fraudulent provider practices do not reach the level of intent required for criminal prosecution. In addition, Congress encouraged States to enact their own false claims laws. Our policy continues to be that FFP is available to MFCUs for investigations involving reasonable indications of either civil or criminal fraud. Where an overpayment has been identified in a matter in which the MFCU has determined that neither civil nor criminal enforcement action is warranted, the MFCU should refer the matter to the State Medicaid agency for collection.

5. Abuse or Neglect of Patients

Section 1903(q)(4) of the Act requires that, to be certified by the Secretary, MFCUs must have procedures for reviewing complaints of abuse or neglect of patients in health care facilities that receive Medicaid payments. In addition, the Act requires that Units have procedures for acting on these complaints under the criminal laws of the State or for referring the complaints to other State agencies for action. To clarify the scope of Units' duties and responsibilities, we propose

to amend § 1007.1 to add definitions of the terms "abuse of patients" and "neglect of patients." We propose to define the term "abuse of patients" to mean willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical or financial harm, pain or mental anguish. We propose to define the term "neglect of patients" to mean willful failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. With regard to each of the terms, we propose to include within the definitions a recognition that the scope of what constitutes "abuse of patients" and "neglect of patients" includes those acts (and, with regard to the crime of neglect, omissions) that may constitute a criminal violation under applicable State law.

6. Misappropriation of Patient Funds

The Department included "misappropriation of [a] patient's private funds" as part of the scope of MFCUs' investigative authority when it issued current § 1007.11(b)(1). In the notice of final rulemaking, the Department explained that investigating "misuse of private funds being held for patients by health care facilities" would be "a natural outgrowth of an investigation of the facility for program fraud or patient abuse or neglect" and would fall under a MFCU's authority to investigate any and all aspects of provider fraud. (43 Fed. Reg. 32078, 32080 (July 24, 1978)).

We are maintaining this authority in the revised regulation and are including a definition of the term "misappropriation of patient funds" to mean the wrongful taking or use, as defined under applicable State law, of funds or property of a patient residing in a health care facility or board and care facility.

We chose not to specify that the patient's funds have to be held in the facility, given that misappropriation of a patient's funds may include financial fraud regarding a patient's assets that are maintained in financial accounts in any location. We also chose not to specify that the perpetrator of the misappropriation of patient's funds has to be an employee of the facility where the patient resides. Because of the many scenarios that exist with respect to misappropriation of patient funds, we invite comment on the rule not specifying the location of the patient funds or the possible perpetrator of the misappropriation.

7. Board and Care Facility

Congress, in the initial MFCU legislation, required MFCUs to investigate patient abuse or neglect only in health care facilities receiving Medicaid payments. In 1999, as part of TWWIIA, Congress amended section 1903(q)(4) of the Act to give Units the option to investigate patient abuse or neglect in non-Medicaid "board and care" facilities, as defined in the statute.

We are proposing to amend § 1007.11 to incorporate the statutory authority for MFCUs to choose to investigate complaints of abuse or neglect in board and care facilities, regardless of the source of payment, and to add the statutory definition of "board and care facility" to the definitions at § 1007.1. Such facilities include assisted living facilities in current terminology.

8. Health Care Facility

We are proposing to add a definition of "health care facility" to clarify the scope of MFCU-required functions and responsibilities in connection with the investigation of complaints of neglect or abuse of patients in such facilities, consistent with section 1903(q)(4)(A) of the Act and with Medicaid program regulations.

Specifically, 42 CFR § 447.10(b) defines a "facility" as "an institution that furnishes health care services to inpatients" and 42 CFR § 435.1010 defines an "institution" as "an establishment that furnishes (in single or multiple facilities) food, shelter, and some treatment or services to four or more persons unrelated to the proprietor," and "in an institution" as an individual who is admitted to live there and receive treatment or services provided there that are appropriate to his requirements." Consistent with these definitions, we propose to add a definition at § 1007.1 to clarify that a "health care facility" is "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."

9. Provider

We propose to modify the definition of provider to include those who are required to enroll in a State Medicaid program, such as ordering and referring physicians. While we believe the regulation's longstanding definition of provider includes managed care and other types of providers that operate in the current healthcare environment, we think that including ordering and referring physicians in the definition clarifies that providers who are not furnishing items or

services for which payment is claimed under Medicaid can be the subject of a MFCU investigation and prosecution.

1007.3 Statutory Basis and Scope

The Secretary delegated to OIG the authority under sections 1903(a)(6) and (b)(3) to pay the FFP amounts of State expenditures for the establishment and operation of a MFCU and, under section 1903(q), to determine whether a MFCU meets the statutory requirements to be certified as eligible for Federal payments. We propose to revise § 1007.3 to more comprehensively set forth the statutory basis and organization of this rule, and to explicitly reference OIG's authority to certify whether a Unit has demonstrated that it is effectively carrying out its required functions under this part.

We also propose to revise § 1007.3 to reflect current law at § 1902(a)(61) of the Act requiring a State to provide in its Medicaid State plan that it operates a MFCU that "effectively carries out the functions and requirements" described in Federal law, 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 and that the State adequately protects Medicaid patients from abuse and neglect without the existence of a Unit. CMS retains the authority to determine a State's compliance with Medicaid State Plan requirements in accordance with § 1902 of the Act.

Congress initially established a matching rate of 90 percent for 12 quarters to give States an incentive to develop a MFCU. Later, as a continuing incentive, Congress provided that after the initial 12 quarters of 90 percent Federal matching, MFCUs would receive Federal matching of 75 percent of the ongoing costs of operating a MFCU.

Regulations at both § 1007.3 and § 1007.19(a) provide that a State will receive Federal reimbursement for 90 percent of the costs of establishing and operating a State MFCU. To eliminate redundancy, and to reflect the current statute's FFP provisions, we propose to remove the statement regarding 90 percent Federal funding at § 1007.3. We propose to retain the provision at current § 1007.19(a) and to amend it to reflect the current statute's limitation of 75 percent FFP for the operation of a MFCU after the initial 12 quarters.

Subpart B--Requirements for Certification

We propose to add a new Subpart B "Requirements for Certification," containing sections 1007.5 through 1007.17.

1007.5 Single Identifiable Entity Requirement

Section 1903(q) of the Act defines the term "State Medicaid fraud control unit" to mean "a single identifiable entity of the State government which the Secretary certifies (and recertifies) as meeting" statutory requirements. This basic requirement is reflected in current § 1007.5 and is widely accepted as a prerequisite for establishing and operating a Unit. We propose to amend

the MFCU regulations to define the phrase "single identifiable entity" and to clarify that Units must satisfy the definition to be certified and recertified.

We propose that Units have the following characteristics to be considered a "single identifiable entity in State government" and to be eligible for certification and recertification. Units must: (1) be a single organization reporting to the single Unit director; (2) operate under its own budget that is separate from that of its parent division or agency; and (3) have the headquarters office and any field offices each in their own contiguous space.

