August 1995 proposals. The changes since the proposals are addressed in the preamble discussions on the relevant sections of part 70 (e.g. § 70.2).

Please send comments directly to Docket A–93–50 at the address previously provided and specify that they are in response to this document. Comments will be forwarded from the Air Docket to the Operating Permits Group of EPA.

Dated: March 17, 1998.

Richard D. Wilson,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 98–7765 Filed 3–24–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1003, 1005 and 1006

RIN 0991–AA90

Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting From the Health Insurance Portability and Accountability Act of 1996

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of proposed rulemaing.

SUMMARY: This proposed rule would revise the OIG's civil money penalty (CMP) authorities, in conjunction with new and revised provisions set forth in the Health Insurance Portability and Accountability Act of 1996. Among other provisions, this proposed rulemaking would codify new CMPs for: Excluded individuals retaining ownership or control interest in an entity; upcoding and claims for medically unnecessary services; offering inducements to beneficiaries; and false certification of eligibility for home health services. This rule would also codify a number of technical and conforming changes consistent with the OIG's existing sanction authorities.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on May 26, 1998.

ADDRESSES: Pleas mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–25–P, Room 5527 Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–25–P.

Comments will be available for public inspection April 8, 1998 in Room 5524 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, D.C., on Monday through Friday of each week from 8 a.m. to 4:30 p.m., (202) 619–0089.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619–0089, OIG Regulations Officer.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview of the OIG Civil Money Penalty Authorities

In 1981, Congress enacted the civil money penalty (CMP) statute, section 1128A of the Social Security Act (the Act) (42 U.S.C. 1320a–7a), as one of several administrative remedies to combat increases in health care fraud and abuse. The CMP law authorized the Secretary and the inspector General to impose CMPs, assessment and program exclusions on individuals and entities whose wrongdoing caused injury to Department programs or their beneficiaries. The statutory penalty and assessment amounts under section 1128A generally provided for a penalty of no more than $2,000 for each item or service at issue, and an assessment in lieu of damages of not more than twice the amount claimed.

Since 1981, Congress has greatly expanded the CMP provisions to apply to numerous types of fraudulent and abusive activities related to Medicare and State health care programs. Specifically, new statutory provisions provided the Secretary and the OIG with the authority to sanction such improper practices as: (1) Hospitals paying physicians to reduce or limit services provided to program beneficiaries; (2) health maintenance organizations (HMOs) failing to provide medically necessary items and services; (3) individuals and entities engaging in certain misleading or fraudulent practices with respect to the marketing and selling of supplemental (Medigap) insurance policies; and (4) hospitals failing to examine and treat, or to properly transfer, emergency room patients (patient dumping).

In 1987, the Medicare and Medicaid Patient and Program Protection Act (MMPPPA), Public Law 100–93, was enacted to improve the ability of the Department ''to protect the Medicare and Medicaid programs from fraud and abuse, and to protect the beneficiaries of these programs from incompetent practitioners and from inappropriate and inadequate care.'' The MMPPPA significantly revised and expanded the OIG's CMP and exclusion sanction authorities. Final OIG regulations addressing amendments to out exclusion and CMP authorities resulting from Public Law 100–93 were published in the **Federal Register** on January 29, 1992 (57 FR 3298).

B. The Health Insurance Portability and Accountability Act of 1996

In the first significant amendments to the OIG's sanction authorities since MMPPPA, the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104–191, sets forth a number of important improvements to the OIG's authorities intended to curtail and eliminate health care fraud and abuse. With regard to the sanction authorities, HIPAA expanded the scope of certain basic fraud authorities by extending the application of current CMP provisions beyond those funded by the Department to include all Federal health care programs. The HIPAA also significantly revised and strengthened the OIG's existing CMP authorities pertaining to violations under Medicare and the State health care programs.

Among other provisions related to our CMP authority, HIPAA (1) increases the maximum penalty amounts per false claim from $2,000 to $10,000; (2) allows CMPs to be assessed for incorrect coding, medically unnecessary services, and persons offering remuneration to induce a program beneficiary to order from a particular provider or supplier receiving Medicare or State health care funds; and (3) establishes a new CMP for the false certification of eligibility for Medicare-covered home health services.

While the majority of these revisions to the OIG's CMP authorities under section 1128A of the Act are effective on January 1, 1997,[1] these provisions do allow the Department some policy discretion in their implementation. As a result, we are developing this proposed rulemaking to address these HIPAA penalty provisions, along with other technical revisions and conforming policy changes to the OIG's sanction authorities codified in 42 CFR parts 1003, 1005, and 1006.

[1] Section 232 of HIPAA applies to certifications made on or after August 21, 1996, the enactment date of the statute.

II. Provisions of the Proposed Rule

A. Extension of Current CMP Authority to All Federal Health Care Programs

Section 231(a) of HIPAA amended section 1128A of the Act to allow for the Federal government-wide application of CMPs for false claims to other health care programs, as defined in section 1128B(f) of the Act. Specifically, under section 231(a), the Medicare and State health care programs' CMP authorities for specified fraud and abuse violations, like the Medicare criminal statutes, will now apply to similar violations involving all Federal health care programs, such as CHAMPUS, Veterans, and the Public Health Service programs. (The Federal Employee Health Benefits Plan is expressly excluded from this definition of ''Federal health care program.'')

As a result, we would amend §§ 1003.100(b)(1)(i), 1003.102(a)(3), 1003.109(a), as well as the definitions for the terms *claim* and *exclusion* set forth in § 1003.101, to apply CMP coverage to all applicable Federal government health care programs. The definition for the term *program* currently set forth in § 1003.101 would also be deleted.

B. Increases in Civil Money Penalty Amounts

Prior to HIPAA, many of the CMP and assessment amounts authorized by section 1128A of the Act, and codified in § 1003.103 of the OIG regulations, remained consistent with the penalty and damage amounts contained in the False Claims Act (FCA) (31 U.S.C. 3729), and had not been revised since the 1986 amendments to that Act. Section 231(c) of HIPAA generally increases the amount of authorized CMPs from $2,000 to $10,000 per item or service improperly claimed or prohibited practice, and raises the authorized assessment amount from double to triple the amount claimed. This amendment to the OIG's authorized CMP amounts is consistent with the penalty and assessment amounts in the FCA which were increased by statute in 1986.

In accordance with section 231(c) of HIPAA, we are proposing to amend § 1003.103(a) to address the increased penalty amount, and § 1003.104 to address the revised assessment amount.