We believe that each of these three characteristics is necessary to ensure that Unit is able to operate independently of its parent agency and to maintain its independent character as a single, identifiable entity. We believe that these characteristics are consistent with the statement at time of enactment by the Senate Committee on Finance that "a separate Statewide investigative entity" substantially increases the rate of prosecutions and convictions (Senate Report 95-453 (September 26, 1977), page 35). We also believe, on the basis of our observation and knowledge of the 50 existing Units, that Units generally share these characteristics and operate under the assumption that each of the characteristics is required for certification purposes. We invite comment on these newly articulated requirements for determining whether a Unit would be considered a single identifiable entity.

Specifically, we believe that all Unit employees reporting to a single Unit director provides the most efficient management structure and helps to ensure that the Unit can act independently of its parent agency. Secondly, to ensure that a Unit has the resources to undertake its mission, to

operate efficiently and effectively, and to continue as an ongoing operation, we believe a Unit should operate under its own budget that is separate from that of its parent agency.

Finally, we also believe that having headquarters and any field offices each in their own contiguous space leads to the most efficient conduct of Unit business by fostering a Unit's multidisciplinary approach of investigators, attorneys, auditors, and other employees working together on cases and helps ensure that employees devote their exclusive effort to MFCU purposes. Further, we believe that allowing MFCU employees to work in non-contiguous space alongside other State employees would undermine the ability of MFCU management to monitor whether MFCU employees are devoted exclusively to the mission of the MFCU. Headquarters or field offices would be considered duty stations, and telework and other "out of duty office" work arrangements are not precluded, if permitted under State policies. We believe that all Unit offices currently operate in contiguous space, although in certain larger Units the contiguous space may, for example, be on separate floors of the same building. We believe that such arrangements qualify as "contiguous" as long as the separation permits the Unit's three professional groups to interact effectively in the course of their duties. For example, OIG does not believe that an office arrangement would be contiguous if all or groups of Unit investigators, or attorneys, were located in a different space from the rest of the Unit.

1007.7 Prosecutorial Authority Requirement

Section 1903(q)(1) of the Act provides for three alternative prosecutorial arrangements for a State MFCU, depending on the location of criminal prosecuting authority in the State. Current §

1007.7(b) states that if there is no State agency with Statewide authority and capability for criminal fraud prosecutions, the Unit must establish formal procedures that ensure that the Unit refers suspected cases of criminal fraud to the appropriate prosecuting authorities. We propose that § 1007.7(b) be amended to also include such procedures for patient abuse and neglect prosecutions, consistent with the language of the statute.

Section 1007.7(c) requires a formal working relationship with the office of the State Attorney General. We propose that § 1007.7(c) be amended to reference the office of the State Attorney General "or another office with Statewide prosecutorial authority." We also propose to amend §§ 1007.7(b) and 1007.7(c) to clarify that the formal procedures be written. Finally, we propose to make a minor wording change to emphasize the requirement that a Unit be organized according to one of three prosecutorial arrangements and to change the name of § 1007.7 to "What are the prosecutorial authority requirements for a Unit?" to more accurately describe its contents.

1007.9 Relationship to, and Agreement with, the Medicaid Agency

Current § 1007.9(d) requires that the MFCU enter into an agreement with the Medicaid agency to ensure the Unit has access to fraud case referrals and case information. Companion regulations governing fraud control activities of the Medicaid agency impose obligations on the Medicaid agency to identify, investigate, and refer suspected fraud cases, but do not explicitly require an agreement with the Unit. CMS enforces the regulations at 42 CFR part 455 (See September 30, 1986 final rule (51 Fed. Reg. 34787)). Given the importance of the working

relationship between the MFCU and Medicaid agency, in this joint proposed rule, OIG and CMS propose to add additional guidance at § 1007.9, and through the addition of a new § 455.21(c), to clarify that both the Medicaid agency and the MFCU must enter into a written agreement, such as a memorandum of understanding (MOU).

We also propose to add to both § 1007.9(d)(3) and to the new § 455.21(c) that the MOU include the following required elements. First, we propose that the MOU must include an agreement to establish a practice of regular communication or meetings between the MFCU and the Medicaid agency to discuss such matters as case updates, new complaints and possible referrals, documentation and data requests, policy changes, fraud trends, and joint activities. Second, we propose that the MOU must establish procedures for how the MFCU and the Medicaid agency will coordinate their efforts as they carry out their respective responsibilities. Third, we propose that the MOU must establish procedures related to payment suspension and notification of acceptance or declination of cases, as found at §§ 1007.9(e) through 1007.9(h). Finally, we propose that the MOU must be reviewed and, if needed, updated by both the MFCU and the Medicaid agency at least every 5 years to ensure that it reflects current law and practice.

We also propose a minor amendment at § 1007.9(f) which requires that any request by the Unit to the Medicaid agency to delay notification to the provider of a payment suspension under § 455.23 must be made in writing. We propose to add the word "promptly" to that provision. In order to avoid the risk of jeopardizing a MFCU investigation, we think it is important for Units to provide prompt written notice to a Medicaid agency if a provider is the subject of an investigation. Further, we also propose a similar amendment to § 1007.9(g) which requires the

Unit to notify the Medicaid agency in writing as to whether the Unit accepts or declines a case referred by the Medicaid agency. We propose that the Unit should make this decision in a timely manner and promptly inform the Medicaid agency of its decision. Again, prompt notification by the MFCU allows the Medicaid agency to uphold a payment suspension, or in the case of a declination, re-establish payments to the provider. Additionally, if a referral is declined by the Unit, the Medicaid agency may pursue administrative actions against the provider in a timely manner.

We propose an amendment at § 1007.9(h) to require the MFCU to provide certification to the Medicaid agency, upon request on a quarterly basis, that any matter accepted on the basis of a referral continues to be under investigation and thus warranting continuation of payment suspension. Under § 455.23(d)(3)(ii), the Medicaid agency must request this certification from the MFCU, but the regulations do not require the MFCU to comply with this request. Placing this responsibility on the MFCU is consistent with the temporary nature of the payment suspension process.

1007.11 Functions and Responsibilities of the Unit

MFCU regulations, in describing the duties and responsibilities of a Unit for patient abuse or neglect, provide in paragraph 1007.11(b)(1): "The unit will also review complaints alleging abuse or neglect of patients in health care facilities receiving payments under the State Medicaid plan and may review complaints of the misappropriation of patient's private funds in such facilities." In implementing a Unit's statutory responsibility for patient abuse or neglect, the

Department thus expanded responsibility for abuse or neglect to the financial crime of "misappropriation of [a] patient's private funds," but made such cases optional ("may review complaints. . . ."). Cases involving private funds have become a substantial part of MFCU caseloads, reflecting the significance of financial abuse in crimes against seniors and other facility residents.

In our proposed definition in paragraph 1007.1 of "abuse of patients," we have included "financial harm" as one element. Consistent with this definition and with the recognized importance of financial abuse as a type of patient abuse or neglect, we propose to revise the regulation at 1007.11(b)(1) to require the Unit to review complaints involving misappropriation of funds. We believe that making the review of such complaints mandatory is consistent with the broad statutory responsibility for patient abuse or neglect.