C. Clarification of the Knowledge Standard for Civil Money Penalties

The CMP statute was originally intended to provide an alternative administrative enforcement tool when injury to government programs and beneficiaries was not redressed through traditional civil or criminal remedies. Section 1128A of the Act and our implementing regulations have applied the ''knows or should know'' standard of proof for the Medicare and State health are programs' CMP provisions regarding false claims and other prohibited acts. The term ''should know'' has historically placed a duty on health care providers to use ''reasonable diligence'' to ensure that claims submitted to Medicare were true and accurate. The reason this standard was chosen was that the Medicare system relies heavily on the honesty and good faith of providers in submitting their claims. (The ''should know'' standard did not impose liability for honest mistakes; if the provider exercised reasonable diligence and still made a mistake, the provider was not liable.)

However, to make the knowledge standard consistent with the FCA, section 231(d) of HIPAA defined the term ''should know'' to mean ''reckless disregard'' or ''deliberate ignorance'' of the truth, with no proof of specific intent required. Under the newly defined ''should know'' standard in these proposed regulations, individuals and entities would only be liable if they act with deliberate ignorance or reckless disregard of information pertaining to the falsity of a claim or other fraud. No specific intent to defraud is required. The terms should know and should have known would be specifically defined in § 1003.101, with corresponding revisions made in §§ 1003.100(b)(1)(i) and 1003.102(a) and (b).

In addition, we are proposing to add a new paragraph (e) to § 1003.102, defining the term ''knowingly,'' to clarify congressional intent to apply the FCA standard of knowledge to the presentment of a claim under the CMP law.

D. New Civil Money Penalty for Excluded Individuals Retaining Ownership or Control Interest in a Participating Entity

Prior to HIPAA, if an individual retained a direct or indirect ownership or control interest in, or had a management role with, a health care entity that participates in Medicare or any State health care program after the individual had been excluded, the entity itself was at risk of exclusion under section 1128(b)(8) of the Act for as long as the individual maintained his or her relationship with that entity. However, the individual faced no additional liability unless he or she filed, or caused to be filed, a claim for reimbursement. This created a major loophole through which excluded individuals were often able, without penalty, to continue to reap the benefit of participation in Medicare and the State health care programs while excluded.

Section 231(b) of HIPAA specifically set forth new CMP authority designed to deter such affiliations by subjecting the excluded individual to a CMP of up to $10,000 for each day an excluded individual retained a prohibited relationship with a participating entity. This new CMP provision is to apply only to those with an ownership or control interest in a participating entity who know, or should know, of the action constituting the basis for the exclusion, or any excluded persons who retain positions as officers or managing employees of a participating entity. The imposition of the new CMP authority against an excluded individual will prevent excluded parties from continuing to benefit from government health care financing programs through indirect participation.

Under § 1003.102, Basis for civil money penalties and assessments, we propose to add a new paragraph (b)(11) to codify this new authority. Conforming revisions are also being proposed to § 1003.100, Basis and purpose, through the addition of a new paragraph (b)(1)(xi), and to § 1003.103, Amount of penalty, through the addition of a new paragraph (h). In addition, technical changes are being proposed to §§ 1003.105 and 1003.106.

E. New Civil Money Penalties for the Submission of Claims for Upcoding and for Medically Unnecessary Services

The OIG has historically viewed as unlawful under the statute (1) the claiming of an inappropriately elevated medical procedure code in order to obtain program reimbursement exceeding the amount allowed for the item or service rendered (upcoding); (2) a pattern of claiming reimbursement for services that an individual or entity knows, or should know, are not medically necessary; and (3) the routine waiver of Medicare part B copayments and deductibles. To clarify that these actions are unlawful practices, section 231(e) of HIPAA expressly rendered upcoding and the claiming of medically unnecessary services as violations of the CMP statute. (Section 231(h) of HIPAA further addressed the practice of routinely waiving deductible and coinsurance amounts, and is discussed below in section F.)

Section 231(e) of HIPAA establishes specific CMP authority for a pattern or practice of submitting claims, or causing claims to be submitted, based on a code that the person ''knows or should

know'' will result in greater payment than the code that should have been claimed.

To codify the upcoding prohibition, we would clarify § 1003.102(a)(1) of the regulations to indicate that the OIG may impose a penalty and assessment against any person it determines has presented or caused to be presented a claim for any item or service that the person knows, or should have known, was not provided as claimed, including any claim that is part of a pattern or practice of claims based on upcoding. A new § 1003.102(a)(6) would also be added to implement the OIG's authority to impose a CMP and assessment for any claim for an item or service that was medically unnecessary and part of a pattern or practice of such claims.

F. New Civil Money Penalty for the Offering of Inducements to Beneficiaries

Section 231(h) of HIPAA establishes a new CMP against individuals or entities that know, or should know, that offering remuneration or inducements to a program beneficiary will influence the patient's decision to order or receive any item or service from a particular provider, practitioner or supplier reimbursable under Medicare or the State health care programs. Remuneration includes both the waiver of all or part of the coinsurance and deductible amounts, and ''transfers of items and services for free or for other than fair market value.'' As a result, we are proposing to add a new § 1003.102(b)(12) to codify the new CMP authority for the offering of inducements to beneficiaries, with a conforming change also being made with the addition of a new § 1003.100(b)(1)(xii). In addition, new factors that take into account the degree of culpability and the amount of remuneration offered or transferred with respect to this authority are also being proposed for inclusion in new § 1003.106(a)(1)(i), (a)(1)(vii) and (b)(2)(iv).

This provision is a separate and distinct authority, completely independent of the Medicare and State health care program anti-kickback statute (42 U.S.C. 1320a–7b(b)). Specifically, the anti-kickback statute is an intent-based statute; that is, in order to provide a violation it is necessary to show specific intent to induce referrals or orders for services. Under this new CMP authority, individuals and entities risk imposition of CMPs if they offer remuneration under circumstances where they know or should know that it is likely to influence the selection of the health care provider or service.

For purposes of this provision, we wish to clarify that the offering of remuneration or inducements to program beneficiaries (other than increased coverage, reduced cost-sharing amounts and reduced premium amounts permitted by section 1876 of the Act) to enroll in a Medicare or Medicaid managed health care plan would violate this statutory provision, as such plans restrict beneficiaries to particular providers, practitioners or suppliers.

Statutory exceptions. There are three statutory exceptions to the definition of remuneration in this CMP provision. The first relates to waivers for coinsurance and deductibles that meet certain conditions, the second is for differentials in coinsurance and deductibles as part of a benefits plan design under certain conditions, and the third is for incentives given to individuals to promote the delivery of preventive care as determined by the Secretary. In accordance with section 231(h) of HIPAA, these three exceptions apply only to this CMP provision and have no application to the anti-kickback statute.

The first statutory exception relating to the waiver of coinsurance and deductible amounts exempts from this statutory provision waivers to indigent beneficiaries or after responsible collection efforts have failed.[2] The second exception relating to differentials in coinsurance and deductible amounts as part of a benefits plan design applies where (1) The differentials have been disclosed in writing to all beneficiaries, third-party payors and providers and (2) the differentials meet standards defined by the Secretary. We do not interpret the limited exception for differentials as authorizing any benefit plan design that directly or indirectly attempts to waive a beneficiary's obligation to pay deductible or coinsurance amounts under a Federal health care program. For example, a private insurance company's ''coordination of benefits'' provision does not operate to relieve a provider of its obligation to bill applicable coinsurance amounts to Medicare beneficiaries. Of course, a private insurer or employer may assume responsibility to pay such deductible or coinsurance amounts for its enrollees. At this time, we are choosing not to set forth in regulations a definition of differentials in coinsurance that are part of a plan design. Rather, we are seeking public comments on how best to define these standards in regulations for purposes of this provision.

The third exception from the statutory definition of remuneration under HIPAA protects *incentives* given to individuals to promote the delivery of preventive care. (However, the exception does not include the direct rendering of preventive medical care.) Specifically, the exception includes the provision of incentives to individuals who are eligible for benefits under a Federal health care program (as defined by section 1128B(f) of the Act) where such incentives are provided for the purpose of inducing individuals to obtain preventive care. The HIPAA requires the Secretary to identify what constitutes ''preventive care'' for purposes of this provision. Accordingly, we propose to define preventive care within the definition of remuneration at § 1003.101 to mean annual physicals and care associated with, and integral to, preventing the need for treatment or diagnosis of a specific illness, symptom, complaint or injury (including, but not limited to, prenatal and postnatal care, flu shots and immunizations for childhood diseases, AIDS and HIV testing, mammograms, pap smears and prostate cancer screenings, eye examinations, treatment for alcohol and drug addiction, and treatment designed to prevent domestic violence) where such care is provided or directly supervised by the medical provider that has provided the incentive.

Examples of incentives permitted under this provision would include, but would not be limited to, (1) Transportation to and from preventive care services; (2) car seats, baby formula and child safety devices provided for participating in prenatal or parenting classes; and (3) tee shirts, exercise videos and water bottles provided for participating in a post-cardiac care fitness program. Examples of impermissible incentives would include, but would not be limited to, items or services related to the promotion of general health and fitness (excluding an annual physical), such as health club memberships, nonprescription vitamins, nutritional supplements and beauty aids. Also, we believe incentives permitted under section 231(h) of HIPAA and these regulations would not include cash (or cash equivalents).

The conference report accompanying this new CMP made it clear that ''this provision (does) not preclude the provision of items and services of nominal value, including, for example,

[2] In the Balanced Budget Act of 1997, Pub. L. 105–33, a technical correction was made in section 4331(e)(1) to indicate that remuneration does not include a waiver of coinsurance and deductible amounts that are permissible under section 1128B(b)(3) of the Act or in regulations developed by the Secretary.

refreshments, medical literature, complimentary local transportation services, or participation in free health fairs.'' We are interpreting this statement to mean that the aggregate value of such services provided to any individual must be nominal. Hence, the frequent rendering of items and services to any individual may preclude such items and services as being classified as nominal in value.

G. New Civil Money Penalty for the False Certification of Eligibility for Home Health Services

Section 232 of HIPAA established a new CMP for false certification of eligibility to receive home health care. Specifically, under this provision if a physician falsely certifies the medical necessity for Medicare-covered home health services, *Knowing* that the care is not necessary, he or she may be subject to a CMP of the greater of $5,000 or 3 times the amount of the Medicare payments made for the home health care services. This provision applies to false certifications made on or after August 21, 1996. The new authority would be codified in proposed §§ 1003.100(b)(1)(xiii), 1003.102(b)(13) and 1003.103(g) of the regulations.

H. Other Conforming and Technical Regulatory Revisions

In addition to the changes to the OIG regulations at 42 CFR part 1003 designed to comply with the revised CMP sanction provisions required by HIPAA, we are proposing a number of technical changes in part 1003 to clarify and expand the applicability of existing regulations and procedures. In addition, with regard to the applicability of the appeals of exclusions, CMPs and assessments, limited changes are also being proposed in 42 CFR part 1005 with regard to motions to compel discovery and interlocutory appeals to the Departmental Appeals Board (DAB), and the scope of an administrative law judge's (ALJ) authority to issue subpoenas *duces tecum* is being clarified to include the authority to subpoena documents at or prior to the administrative hearing.

Section 1003.100, Basis and purpose—The current language in § 1003.100(b)(1)(viii) provides for the imposition of CMPs and, as applicable, assessments against persons who have ''submitted certain prohibited claims against the Medicare program.'' As a technical change, we propose to delete this language and redesignate the existing paragraphs accordingly, since many CMPs (including several new CMP authorities in HIPAA) do not involve the submission of claims as the prohibited conduct.

Section 1003.102, Basis for civil money penalties and assessments—We are proposing to delete the current regulatory language currently set forth in paragraphs (b)(2) and (b)(3) of this section, and reserve these paragraphs. The authority contained in § 1003.102(b)(2) addresses CMPs for non-participating physicians billing for actual charges in excess of the maximum allowable actual charge. The statutory freeze for actual charges exceeding the maximum allowed has expired, making this authority no longer valid. Section 1003.102(b)(3) addresses CMPs for billing for the services of an assistant at routine cataract surgery. As this authority has now been delegated to the Health Care Financing Administration, we are proposing to delete it from the OIG regulations. Conforming changes would also be made through the deletion of paragraphs (c) and (e) in § 1003.107.

Section 1003.103, Amount of penalty; and section 1003.105, Exclusion from participation in Medicare and State Health care programs—We are proposing to update the regulatory language currently set forth in §§ 1003.103(e) and 1003.105(a)(1), relating to patient anti-dumping provisions, consistent with the statutory amendments to the knowledge standard and penalty amounts.