The TWWIIA amended section 1903(q) of the Act to allow MFCUs to receive FFP for the investigation and prosecution of Medicare or other Federal health care cases that are primarily related to Medicaid, with the approval of the Inspector General of the relevant Federal agency (most typically, the Inspector General for HHS). We propose to revise § 1007.11 to specify that the MFCU must obtain written permission from the relevant Federal Inspector General to investigate cases of provider fraud in health care programs other than Medicaid. OIG issued guidance for seeking approval for this extended investigative authority from HHS-OIG in State Fraud Policy Transmittal No. 2000-1 (September 7, 2000). In order for OIG to effectively monitor these approvals, we propose to codify at § 1007.17(a)(1)(i) the requirement from the

policy transmittal that Units report annually to OIG of any approvals for extended investigative authority from any Federal Inspector General.

TWWIIA also gave MFCUs the option to review complaints of patient abuse or neglect in non-Medicaid board and care facilities, as defined in the statute, and to have procedures for acting on such complaints. For the regulation, we interpret the law's requirement to have "procedures for acting on such complaints" to mean that Units can investigate cases arising from those complaints. Consistent with our proposal to permit investigation of misappropriation of patient funds in health care facilities, we also propose to permit such investigations in board and care facilities.

At new § 1007.11(a)(3), we propose that applicable State laws pertaining to Medicaid fraud include criminal statutes as well as civil false claims statutes or other civil authorities. Further, at new § 1007.11(e)(4), we propose that if no State civil fraud statute exists, MFCUs should make appropriate referrals of meritorious civil cases to Federal investigators or prosecutors, such as the U.S. Department of Justice or the U.S Attorney's Office, as well as to the HHS-OIG Office of Investigations and Office of Counsel to the Inspector General. OIG believes that assessing civil penalties and damages is an appropriate law enforcement tool when providers lack the specific intent required for criminal conviction but satisfy the applicable civil standard of liability. This proposal is consistent with State Fraud Policy Transmittal No. 99-01 (December 9, 1999) which encouraged MFCUs to pursue potential civil remedies when no potential criminal remedy exists. Additionally, as discussed in Section B, we propose to add a definition of "fraud" that clarifies MFCU authority to investigate and prosecute both criminal and civil fraud.

At § 1007.11(c), we propose to clarify that when a Unit discovers that overpayments have been made to a provider or facility, the Unit must either recover the overpayment as part of its resolution of a fraud case or refer the matter to the proper State agency for collection.

At § 1007.11(e)(1) and (2), we propose to retain the current requirement that a Unit make available to Federal investigators and prosecutors and OIG attorneys all information in its possession concerning Medicaid fraud and that the Unit coordinate with such officials any Federal and State investigations or prosecutions involving the same suspects or allegations. The Federal and State governments share responsibility for the investigation and prosecution of Medicaid provider fraud, and Federal agencies may need to coordinate an action in a particular State with other Federal law enforcement efforts.

We also propose to expand paragraph (e) in three other ways to further ensure the effective collaboration between the Units, OIG investigators and attorneys, other Federal investigators and prosecutors.

First, we propose in paragraph (e)(3) to specify that a MFCU establish a practice of regular meetings or communication with OIG investigators and Federal prosecutors. In States in which OIG does not have the resources to maintain a regular presence, such communication could be by telephone or video conference. Given OIG's coordinating role on Federal health care fraud cases, we believe that regular contact with OIG investigators is critical in each of the States. For Federal prosecutors, the Unit should establish a schedule of meetings or regular communication

with one or more of the U.S. Attorneys' Offices with jurisdiction in the State. In most jurisdictions, it is standard practice for the U.S. Attorney to operate a health care fraud task force, and regular communication can be achieved through regular participation by the Unit on the health care fraud task forces.

We believe that requiring regular meetings or communication with OIG investigators and with Federal prosecutors will strengthen relationships, enhance the effectiveness of fraud investigations and prosecutions, and ultimately improve the integrity of the Medicaid program. We believe that such communication is routine in most of the Units, but we also know through our onsite reviews that there are Units with a lack of communication with OIG investigators and Federal prosecutors.

Second, we propose to specify in paragraph (e)(4) that Units make appropriate referrals to OIG investigators and attorneys, other Federal investigators, and Federal prosecutors. It is not unusual for Units to investigate cases of Medicaid fraud that involve Medicare or other Federal programs, and such cases should be referred to OIG investigators, unless the MFCU receives authority under § 1007.11(a)(2) to investigate the Medicare or other program fraud itself. Many such referred cases will be investigated jointly by the MFCU and the Federal Government, and the investigation will benefit from the combined skills and resources of both offices. Also, health care fraud cases often involve both criminal fraud as well as the possibility of a civil recovery through application of a civil false claims act. As a matter of policy, we have for many years requested MFCUs to refer such civil cases to Federal investigators or prosecutors for possible application of the Federal civil false claims act. Many States have the ability to pursue

civil actions either through State civil false claims acts or other State authority, but other States may lack the ability to prosecute such cases. Also, in many States, there may be a lack of investigative resources to pursue such cases even if the State has the authority to do so.

Finally, we further propose in paragraph (e)(5) that Units develop written procedures for those items addressed in paragraphs (1)through(4). We believe that most Units comply with each of these steps as a routine part of their process, but we also believe that it is important to formalize them as part of the Unit's written procedures because of the critical importance of case coordination. This will also permit OIG, in its oversight of the Units, to verify that coordination procedures are in place. Our proposal does not specify what the procedures should be, but would allow the MFCU and its Federal partners to tailor procedures to most effectively meet the needs in their State. An example of an established procedure for paragraph (e)(3) would be the sharing between the Unit and OIG's Office of Investigations weekly or monthly reports describing newly opened cases as well as a schedule of monthly or quarterly meetings.

We propose to revise § 1007.11(f) to require a Unit to provide adequate safeguards to protect sensitive information and data under the Unit's control. Under the current regulation at § 1007.11(f), MFCUs have been required to safeguard privacy rights and to prevent the misuse of information under their control. In the past, this requirement largely referred to paper case files and other case-related materials, such as evidence. Many MFCUs now maintain case information in an electronic format and do not rely exclusively on paper case files. Because Unit electronic record and data systems may contain personally identifiable and other sensitive information, Units need to protect that information with a robust data security program. Such a

program should guard against unauthorized access or release of case information as well as unauthorized intrusions from external sources.

Finally, consistent with the MFCU mission to prosecute Medicaid provider fraud and patient abuse or neglect, we propose to amend the regulations at new § 1007.11(g) to require that a Unit transmit to OIG, for purposes of excluding convicted individuals and entities from participation in Federal health care programs under section 1128 of the Act, pertinent documentation on all convictions obtained by the Unit, including those cases investigated jointly with another law enforcement agency, as well as those prosecuted by another agency at the local, State, or Federal level. This requirement would be consistent with the longstanding published performance standard for MFCUs that such referrals be made. By referring convicted individuals or entities to OIG for exclusion, MFCUs help to ensure that such individuals and entities do not have the opportunity to defraud Medicaid and other Federal health programs or to commit patient abuse or neglect. Historically, referrals by MFCUs have constituted a significant part of the exclusions imposed each year by OIG.

We propose that such information be provided within 30 days of sentencing or, if MFCUs are unable to obtain pertinent information from the sentencing court within 30 days, as soon as reasonably practicable. We propose this "reasonableness" provision because we are aware that courts may on occasion not provide pertinent documents to MFCUs in a timely manner. In assessing whether such additional time is reasonable, OIG will assess the steps the MFCU has taken to obtain the court documents in a timely manner.

Finally, at § 1007.11(a) through (c), in describing the activities for which a Unit is responsible, we propose to revise references to "the State [Medicaid] plan" to instead refer to "Medicaid," and to refer to a "provider" (defined in section § 1007.1 in relationship to Medicaid), rather than "provider of medical assistance under the State Medicaid plan." This reflects the reality that many States operate under State plan waiver programs and that provider activities in waiver programs were not intended to be excluded from a Unit's responsibility. This is consistent with the statute's broad description of a Unit's function as extending to "any and all aspects of fraud in connection with . . . any aspect of the provision of medical assistance . . . ." Section 1903(q)(3) of the Act, 42 U.S.C. § 1396b(q)(3).

1007.13 Staffing Requirements

Full-time and part-time employees and exclusive effort

Current regulations at § 1007.19(e)(4) prohibit FFP for "any management function for the Unit, any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution of suspected providers that is not performed by a *full-time employee of the Unit.*" (Emphasis added.) Similarly, the current definitions at § 1007.1 define "employ" or "employee" to mean "full-time duty intended to last at least a year." In recognition of changes to the modern workplace, OIG has taken a flexible approach with respect to the employment of professional employees who may wish to have part-time schedules. OIG has thus also interpreted the "full-time" rule to permit FFP for professional employees who are employed on a part-time basis, as long as their professional activities are devoted "exclusively" to MFCU purposes.

We therefore propose to revise the regulations to clarify that MFCU professional employees do not need to be "full time" to receive FFP, but to retain the longstanding policy and practice that FFP is permitted only for MFCU professional employees who are devoted "exclusively" to the MFCU mission except for limited circumstances that are specifically described in the regulation. Therefore, we propose to add definitions in 1007.1 of "part-time employee," "full-time employee," "professional employee," and "exclusive effort."

We thus propose to add a new § 1007.13(d) that describes the requirements for professional employees to receive FFP. Paragraph (d)(1) would require that, for professional employees to be eligible for FFP, they must devote their "exclusive effort" to the work of the Unit. This proposal is also reflected in § 1007.19(e)(4), which would prohibit FFP for "the performance of any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution of suspected providers by a person other than an employee who devotes exclusive effort to the Unit's work."

New § 1007.13(d) would also describe, in paragraphs (d)(2) and (d)(3), two circumstances in which professional employees may perform limited non-MFCU activities: outside employment during non-duty hours and temporary non-MFCU assignments. These proposals, discussed separately, are consistent with longstanding MFCU practice and OIG policy as expressed in State Fraud Policy Transmittal No. 2014-1 (June 3, 2014).

As also stated in the preamble to the regulations regarding the prohibition of FFP for other than a professional "full time employee," we believe that "exclusive effort" by professional employees

is necessary because the employment of temporary staff, or the occasional pursuit of isolated cases by different investigators and prosecutors, will undermine a Unit's ability to create an effective team with specialized knowledge of health care fraud and patient abuse or neglect. 43 Fed. Reg. 32078 (July 24, 1978). We also believe that the character of a MFCU as a "single identifiable entity," and the development of specialized expertise in Medicaid fraud and patient abuse or neglect, would be frustrated by the employment of professional employees whose responsibilities are split between the MFCU and another agency. We believe that the long-standing policy and practice of MFCUs employing professional employees devoted exclusively to the MFCU mission has been key to the success of MFCUs.

One limitation on the use of part-time professional employees is the certification requirement found at § 1007.13(a), retained in this rulemaking, that MFCUs "will employ sufficient professional, administrative, and support staff to carry out its duties and responsibilities in an effective and efficient manner." For example, Unit management may want to consider whether employing key staff, such as the director or chief investigator, on a part-time basis would undermine the Unit's effectiveness and efficiency.

Outside employment

We further propose, in § 1007.13(d)(2), to reflect the restrictions contained in our current policy regarding outside employment of professional employees during non-duty hours. Specifically, in subsection (d)(2), we propose that, to be eligible for FFP, professional employees may not be employed by other State agencies during non-duty hours. As stated previously, we believe it is

important to maintain the separate nature of the MFCU because of the potential compromise between the MFCU mission and other missions of the State.

We do not have the same concerns about employment outside of State government. As part of paragraph (d)(2), we also propose that professional employees may obtain employment outside of State government, if State law allows it, but only if the outside employment presents no conflict of interest to Unit activities. A common example of such employment would be a MFCU auditor working as a tax accountant during his or her off-hours. The Unit should follow its State's process to ensure that any proposed outside employment is in accordance with applicable professional standards and State ethics rules or policies. In the absence of a State process, the MFCU should develop its own process to avoid conflicts of interest between a professional employee's outside employment and the work of the MFCU.

Temporary non-MFCU assignments

In proposed § 1007.13 (d)(3), we reflect the current policy and practice regarding temporary, non-MFCU assignments. Paragraph (d)(3) would permit MFCU professional employees to engage in temporary assignments that are not within the functions and responsibilities of a MFCU only if such assignments are truly limited in duration. As with other non-MFCU activities, such assignments would not be funded by the Federal MFCU grant. For example, MFCU professional employees have been deployed to assist in maintaining order during natural disasters and other Statewide emergencies.

We expect that such situations will be unusual and infrequent, so MFCU directors should assess each on a case-by-case basis and may consult with OIG in determining whether the assignments are appropriate. Before directing staff to take a temporary assignment, a Unit should determine whether the assignment has a limited and defined duration and whether the assignment would pose any conflict with MFCU operations. The Unit may also want to consider whether the skills and expertise of the employees(s) are necessary for the assignment. If a MFCU permits temporary non-MFCU assignments, the Unit must document all hours spent on the assignment and ensure that the hours are excluded from the MFCU's financial status reports for purposes of receiving FFP.

Direction and supervision of the Unit

We propose to add a requirement at § 1007.13(c) that the Unit must employ a director who supervises all Unit employees. Regulations do not specify that a MFCU must have a director, although all MFCUs for many years have operated with a director. We have found that having a director to whom all Unit employees ultimately report is critical to the successful management and operation of a MFCU. We also propose to define "director." We further note that in some small Units, the director is the Unit's only attorney and can be considered the one required attorney under § 1007.13(b).