Section 1003.106, Determinations regarding the amount of the penalty and assessment—We are proposing to broaden the language in paragraph (a)(1) of this section to include all existing and new CMP authorities. In addition, we would amend § 1003.106(b)(5), the factor addressing financial condition, by deleting the first sentence in this paragraph. The current language indicates that it should be considered a mitigating circumstance ''if the imposition of the penalty or assessment without reduction will jeopardize the ability of the respondent to continue as a *health care provider*;; (underling added). Since this penalty authority is intended to apply not only to direct providers of health care, but also to those involved in other related activities and positions (such as a transporter of patients or a CEO of a drug company), we believe this factor does not represent a generally applicable standards, and therefore propose deleting this factor.

Section 1003.107, Determinations regarding exclusions—We would amend paragraph (b) of this section to incorporate reference to the new CMP authorities being set forth in § 1003.102(b) (11) and (12) referenced above.

Section 1005.1. Definitions—While the terms ''OIG'' and ''Inspector General'' are defined, respectively, at the beginning of parts 1001 and 1003, part 1005 does not currently set forth such a definition. We would revise the definitions section of part 1005 to include a definition for the term ''Inspector General.''

Section 1005.7. Discovery—We are proposing a revision to § 1005.7(e) to provide for motions to compel discovery once a request for production of documents has been received. Presently, the language in paragraph (e) states that ''[A]fter a party has been served with a request for production of documents, that party may file for a protective order.'' However, there is no provision currently authorizing a motion to compel requested discovery. Thus, the burden is now on the person who wishes to withhold requested documents to file a motion, instead of upon the party who has requested the documents, and who can best explain their relevance. As in the Federal Rules of Civil Procedure, we believe that motions to compel discovery should be authorized by these administrative hearing regulations, so that the party requesting discovery will be responsible for invoking a judicial determination of a discovery dispute. The revision we propose would allow either party to object to discovery requests, and if a motion to compel is filed, a request for a protective order may be requested in response.

Specifically, we would revise § 1005.7(e) to make clear that a party has a right to object to discovery requests without requiring that party to file for a protective order, leaving it to the party seeking the documents to justify why access is appropriate in a motion to compel discovery. Any objections to production of documents would have to be filed with the opposing party within 15 days of receiving the discovery request. The party seeking the production of documents may then file a motion to compel discovery within the next 15 days or any other time frame set by the ALJ. We welcome comments on this clarifying change.

Section 1005.9. Subpoenas for attendance at hearing—We would revise paragraph (b) of § 1005.9 to clarify that this provision is intended to authorize an administrative law judge to issue a subpoena to any individual to attend the hearing and to provide documentary evidence at or prior to the hearing. The existing language in this section has been misconstrued in some instances as only authorizing the production of documents at the hearing. We are clarifying this language to

indicate that an ALJ may issue a subpoena *duces tecum* requiring documents to be produced before the hearing. We believe the proposed language should fully clarify the intent of this provisions.

Section 1005.15, The hearing and burden of proof—Section 1005.2(b) of the regulations defines a ''respondent'' as the party appealing a CMP, and a ''petitioner'' as the party appealing an exclusion. The existing language in paragraph (b) of § 1005.15, however, currently incorrectly uses the term ''respondent'' to refer to several exclusion authorities. We propose revising § 1005.15(b) to make the language in this paragraph consistent with the way parties are currently defined in § 1005.2(b).

Section 1005.21, Appeal to DAB—We would revise the current language in paragraph (d) of this section to allow for interlocutory appeals to the DAB in one limited situation; that is, on the timeliness of filing of the hearing request. Otherwise, in many cases a final ruling on the timeliness of a hearing request will be rendered meaningless because the hearing will take place before an appeal of an appeal of an ALJ's ruling on timeliness can occur.

Deletion of reference to the Office of the General Counsel in §§ 1003.126, 1003.128 and 1006.4—We would make a technical revision in §§ 1003.126, 1003.128(b) and 1006.4(b)(2) by deleting the current reference to ''the Office of the General Counsel.'' Section 1003.126 gives the Office of the General Counsel (OGC) the exclusive authority to settle a case prior to a final decision of the Secretary. Paragraph (b) of § 1003.128 authorizes the OGC ''after consultation with the IG'' to compromise any penalty and assessment imposed by the Secretary. Section 1006.4(b) addresses attendance at investigational inquiries. The current language indicates that both representatives of the OIG and the OGC may attend and ask questions. With the consolidation of the IG Division of Office of the General Counsel into the OIG, these references to the OGC are no longer appropriate, and the regulatory language should be revised to give the OIG exclusive authority to settle or compromise cases, and to attend investigational inquiries.

III. Regulatory Impact Statement

Executive Order 12866 and Regulatory Flexibility Act

The Office of Management and Budget (OMB) has reviewed this proposed rule in accordance with the provisions of Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and has determined that it does not meet the criteria for a significant regulatory action. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety distributive and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a number of businesses the Secretary must specifically consider the economic effect of a rule on small business entities and analyze regulatory options that could lessen the impact of the rule.

As indicated above, the provisions contained in this proposed rulemaking are primarily intended to comply with amended statutory authority by (1) expanding the protection of certain basic fraud authorities beyond the Department to include other Federal health care programs, (2) strengthening current legal authorities pertaining to our imposition of CMPs against individuals and entities engaged in prohibited actions and activities, and (3) codifying other new and revised OIG sanction authorities set forth in Public Law 104–191.

We believe that these regulations will not have a significant ecomonic effect on Federal, State or local economies, nor will they have a significant economic effect on a substantial number of small entities. The CMP statute, as enacted by Congress in 1981, was an administrative remedy to combat increases in health care fraud. The CMP provisions have been expanded upon since their original enactment to counteract evolving fraudulent and abusive practices. These proposed regulations merely continue the approach of authorizing CMP sanctions against individuals and entities that abuse Federal and State health care programs as emerging fraudulent practices are identified. These remedial sanctions are addressed to a limited group of individuals and entities; that is, providers who abuse the Federal health care programs to the detriment of the beneficiaries and the public fisc.

The revised CMP provisions set forth in this proposed rule that address the upcoding of claims, and claims for medically unnecessary services, are essentially clarifications of existing OIG authorities. In addition, with respect to the new penalty authorities being codified, such as the CMP for excluded individuals retaining ownership or control interest in an entity and the CMP for the false certification of eligibility for home health services, these provisions target egregious conduct that is limited in scope and nature.

The proposed regulations would implement congressional intent in the area of fraud and abuse in health care programs. The regulations target areas of fraud, not industry; the scope of effect is narrow and targeted specifically to those individuals defrauding or abusing the Medicare and State health care programs. There should be no increase in paperwork or reporting burdens in any pre-existing programs as a result of these regulations.

Similarly, while increases in the authorized CMP amounts from $2,000 to $10,000 per false item or service claimed or prohibited practice may increase overall penalty amounts and recoveries, the process for deriving any settlement will remain essentially the same. While the rise in the amount of penalty from $2,000 to $10,000 is an increase, it is only proportionate to the amount of fraud against the public fisc. It also serves as a deterrent to health care fraud, consistent with congressional intent in the enactment of HIPAA. This penalty amount increase should not significantly affect the health case industry; the only effect is remedial against those who perpetrate fraud against the system and thus violate Federal and State law. This increased maximum amount per false claim or prohibited practice may, in certain circumstances, reduce OIG investigative costs since fewer individual false claims will need to be developed and proved in order for the Government to recover appropriate penalties and assessments. In addition, we believe settlements with individuals and entities may become more likely since the OIG's bargaining power is now enhanced in the face of greater potential financial exposure for the individual or entity.

Overall, we believe that any increase in CMP recoveries will not be significant since the vast majority of individuals, organizations and entities addressed by these regulations do not engage in such prohibited activities and practices. As indicated, these proposed regulations are narrow in scope and effect, serve to codify or revise existing OIG sanctions, comport with congressional and statutory intent, and strengthen the Department legal authorities against those who defraud or otherwise act improperly against the Federal and State health care program. Since there is no significant economic effect on the industry as a whole, there is little likelihood of effect on Federal or State expenditures to implement these

regulations. While some sanctions addressed in this rule may have a minor impact on small entities, it is the nature of the violation and not the size of the entity that will result in an action by the OIG. In conclusion, we believe that the aggregate economic impact of these regulations will be minimal, affecting only those limited few who have chosen to engage in prohibited arrangements, schemes and practices in violation of statutory intent. As a result, we have conducted, and the Secretary certifies, that this proposed rule should not have a significant economic impact on a substantial number of small entities that would require a regulatory flexibility analysis.

Paperwork Reduction Act

This proposed rule would impose no new reporting or recordkeeping requirements necessitating clearance by OMB.

List of Subjects

42 CFR Part 1003

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Penalties.

42 CFR Part 1005

Administrative practice and procedure, Fraud, Penalties.

42 CFR Part 1006

Administrative practice and procedure, Fraud, Investigations, Penalties.

Accordingly, 42 CFR Parts 1003, 1005 and 1006 is proposed to be amended as set forth below:

PART 1003—[AMENDED]

A. Part 1003 would be amended as follows:

1. The authority citation for part 1003 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 1320–7, 1320a–7a, 1320b–10, 1395dd(d)(1). 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c) and 11137(b)(2).

2. Section 1003.100 would be revised to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1140, 1876(i)(6), 1877(g), 1882(d) and 1903(m)(5) of the Social Security Act, and sections 421(c) and 427(b)(2) of Pub.L. 99–660 (42 U.S.C. 1320a–7, 1320a–7a,1320a–7(c), 1320b(10), 1395mm, 1395ss(d), 1396b(m), 11131(c) and 11137(b)(2)).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who—

(i) Have knowingly submitted certain prohibited claims under Federal health care programs;

(ii) Seek payment in violation of the terms of an agreement or a limitation on charges or payments under the Medicare program, or a requirement not to charge in excess of the amount permitted under the Medicaid program;

(iii) Give false or misleading information that might affect the decision to discharge a Medicare patient from the hospital;

(iv) Fail to report information concerning medical malpractice payments or who improperly disclose, use or permit access to information reported under part B of title IV of Public Law 99–660, and regulations specified in 45 CFR part 60;

(v) Misuse certain Departmental and Medicare and Medicaid program words, letters symbols or emblems;

(vi) Violate a requirement of section 1867 of the Act § 489.24 of this title;

(vii) Substantially fail to provide an enrollee with required medically necessary items and services, or engage in certain marketing, enrollment, reporting, claims payment, employment or contracting abuses, or that do not meet the requirements for physician incentive plans for Medicare specified in §§ 417.479(d) through (f) of this title;

(viii) Present or cause to be presented a bill or claim for designated health services (as defined in § 411.351 of this title) that they know, or should know, were furnished in accordance with a referral prohibited under § 411.353 of this title;

(ix) Have collected amounts that they know or should know were billed in violation of § 422.353 of this title and have not refunded the amounts collected on a timely basis;

(x) Are physicians or entities that enter into an arrangement or scheme that they know or should know has as a principal purpose the assuring of referrals by the physician to a particular entity which, if made directly, would violate the provisions of § 411.353 of this title;

(xi) Are excluded, and who retain an ownership or control interest of five percent or more in an entity participating in Medicare or a State health care program, or who are officers or managing employees of such an entity (as defined in section 1126(b) of the Act);

(xii) Offer inducements to influence Medicare or State health care program beneficiaries to order or receive particular items or services; or

(xiii) Are physicians who knowingly misrepresent that a Medicare beneficiary requires home health services;

(2) Provides for the exclusion of persons from the Medicare or State health care programs against whom a civil money penalty or assessment has been imposed, and the basis for reinstatement of persons who have been excluded; and

(3) Sets forth the appeal rights of persons subject to a penalty, assessment and exclusion.

3. Section 1003.101 would be amended by republishing the introductory text; by revising the definition for the terms *Claim* and *Exclusion;* by removing the terms *General Counsel* and *Program;* and by adding, in alphabetical order, definitions for the terms *Remuneration* and *Should know,* or *should have known* to read as follows:

§ 1003.101 Definitions.

For purposes of this part:

* * * * *

Claim means an application for payment for an item or service to a Federal health care program (as defined in section 1128B(f) of the Act).

* * * * *

Exclusion means the temporary or permanent barring of a person from participation in a Federal health care program (as defined in section 1128B(f) of the Act).

* * * * *

Remuneration, as set forth in § 1003.102(b)(12), is consistent with the definition contained in section 1128A(i)(6) of the Act. For purposes of this definition of remuneration, preventive care means annual physicals and care associated with, and integral to, preventing the need for treatment or diagnosis of a specific illness, symptom, complaint or injury.

* * * * *

Should know or *should have known* means that a person, with respect to information—

(1) Acts in deliberate ignorance of the truth or falsity of the information; or

(2) Acts in reckless disregard of the truth or falsity of the information.

For purposes of this definition no proof of specific intent to defraud is required.