Proposed § 1007.13(d)(4) would further require that professional employees must be under the direction and supervision of the MFCU director (or, in larger Units, a subordinate Unit manager). This requirement has been a part of OIG's longstanding interpretation of the full-time rule and

the statutory definition of a Unit as a "single, identifiable entity." Allowing attorneys or investigators to report to supervisory officials outside the Unit would both undermine the ability of the Unit director to effectively manage the Unit and would interfere with the ability of MFCU professional employees to collaborate as a team.

Use of consultants and other contracts

Consistent with the proposal to require exclusive effort by professional employees to receive FFP, we also propose to clarify, in § 1007.13(g)(2), that the Unit may not receive FFP when it relies on individuals not employed directly by the MFCU for the investigation or prosecution of cases, including through consultant agreements or other contractual arrangements. As with the exclusive effort rule, we believe that the contracting out of investigative or legal functions would undermine the character of MFCUs as single, identifiable entities. This proposal is consistent with a longstanding practice of not allowing the contracting out of the investigation or prosecution of cases. We note that this proposal does not affect those MFCUs contained in state entities that lack the authority to prosecute fraud or patient abuse or neglect. Such MFCUs rely on non-MFCU prosecutors in other government agencies, who are not paid on the grant, to bring MFCU cases to trial.

However, we also propose to clarify at § 1007.13(g)(1) that Units may receive FFP for the employment of, or have available through consultant agreements or other arrangements, individuals with particular knowledge, skills, and/or expertise that a Unit believes will support the Unit in the investigation or prosecution of cases. For example, Units may have consultant

agreements with expert witnesses or other forensics experts or may employ nurses to support investigations and prosecutions.

MFCU employee training

Regulations do not address training of MFCU professional employees. Because of the importance of training for MFCU professionals, we propose to add a requirement at § 1007.13(h) that a Unit must provide training for its professional employees for the purpose of establishing and maintaining proficiency in the investigation and prosecution of Medicaid fraud and patient abuse and neglect. This requirement is consistent with MFCU performance standards, which state that a Unit "conduct training that aids in the mission of the Unit."

Other staffing issues

We propose to clarify several staffing issues by this regulation, including requiring a director; allowing part-time administrative and support staff; and clarifying the qualifications of attorneys, auditors, and the senior investigator.

We clarify at § 1007.13(e) that a Unit may hire administrative and support staff on a part-time basis. Part-time administrative and support staff, unlike professional employees in the new § 1007.13(d)(2), may hold another part-time State job or allocate their time between two offices within the Office of the Attorney General, for example. In those instances, we will continue to

require that all claims for Federal reimbursement for part-time support staff be supported with proper documentation of hours worked.

We also propose minor clarifications at § 1007.13(b) of the qualifications of attorneys, auditors, and the senior investigator. For attorneys, we propose that they must be capable of prosecuting health care fraud or criminal cases. For auditors, we propose a minor change, that an auditor be capable of reviewing financial records, rather than the current language, that an auditor is "capable of supervising the review of financial records." We also propose to expand requirements to include that an auditor be capable of advising or assisting in the investigation of patient abuse and neglect. For the senior investigator, we propose to eliminate the prerequisite of "substantial experience in commercial or financial investigations," and propose instead only that the senior investigator be capable of supervising and directing the investigative activities of the Unit. Further, consistent with 1007.13(a), requiring that a Unit hire sufficient staff to carry out its duties and responsibilities effectively and efficiently, we propose the requirement that Units hire one "or more investigators."

1007.15 Certification

We propose at § 1007.15(b) to clarify that initial certification will be based on the information and documentation specified at § 1007.15(a). To receive Federal reimbursement, a MFCU must be certified and annually recertified by OIG, consistent with section 1903(a)(6) of the Act. For initial certification, a Unit must meet the basic requirements established in section 1903(q) as implemented in this part. Basic certification requirements include organization, location,

relationships with the Medicaid agency, Unit duties and responsibilities, and staffing. We also propose to eliminate the requirement at § 1007.15(a)(6) that an initial application include a projection of caseload. We believe that it is unrealistic for State or territory preparing an initial application to provide any meaningful caseload projection.

1007.17 Recertification

A MFCU must be recertified annually by OIG to receive Federal reimbursement for a portion of its costs. Forty-nine States and the District of Columbia have established and operate a Unit. We propose to revise regulations to reflect the recertification process that has evolved since the program began. The proposed regulation at § 1007.17 would: (1) describe the information that must be provided to OIG, including the recertification reapplication and statistical reporting; (2) describe other information considered for recertification; (3) clarify the basis for recertification by OIG; (4) create a procedure in which OIG notifies the Unit whether the reapplication is approved or denied by the Unit's recertification date; (5) clarify that an approved reapplication may be subject to special conditions; and (6) establish basic procedures for reconsideration of an OIG denial of recertification.

Requirements for recertification

Section 1903(q)(7) of the Act requires a Unit to submit to the Secretary an application and "annual report containing such information as the Secretary determines, by regulations, to be necessary to determine whether the entity meets the other requirements of this paragraph."

Current regulations at § 1007.17 describe the content of the "annual report," including certain statistical data and budget information, a narrative evaluating performance, any specific problems that have arisen over the year, and other matters that have impaired the Unit's effectiveness.

We propose to revise § 1007.17(a) to describe the information that Units must submit annually to OIG to fulfill the statutory mandate that Units provide "annual reports" to the Secretary. Under our proposal, Units may choose to no longer submit a document labeled "annual report," so long as the items described in the proposed regulation are submitted to OIG on an annual basis in the timeframes established for each Unit as part of its annual reapplication. Such information includes statistical and other information provided to OIG in an electronic format. We describe below the items that must be submitted by each MFCU over the course of the year that satisfy the requirement for an annual report.

Narrative and approved data mining activities. First, as part of the reapplication, at the new § 1007.17(a)(1), we would continue to require the narrative from current § 1007.17(h) that evaluates the Unit's performance, describes any specific problems it has had in connection with the procedures and agreements under this part, and discusses other matters that have impaired its effectiveness. The narrative should also include any extended investigative approvals, pursuant to proposed § 1007.11(a)(2). Second, for Units that have received OIG approval to conduct data mining under § 1007.20, we would also continue to require that they submit information on their data mining activities.

Information Request. At the new § 1007.17(a)(1)(iii), we propose an annual requirement that Units provide information to OIG addressing their compliance with this part and adherence to MFCU performance standards. This proposed provision would align the regulation with current practice in which the Units, as part of their reapplication, provide information requested by OIG for that year. We have also included in the proposed regulation a requirement that Units advise OIG of significant changes since the prior year's recertification. This would replace a provision contained in § 1007.15(c)(1), requiring the Unit to advise the Secretary of any significant changes in the information and documentation submitted with the initial MFCU application. However, we think it is more appropriate for a Unit to advise OIG of significant changes that occurred during the prior year, rather than since its initial application, which for some Units could be 30 years or more. The information requested by OIG prompts a Unit to answer questions about all aspects of its operations, which should lead to responses that describe any significant changes.