* * * * *

4. Section 1003.102 would be amended by revising the introductory text of paragraph (a) and paragraphs (a)(1) and (a)(3); republishing the introductory text of paragraph (a)(4) and revising paragraphs (a)(4)(iii) and paragraph (a)(5); adding a new

paragraph (a)(6); republishing the introductory text of paragraph (b) and revising introductory paragraph (b)(1); removing and reserving paragraphs (b)(2) and (b)(3); revising paragraphs (b)(4) and (b)(9); and by adding new paragraphs (b)(11) through (b)(13) and (e) to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has knowingly presented, or caused to be presented, a claim which is for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that is part of a pattern or practice of claims based on codes that the person knows or should know will result in greater payment to the person than the code applicable to the item or service actually provided;

* * * * *

(3) An item or service furnished during a period in which the person was excluded from participation in the Federal health care program to which the claim was made;

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

* * * * *

(iii) Represented to the patient at the time the service was furnished that the physician was certified in a medical specialty board when he or she was not so certified;

(5) A payment that such person knows, or should know, may not be made under § 411.353 of this title; or

(6) An item or service that is medically unnecessary, and which is part of a pattern or practice of such claims.

(b) The OIG may impose a penalty, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

(1) Has knowingly presented or caused to be presented a request for payment in violation of the terms of—

* * * * *

(4) Has knowingly given or caused to be given to any person, in the case of inpatient hospital services subject to the provisions of section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence the decision when to discharge such person or another person from the hospital.

* * * * *

(9) Has not refunded on a timely basis, as defined in § 1003.101, amounts collected as the result of billing an individual, third party payer or other entity for a designated health service that was provided in accordance with a prohibited referral as described in § 411.353 of this title.

* * * * *

(11) Who is not an organization, agency or other entity, and who is excluded from participating in Medicare or a State health care program in accordance with sections 1128 or 1128A of the Act, and who—

(i) Knows or should know of the action constituting the basis for the exclusion, and retains a direct or indirect ownership or control interest of five percent or more in an entity that participates in Medicare or a State health care program; or

(ii) Is an officer or managing employee (as defined in section 1126(b) of the Act) of such entity.

(12) Offers or transfers remuneration (as defined in section 1128(i)(6) of the Act) to any individual eligible for benefits under Medicare or a State health care program, that such person knows or should know is likely to influence such individual to order or to receive from a particular provider, practitioner or supplier any item or service for which payment may be made, in whole or in part, under Medicare or a State health care program.

(13) Is a physician and who executes a document falsely by certifying that a Medicare beneficiary requires home health services when the physician knows that the beneficiary does not meet the eligibility requirements set forth in sections 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

* * * * *

(e) For purposes of this section, the term ''knowingly'' is defined consistent with the definition set forth in the Civil False Claims Act (31 U.S.C. 3729(b)).

5. Section 1003.103 would be amended by revising paragraphs (a) and (e); and by adding new paragraphs (g) and (h) to read as follows:

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b) through (h) of this section, the OIG may impose a penalty of not more than—

(1) $2,000 for each wrongful act occurring before January 1, 1997 that is subject to a determination under § 1003.102; and

(2) $10,000 for each wrongful act occurring on or after January 1, 1997 that is subject to a determination under § 1003.102.

* * * * *

(e) For violations of section 1867 of the Act or § 489.24 of this title, the OIG may impose—

(1) Against each participating hospital with an emergency department, a penalty of not more than $50,000 for each negligent violation occurring on or after May 1, 1991, except that it the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed $25,000; and

(2) Against each responsible physician, a penalty of not more than $50,000 for each negligent violation occurring on or after May 1, 1991.

* * * * *

(g) For violations of § 1003.102(b)(3) the OIG may impose a penalty of not more than the greater of—

(1) $5,000; or

(2) Three times the amount of Medicare payments for home health services that are made with regard to the false certification of eligibility by a physician in accordance with sections 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(h) The OIG may impose a penalty of not more than $10,000 per day for each day that the prohibited relationship described in § 1003.102(b)(11) occurs. 6.

6. Section 1003.104 would be revised to read as follows:

§ 1003.104 Amount of assessment.

(a) The OIG may impose an assessment, where authorized, in accordance with § 1003.102, of not more than—

(1) Two times the amount for each item or service wrongfully claimed prior to January 1, 1997; and

(2) Three times the amount for each item or service wrongfully claimed on or after January 1, 1997.

(b) The assessment is in lieu of damages sustained by the Department or a State agency because of that claim.

7. Section 1003.105 would be amended by revising paragraph (a)(1); removing existing paragraph (b)(1); and by redesignating existing paragraphs (b)(2) and (b)(3) respectively as new paragraphs (b)(1) and (b)(2) to read as follows:

§ 1003.105 Exclusion from participation in Medicare and State health care programs.

(a)(1) Except as set forth in paragraph (b) of this section, the following persons may be subject, in lieu of or in addition to any penalty or assessment, to an exclusion from participation in Medicare for a period of time determined under § 1003.107. There will be exclusions from State health care

programs for the same period as the Medicare exclusion for any person who—

(i) Is subject to a penalty or assessment under § 1003.102(a), (b)(1), (b)(4), (b)(11) or (b)(12); or

(ii) Commits a gross and flagrant, or repeated, violation of section 1867 of the Act or § 489.24 of this title on or after May 1, 1991. For purposes of this section, a gross and flagrant violation is one that presents an imminent danger to the health, safety or well-being of the individual who seeks emergency examination and treatment or places that individual unnecessarily in a high-risk situation.

* * * * *

8. Section 1003.106 would be amended by revising paragraph (a)(1); republishing the introductory text of paragraph (b) and revising paragraphs (b)(2) and (b)(5); revising the introductory text of paragraph (c) and paragraph (c)(3); redesignating existing paragraphs (d) and (e) as new paragraphs (e) and (f); revising the introductory text of new redesignated paragraph (e); and by adding a new paragraph (d) to read as follows:

§ 1003.106 Determinaitons regarding the amount of the penalty and assessment.

(a) *Amount of penalty.* (1) In determining the amount of any penalty or assessment in accordance with § 1003.102(a), (b)(1), (b)(4) and (b)(9) through (b)(13), the Department will take into account—

(i) The nature of the claim, referral arrangement or other wrongdoing;

(ii) The degree of culpability of the person against whom a civil money penalty is proposed;

(iii) The history of prior offenses of the person against whom a civil money penalty is proposed;

(iv) The financial condition of the person against whom a civil money penalty is proposed;

(v) The completeness and timeliness of the refund with respect to § 1003.102(b)(9);

(vi) The amount of financial interest involved with respect to § 1003.102(b)(11);

(vii) The amount of remuneration offered or transferred with respect to § 1003.102(b)(12); and

(viii) Such other matters as justice may require.