Statistical report. Under the new § 1007.17(a)(2), we propose to amend the regulations to include the requirement that MFCUs submit an annual statistical report by November 30 of each year for the prior Federal fiscal year (FFY), containing the required data elements developed by OIG in collaboration with the MFCUs. Units submit to OIG statistical reports that include information on staffing, investigations, criminal prosecutions and civil actions, and other case outcomes. The statistical reports would be used, along with other information, to evaluate MFCUs for recertification. The statistical data provided by the Units would also enable OIG to assess performance and identify trends for all MFCUs.

We propose that the requirement for a separate annual statistical report replace the statistics that are required as part of the current annual report at § 1007.17(a) through (e). This would eliminate duplication of reported statistics and provide a standard timeframe (the FFY) for reporting rather than the current annual report requirement, which is tied to the recertification period of each Unit and is often a different year period than the FFY. Further, the current regulation requires the Unit to submit projected performance statistics for the upcoming recertification period. We no longer require this level of detail because of the difficulty of providing projected statistics. Finally, the current regulation requires a Unit to submit its costs incurred for the recertification period. Because a Unit submits an official Federal financial form (SF-425) reporting its costs to OIG for the FFY, we do not need an unofficial accounting of costs for the recertification period which, as noted, is often different from the FFY.

We also propose at the new § 1007.17(b) to include other information not submitted by the MFCU, but which, when appropriate, is reviewed for recertification. This would include information obtained during periodic onsite reviews and other information OIG deems necessary or warranted. It may also include obtaining feedback from stakeholders, such as the Medicaid program integrity director and the OIG special agent-in-charge, on their working relationships and business processes with the MFCU.

Basis for recertification

Section 1007.15(d) describes items that OIG considers when recertifying a MFCU, including the information on the MFCU's reapplication, the annual report, the effective use of resources in

investigating and prosecuting fraud, and "other reviews or information" deemed necessary or warranted. We propose to describe at the new § 1007.17(c) OIG's basis for recertifying a MFCU, including specifying the "other reviews or information" OIG deems necessary or warranted. To determine whether a Unit has demonstrated that it effectively carries out the functions and responsibilities of this part for purposes of recertification, OIG examines a Unit's compliance with this part and other applicable Federal regulations as well as with OIG policy transmittals. OIG consults with MFCU stakeholders. OIG also uses the statutory performance standards that Units must satisfy under § 1902(a)(61) of the Act as a guideline in evaluating whether a Unit is effectively and efficiently carrying out its duties and responsibilities.

Further, as described in § 1007.11, in addition to the responsibility of having a Statewide program for investigating and prosecuting (or referring for prosecution) Medicaid fraud, MFCUs are also responsible for reviewing complaints alleging abuse or neglect of patients in health care facilities receiving payments under the State Medicaid plan and either investigating the complaints or referring them to the appropriate authority, which we interpret to mean that Units can investigate and prosecute cases arising from those complaints. At § 1007.17(c)(5), we propose to also include effective performance of the latter responsibility as an additional consideration in OIG's recertification review. OIG is aware that Units apportion their resources between the two responsibilities in different ways but believes that Units should not neglect one type of case.

Recertification notification and denial of recertification.

Section 1007.15(d)(l) provides that a Unit will be notified promptly whether its reapplication has been approved. We propose to modify the notice procedure at proposed § 1007.17(d) to state that OIG will provide notice of approval or denial of recertification by the Unit's recertification date. We also propose that the recertification approval may be subject to special conditions or restrictions, as provided in 45 CFR § 75.207, and may require corrective action. Further, if an application for recertification is denied, we propose in the new § 1007.17(e) that a Unit may request reconsideration of a denial by providing written information addressing the findings on which the denial was based. Within 30 days of receipt of the request for reconsideration, OIG provides a final decision, and its basis, in writing to the Unit and notifies CMS if the Unit does not meet the requirements for recertification. Under section 1903(a)(6), the Federal Government may not provide FFP in costs incurred by a Unit that is not certified by OIG as meeting the requirements for operating a Unit as found at section 1903(q).

Subpart C--Federal Financial Participation

1007.19 FFP Rate and Eligible Costs

In the initial legislation establishing MFCUs, Congress provided that Federal funds would reimburse States for 90 percent of their MFCU costs for 12 quarters in order to encourage the development of State MFCUs. In 1980, Congress amended section 1903(a)(6) to provide a continuing incentive by authorizing ongoing Federal reimbursement at 75 percent of a MFCU's allowable costs after the first 12 quarters of operation.

We propose to modify § 1007.19(a) to reflect that, under law, FFP is available at the rate of 90 percent during the first 12 quarters of a Unit's operation and at 75 percent thereafter, beginning with the 13th quarter of a Unit's operation. We also propose other modifications to clarify that each quarter of reimbursement at the 90 percent matching rate is counted in determining when the 13th quarter begins. Quarters of MFCU operation do not have to be consecutive to accumulate for purposes of determining when the 90 percent matching period has ended.

We also propose to amend § 1007.19(d) to clarify in regulation that a Unit may receive FFP for its efforts to increase referrals through program outreach activities. These are activities that most Units currently undertake as a part of their responsibilities under the grant but are not addressed in the program regulations in part 1007. Permissible program outreach activities by the Units may include efforts to educate Medicaid providers, law enforcement entities, and the public about Medicaid fraud, patient abuse or neglect, and MFCU authority and jurisdiction. Program outreach activities may also include the dissemination of outreach and educational materials specifically designed to increase awareness of the MFCU mission that could lead to referrals to the Unit. These outreach materials must be of a de minimus cost and be useful and practical.

We propose to amend § 1007.19(e)(2) to clarify the prohibition on the ability of Units to receive FFP to "identify situations in which a question of fraud may exist." Specifically, the provision prohibits FFP "for expenditures attributable to: [. . .] , except as provided under § 1007.20 [allowing Units to seek OIG approval to conduct data mining], efforts to identify situations in which a question of fraud may exist, including the screening of claims and analysis of patterns and practice that involve data mining as defined in § 1007.1." We are proposing to replace

"*including* the screening of claims . . ." with "*by* the screening of claims . . ." to clarify the ability of Units to engage in activities, other than data mining, to identify potential civil or criminal fraud in the Medicaid program.

We believe that this revision to the Unit's permissible activities is supported by the following: MFCUs have the ability to work with a variety of State agencies and private referral sources to identify possible fraud and to undertake sophisticated detection activities, such as undercover operations. None of these activities interferes with the program integrity activities of the State Medicaid agency, which we believe was the initial intended purpose of the prohibition. Our proposal would remove from the Medicaid agency the sole burden of identifying potential fraud and would allow MFCUs to be less dependent on referrals from Medicaid agencies.

1007.21 Disallowance Procedures

We propose to amend the regulation in the new § 1007.21 to establish procedures for taking formal disallowances of FFP, for Units to request reconsideration of disallowances and to appeal to the HHS Departmental Appeals Board. The proposal is similar to CMS's requirements for the appeal of disallowances by State Medicaid agencies found at 42 CFR § 430.42.

Subpart D—Other Provisions

1007.23 Other Applicable HHS Regulations

We propose to update the listing, contained in § 1007.21, of other applicable HHS regulations that were amended after the current MFCU regulations were promulgated. Specifically, we have updated the reference to the Department's award administration regulations now contained in 45 CFR part 75. 45 CFR part 75 establishes the HHS specific regulations for the Office of Management and Budget (OMB) interim final rule of the Uniform Guidance (UG) at 2 CFR part 200, published on December 26, 2014. We are also updating references to regulations governing HHS Departmental Appeals Board procedures and HHS nondiscrimination policies.

III. Regulatory Impact Statement

We have examined the impact of this rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold,

and thus is not considered a major rule. Since the proposed regulation would only implement current practice and policy, we believe the economic impact to be negligible.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.5 million to $38.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain principles and criteria that an agency must follow when it implements a regulation or other policy that has Federalism implications, defined in the Order to mean that the regulation or policy has substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The Order also requires a level of consultation with State or local officials when an agency formulates and implements a regulation that has Federalism implications, that imposes substantial direct compliance costs on State and local governments, and that is not required by statute.

We do not believe that this proposed regulation has Federal implications as it would not have a substantial direct effect on the States or on the relationship or distribution of power and responsibilities among levels of government. We also do not believe that the proposed regulation would impose substantial direct compliance costs on States. Rather, the regulation would reflect certain statutory changes governing operation of the MFCUs that have already been implemented and would codify policy and practice involving the organization and operation of the Units. We believe that the content of the regulation is consistent with the partnership between the Federal and State governments that has been established for the financing and administration of the larger Medicaid program. We

further believe that any costs related to compliance with the proposed regulation are minimal and not substantial.

However, to the extent that that the proposed regulation is seen as having Federal implications, the proposed regulation is consistent with the principles and criteria established in the Order. The proposed regulation would strictly adhere to constitutional principles and would be deferential to the States with respect to the policymaking and administration of State operations related to the investigation and prosecution of Medicaid provider fraud and patient abuse or neglect. With regard to consultation, the policies contained in the proposed regulation were developed in consultation and collaboration with the States.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

IV. Paperwork Reduction Act

Under the Paperwork Reduction Act (PRA) of 1995, before a collection-of-information requirement is submitted to OMB for review and approval, we are required to provide a 60-day notice in the Federal Register and solicit public comment. We propose to revise the scope of our annual collection of information as part of this NPRM to revise the MFCU oversight regulations contained in 42 CFR part 1007. The collection would contain certain mandatory information required annually as outlined at proposed 42 CFR § 1007.17 which includes a reapplication of a brief narrative, data mining outcomes, and an information request as well as an annual statistical report. All of these items would replace the "Annual Report" required at current § 1007.17.

Specifically, the proposed reapplication contains several elements. First, it would include a brief narrative that evaluates the Unit's performance, describes any specific problems it has had, and discusses any other matters that have impaired its effectiveness. This narrative could be in any format, as determined by each MFCU.

Second, those MFCUs approved by OIG to conduct data mining under 42 CFR § 1007.20 are required by the current regulation to submit the costs expended by the MFCU on 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, and any other relevant indicia of return on investment from data mining activities. The reporting format for data mining activities is determined by each reporting MFCU.

Third, the proposed reapplication would also include an information request concerning compliance with the statute, regulations, and policy transmittals as well as adherence to the MFCU performance standards. The information request would be in a standard question and answer format and has always been a part of the reapplication.

Fourth, and separate from the reapplication, we propose that MFCUs provide a Federal fiscal year (FFY) annual statistical report containing data points found at proposed 42 CFR § 1007.17(b). This is consistent with the MFCU performance standard that a Unit have a case management system that (1) allows efficient access to case information and other performance data from initiation to resolution and (2) allows for reporting of case information. Units maintain case management systems on an ongoing basis and would upload the proposed data to a secure

web portal through a Federal service provider, OMB MAX by November 30 of each year. This annual statistical report would replace the statistical information that we propose to no longer require in an "Annual Report," as at 42 CFR § 1007.17(a) through (e), although some of the data points are the same or similar to the statistics proposed in the annual statistical report. The proposed new data points would be an enhancement to our current information and would, on a FFY basis, more completely and accurately describe Unit staffing, caseload, criminal and civil case outcomes, collections, and referrals.

We estimate that the burden for these proposed collections would be similar to the burden approved under OMB approval No. 0990-0162. First, the currently approved burden estimate for the "Annual Report" is 88 hours per respondent. Because the burden previously assigned to the "Annual Report" would shift to the separate annual statistical report provided at the end of the FFY, we have re-estimated that preparing the brief narrative would take 3 hours per respondent. Based on reports from MFCU officials, providing information on data mining activities, if required, would require 1 hour of additional burden, as is currently approved. We have then shifted most of the balance of the current "Annual Report" burden (80 hours) to the proposed annual statistical report. We believe that most of the burden for preparing the annual statistical report consists of the ongoing updating of the Unit's case management system and not for the uploading of the actual report, so we believe the estimate is accurate. Second, the recertification reapplication information request has not changed from current practice and is approved under OMB No. 0990-0162. However, based on reports from MFCU officials, we have increased the reapplication information request burden estimate by 4 hours per respondent to 9 hours. Thus,

we estimate that after shifting the burden between collections, the total burden would be the same as currently approved.

Based on our knowledge of MFCU staff hourly rates and which MFCU staff person would prepare each collection, we estimate a MFCU official would spend approximately 29 hours at an estimated $38 per hour preparing the reapplication and annual statistical report. We estimate that a MFCU support staff person would spend approximately 64 hours of effort at an estimated hourly rate of $16 per hour to develop draft products, fulfill data entry activities, complete all required administrative functions, and confer with the MFCU supervising official, all of which are necessary to finalize the collection for submission to OIG. Based on these estimated hours and staff wage rates, the weighted average wage rate is $22.85 per hour. Thus, identical to the estimate that was approved under OMB No. 0990-0162, our best estimate is that about 93 burden hours would be expended by each of the 50 MFCUs.

OIG would use the information collected to determine the MFCUs' compliance with Federal requirements and eligibility for continued Federal financial participation (FFP) under the Federal MFCU grant program, as part of the annual recertification process for each MFCU. The collection would also allow OIG to assess performance and trends in Medicaid fraud and patient abuse and neglect across all MFCUs.

In order to evaluate fairly whether this information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency;
- The accuracy of our estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section. Comments on these information collection activities should be sent to the following address within 60 days following the Federal Register publication of this proposed rule: OIG Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 725 17th Street, NW., Washington, DC 20053.

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List of Subjects

42 CFR Part 455 Program integrity: Medicaid.

Fraud
Grant programs-health
Health facilities
Health professions
Investigations
Medicaid

Reporting and recordkeeping requirement

42 CFR Part 1007_State Medicaid fraud control units.

Administrative practice and procedure
Fraud
Grant programs-health
Medicaid
Reporting and recordkeeping requirements

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) respectively, propose to amend 42 CFR part 455 and 1007 as follows:

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

1. The Authority citation for part 455 continues to read as follows:

   Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 455.21 is amended by adding paragraph (c) to read as follows:

§455.21 Cooperation with State Medicaid fraud control units.