* * * * *

(b) *Determining the amount of the penalty or assessment.* As guidelines for taking into account the factors listed in paragraph (a)(1) of this section, the following circumstances are to be considered—

* * * * *

(2) *Degree of culpability.* It should be considered a mitigating circumstance if the claim or request for payment for the item or service was the result of an unintentional and unrecognized error in the process the respondent followed in presenting claims or requesting payment, and corrective steps were taken promptly after the error was discovered. It should be considered an aggravating circumstance if—

(i) The respondent knew the item or service was not provided as claimed or if the respondent knew that the claim was false or fraudulent;

(ii) The respondent knew that the items or services were furnished during a period that he or she had been excluded from participation and that no payment could be made as specified in §§ 1003.102(a)(3) and 1003.102(b)(11), or because payment would violate the terms of an assignment or an agreement with a State agency or other agreement or limitation on payment under 1003.102(b);

(iii) The respondent knew that the information could reasonably be expected to influence the decision of when to discharge a patient from a hospital; or

(iv) The respondent knew that the offer or transfer or remuneration described in 1003.102(b)(12) would influence a beneficiary to order or receive particular items or services under Medicare or a State health care program.

* * * * *

(5) *Final condition.* In all cases, the resources available to the respondent will be considered when determining the amount of the penalty and assessment.

* * * * *

(c) In determining the amount of the penalty and assessment to be imposed for every item or service or incident subject to a determination under §§ 1003.102 (a), (b)(1) and (b)(4)—

* * * * *

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should never be less than double the approximate amount of damages and costs (as defined in paragraph (f) of this section) sustained by the United States, or any State, as a result of claims or incidents subject to a determination under §§ 1003.102 (a), (b)(1) and (b)(4).

(d) In considering the factors listed in paragraph (a)(4) of this section for violations subject to a determination under § 1003.103(e), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

(1) *Degree of culpability.* It would be a mitigating circumstance if the respondent hospital had appropriate policies and procedures in place, and had effectively trained all of its personnel in the requirements of section 1867 of the Act and § 489.24 of this title, but an employee or responsible physician acted contrary to the respondent hospital's policies and procedures.

(2) *Seriousness of individual's condition.* It would be an aggravating circumstance if the respondent's violation(s) occurred with regard to an individual who presented to the hospital a request for treatment of a medical condition that was clearly an emergency, as defined by § 489.24(b) of this title.

(3) *Prior offenses.* It would be an aggravating circumstance if there is evidence that at any time prior to the current violation(s) the respondent was found to have violated any provision of section 1867 of the Act or § 489.24 of this title.

(4) *Financial condition.* In all cases, the resources available to the respondent would be considered when determining the amount of the penalty. A respondent's audited financial statements, tax returns or financial disclosure statements, as appropriate, will be reviewed by OIG auditors to make a determination with respect to the respondent's financial condition.

(5) *Nature and circumstances of the incident.* It would be considered a mitigating circumstance if an individual presented a request for treatment, but subsequently exhibited conduct that demonstrated a clear intent to leave the respondent hospital voluntarily. In reviewing such circumstances, the OIG would evaluate the respondent's efforts to—

(i) Provide the services required by section 1867 of the Act and § 489.24 of this title, despite the individual's withdrawal of the request for examination or treatment; and

(ii) Document any attempts to inform the individual (or his or her representative) of the risks of leaving the respondent hospital without receiving an appropriate medical screening examination or treatment, and obtain informed consent from the individual (or his or her representative) prior to the individual's departure from the respondent hospital.

(6) *Other matters as justice may require.* (i) It would be considered a mitigating circumstance if the respondent hospital—

(A) Developed and implemented a corrective action plan;

(B) Took immediate appropriate action against any hospital personnel or responsible physician who violated section 1867 of the Act or § 489.24 of this title prior to any investigation of the respondent hospital by HCFA; or

(C) Is a rural or county-owned facility that is faced with severe physician staffing and financial deficiencies.

(ii) It would be considered an aggravating circumstance if an individual was severely harmed or died as a result of the respondent's violation of section 1867 of the Act or § 489.24 of this title.

(iii) Other circumstances of an aggravating or mitigating nature will be taken into account if, in the interests of justice, they require either a reduction of the penalty or an increase in order to assure the achievement of the purposes of this part.

(e) In considering the factors listed in paragraph (a)(5) of this section for violations subject to a determination under § 1003.103(f), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

* * * * *

9. Section 1003.107 would be amended by revising paragraph (b); removing existing paragraph (c) and (e); redesignating paragraph (d) as new paragraph (c) and revising it to read as follows:

§ 1003.107 Determinations regarding exclusion.

* * * * *

(b) With respect to determinations to exclude a person under §§ 1003.102(a), (b)(1), (b)(4), (b)(11), or (b)(12), the Department considers those circumstances described in § 1003.106(b). Where there are aggravating circumstances with respect to such determinations, the person should be excluded.

(c) The guidelines set forth in this section are not binding. Nothing in this section limits the authority of the Department to settle any issue or case as provided by § 1003.126.

10. Section 1003.109 would be amended by revising the introductory text of paragraph (a) to read as follows:

§ 1003.109 Notice of proposed determination.

(a) If the Inspector General proposes a penalty and, when applicable, assessment, or proposes to exclude a respondent from participation in a Federal health care program, as applicable, in accordance with this part, he or she must deliver or send by certified mail, return receipt requested, to the respondent written notice of his or her intent to impose a penalty, assessment and exclusion, as applicable. The notice includes—

* * * * *

11. Section 1003.126 would be revised to read as follows:

§ 1003.216 Settlement.

The Inspector General has exclusive authority to settle any issues or case, without consent of the ALJ.

12. Section 1003.128 would be amended by revising paragraph (b) to read as follows:

§ 1003.128 Collection of penalty and assessment.

* * * * *

(b) A penalty or assessment imposed under this part may be compromised by the Inspector General, and may be recovered in a civil action brought in the United States district court for the district where the claim was presented, or where the respondent resides.

* * * * *

PART 1005—[AMENDED]

B. Part 1005 would be amended as follows:

1. The authority citation for part 1005 would continue to read as follows:

Authority: 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a and 1320c–5.

2. Section 1005.1 would be amended by adding, in alphabetical order; a definition for the term *Inspector General* to read as follows:

§ 1005.1 Definitions.

* * * * *

Inspector General (IG) means the Inspector General of the Department of Health and Human Services or his or her designees.