* * * * *

(c) The agency must enter into a written agreement with the unit under which--

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

(2) The unit will agree to comply with the requirements of 42 CFR 1007.11(c); and

(3) The agency and the unit will agree to--

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

(ii) Establish a set of procedures for how they will cooperate and coordinate their efforts; and

(iii) Establish procedures for 42 CFR §§ 1007.9(e) through 1007.9(h).

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

CHAPTER V—OFFICE OF INSPECTOR GENERAL-HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

3. Part 1007 is revised to read as follows:

PART 1007-STATE MEDICAID FRAUD CONTROL UNITS

Subpart-A – General Provisions and Definitions

§1007.1 Definitions.

§1007.3 What is the statutory basis for and organization of this rule?

Subpart-B – Requirements for Certification

§1007.5 What are the single identifiable entity requirements for a Unit?

§1007.7 What are the prosecutorial authority requirements for a Unit?

§1007.9 What is the relationship to the Medicaid agency, and what should be included in the agreement with the agency?

§1007.11 What are the functions and responsibilities of a Unit?

§1007.13 What are the staffing requirements of a Unit?

§1007.15 How does a State apply to establish a Unit and how is a Unit initially certified?

§1007.17 How is a Unit recertified annually?

Subpart-C – Federal Financial Participation

§1007.19 What is the Federal financial participation (FFP) rate and what costs are eligible for FFP?

§1007.20 Under what circumstances is data mining permissible?

§1007.21 What is the procedure for disallowance of claims for FFP?

Subpart-D – Other Provisions

§1007.23 What other HHS regulations apply to a Unit?

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

Subpart-A – General Provisions and Definitions

§1007.1 Definitions.

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

Abuse of patients means any act that constitutes abuse of a patient under applicable criminal State law, including the willful 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 MFCU managers.

Exclusive effort means that professional Unit 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 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 1 year.

Fraud means any act that constitutes criminal or civil fraud under applicable State law. It includes a deception, concealment of a material fact, or misrepresentation made by a person 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 funds means the wrongful taking or use, as defined under applicable State law, of funds or property of a patient residing in a health care facility or board and care facility.

Neglect of patients means any act that constitutes abuse of a patient under applicable criminal State law, including the willful 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 fall short of acts which constitute civil or criminal fraud under applicable Federal and State law, including those that are inconsistent with sound fiscal, business, or medical practices. Program abuse may result in an unnecessary cost to the

Medicaid program, inappropriate charges to beneficiaries or in reimbursement for services that are not medically necessary.

Provider means an individual or entity that furnishes items or services for which payment is claimed under Medicaid, or an individual or entity that is required to enroll in a State Medicaid program, such as an ordering or referring physician.

Unit means the State Medicaid Fraud Control Unit.

§1007.3 What is the statutory basis for and organization of this 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 State MFCU in order to be certified by OIG as eligible for FFP under title XIX. Section 1902(a)(61) of the Act requires a State to provide in its Medicaid State plan that it operates a MFCU 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 the rule. 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 What are the single identifiable entity requirements for a 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.

§1007.7 What are the prosecutorial authority requirements of a 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 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 abuse and 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 abuse and neglect to the appropriate prosecuting authority or authorities, and provides assistance and coordination to such authority or authorities in the prosecution of such cases; or

(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 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 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, so long as the Attorney General's Office maintains oversight responsibility for the prosecution and for coordination between the Unit and the prosecuting authority.

§1007.9 What is the relationship to the Medicaid agency, and what should be included in the agreement with the 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; and

(iii) Establish procedures for §§ 1007.9(e) through 1007.9(h).

(iv) Review and, if needed, update the agreement no less frequently than every 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 What are the functions and responsibilities of a Unit?

(a) The Unit must conduct a Statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws 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.

(3) Such State laws include criminal statutes as well as civil false claims statutes or other civil authorities.

(b)(1) The Unit must also review complaints alleging abuse or neglect of patients, including complaints of the misappropriation of a patient's funds, in health care facilities receiving payments under Medicaid.

(2) At the option of the Unit, it may review complaints of abuse or neglect of patients, including misappropriation of patient funds, residing in 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 must 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 must, 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 must either recover such overpayment as part of its resolution of a fraud case or refer the matter to the proper 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 must 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 must 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, 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, other Federal investigators, and prosecutors on any Unit cases involving the same suspects or allegations.

(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 procedures for items described in 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 sentencing court.

§1007.13 What are the staffing requirements of a 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 must 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 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 fraud and patient abuse and neglect; and

(3) One or more investigators, including a senior investigator who is capable of supervising and directing the investigative activities of the Unit.

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

(d) Professional employees:

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

(2) May be employed outside the Unit during non-duty 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-MFCU assignments for the State government only to the extent that such duties are limited in duration; and

(4) Must 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 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 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 must provide training for its professional employees for the purpose of establishing and maintaining proficiency in Medicaid fraud and patient abuse and neglect matters.

§1007.15 How does a State apply to establish a Unit, and how is a Unit initially certified?

(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) 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 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 How is a Unit recertified annually?

(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 MFCUs approved to conduct data mining under § 1007.20, all costs expended by the MFCU 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; 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 non-monetary penalties categorized by type of case; 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; and 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 sections § 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 for criminally prosecuting complaints alleging abuse or neglect of patients 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) 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

§1007.19 What is the FFP rate and what costs are eligible for FFP?

(a) Rate of FFP. (1) Subject to the limitation of this section, the Secretary 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.

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

(b) Retroactive certification. OIG may grant certification retroactive to the date on which the Unit first met all the requirements of the statute 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 cases involving a beneficiary's eligibility for benefits, unless the suspected fraud also involves 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 Under what circumstances is data mining permissible?

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

(1) The MFCU identifies the methods of coordination between the MFCU and 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) MFCU employees engaged in data mining receive specialized training in data mining techniques;

(3) The MFCU 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 MFCU 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 MFCU.

(iii) The approval is for 3 years.

(iv) A MFCU 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 What is the procedure for disallowance of claims for FFP?

(a) Notice of disallowance. When OIG determines that a Unit's claim or portion of a claim for FFP is not allowable, OIG shall 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 MFCU 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 (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 42 CFR 430.42(c)(5) and (c)(3) 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, 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 MFCUs, 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 increase or decrease.

Subpart-D – Other Provisions

§1007.23 What other HHS regulations apply to a Unit?

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

Part 16-Procedures of the Departmental Grant Appeals Board

Part 75-Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards;

Part 80-Nondiscrimination under Programs Receiving Federal Assistance through HHS, Effectuation of title VI of the Civil Rights Act of 1964;

Part 81-Practice and Procedure for Hearings under 45 CFR part 80;

Part 84-Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance;

Part 91-Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance from HHS;

DATED: June 16, 2016

Daniel R. Levinson
Inspector General

APPROVED: June 23, 2016

Sylvia M. Burwell
Secretary

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