3. Section 1005.7 would be amended by revising paragraphs (e)(1) (e)(2) to read as follows:

§ 1005.7 Discovery.

* * * * *

(e)(1) When a request for production of documents has been received, within 15 days the party receiving that request will either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part will be specified. Upon receiving any objections, the party seeking production may then, within 15 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. (The party receiving a request for production may also file a motion for protective order any time prior to the date the production is due.)

(2) The ALJ may grant a motion for protective order or deny a motion for an order compelling discovery if the ALJ finds that the discovery sought—

(i) Is irrelevant;

(ii) Is unduly costly or burdensome;

(iii) Will unduly delay the proceeding; or

(iv) Seeks privileged information

* * * * *

4. Section 1005.9 would be amended by revising paragraph (b) to read as follows:

§ 1005.9 Subpoenas for attendance at hearing.

* * * * *

(b) A subpoena requiring the attendance of an individual in accordance with paragraph (a) of this section may also require the individual (whether or not the individual is a party) to produce evidence authorized under § 1005.7 at or prior to the hearing.

* * * * *

5. Section 1005.15 would be amended by revising the introductory text of paragraph (b) and paragraph (b)(1) to read as follows:

§ 1005.15 The hearing and burden of proof.

* * * * *

(b) With regard to the burden of proof in civil money penalty cases under part 1003 of this chapter, in Peer Review Organization exclusion cases under part 1004 of this chapter, and in exclusion cases under §§ 1001.701, 1001.901 and 1001.951 of this chapter—

(1) The respondent or petitioner, as applicable, bears the burden of going forward and the burden of persuasion with respect to affirmative defenses and any mitigating circumstances; and

* * * * *

6. Section 1005.21 would be amended by revising paragraph (d) to read as follows:

§ 1005.21 Appeal to DAB.

* * * * *

(d) There is no right to appear personally before the DAB or to appeal to the DAB any interlocutory ruling by the ALJ, except on the timeliness of a filing of the hearing request.

* * * * *

PART 1006—[AMENDED]

C. Part 1006 would be amended as follows:

1. The authority citation for part 1006 would continue to read as follows:

Authority: 42 U.S.C. 405(d), 405(e), 1302 and 1320a–7a.

2. Section 1006.4 would be amended by republishing the introductory text of

paragraph (b) and by revising paragraph (b)(2) to read as follows:

§ 1006.4 Procedures for investigational inquiries.

* * * * *

(b) Investigational inquiries are non-public investigatory proceedings. Attendance of non-witnesses is within the discretion of the OIG, except that—

* * * * *

(2) Representatives of the OIG are entitled to attend and ask questions.

* * * * *

Dated: August 21, 1997.

June Gibbs Brown,

Inspector General.

Approved: December 4, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 98–7506 Filed 3–24–98; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Parts 302, 304 and 307

RIN 0970–AB70

Computerized Support Enforcement Systems

AGENCY: Office of Child Support Enforcement (OCSE), ACF, HHS.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: These proposed regulations would implement provisions of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), related to child support enforcement program automation. Under PRWORA, States must have in effect a statewide automated data processing and information retrieval system which by October 1, 1997, meets all the requirements of title IV–D of the Social Security Act enacted on or before the date of enactment of the Family Support Act of 1988, and by October 1, 2000, meets all the title IV–D requirements enacted under PRWORA. The law further provides that the October 1, 2000, deadline for systems enhancements will be delayed if HHS does not issue final regulations by August 22, 1998.

DATES: Consideration will be given to written comments received by May 11, 1998. We have reduced the standard 60-day comment period specified in E.O. 12866 to 45 days in recognition of the statutory deadline of August 22, 1998 for issuing final rules and the necessity of providing States with the required guidance as soon as practicable to facilitate their development or enhancement of systems.

ADDRESSES: Address comments to: Administration for Children and Families, Department of Health and Human Services, 370 L'Enfant Promenade, S.W., Washington D.C. 20447. Attention: Norman L. Thompson, Associate Deputy Director for Automation and Special Projects, Office of Child Support Enforcement.

Comments will be available for public inspection Monday through Friday, 8 a.m. to 4:30 p.m. on the fourth floor of the Department's offices at the address mentioned above.

FOR FURTHER INFORMATION CONTACT: Betsy Matheson at (202) 401–7386.

SUPPLEMENTARY INFORMATION:

Statutory Authority

These proposed regulations are published under the authority of several provisions of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. Sections 454(16), 454(24), 454A and 455(a)(3)(A) of the Act (42 U.S.C. 654(16), (24), 654A, and 655(a)(3)(A)), contain new requirements for automated data processing and information retrieval systems to carry out the State's IV–D State plan. Other sections, such as section 453 of the Act (42 U.S.C. 653) specify data that the system must furnish or impose safeguarding and disclosure requirements that the system must meet.

These proposed regulations are also published under the general authority of section 1102 (42 U.S.C. 1302) of the Act which requires the Secretary to publish regulations that may be necessary for the efficient administration of the provisions for which she is responsible under the Act.

Background

Full and complete automation is pivotal to improving the performance of the nation's child support program. With a current national caseload of 20 million, caseworkers are dependent on enhanced technology and increased automation to keep up with the massive volume of information and transactions critical to future success in providing support to children.

While most States have sought some level of child support program automation since the inception of the program, it wasn't until enactment of the Family Support Act of 1988 (Pub. L. 100–485), that program automation became a title IV–D State plan requirement. The Family Support Act required that States have in operation by October 1, 1995, a certified statewide system. (This date was subsequently extended to October 1, 1997, under Pub. L. 104–35).

These systems are to be statewide, operational, comprehensive, integrated, efficient, and effective. They are required to provide for case initiation; interface with other systems to obtain information to locate parents; aid in paternity establishment efforts by tracking, monitoring, and reporting on State efforts; monitor compliance with support orders and initiate enforcement action; update and maintain case records; process payments and distribute support; meet reporting requirements and address security and privacy issues.

Under PRWORA, States must build on this comprehensive automated foundation to implement the programmatic enhancements the law included for strengthening child support enforcement, including new enforcement tools and a shift in child support distribution requirements to a family-first policy. By October 1, 2000, States must have in place an automated statewide system that meets all the requirements and performs all the functions specified in PRWORA. This requirement recognizes that case processing changes and Federal and State legislative enhancements to State IV–D programs have little impact without proper automated support. The October 1, 2000 date is a completion date for the entire system, however certain requirements and functions must be met prior to that date. We have included those statutory effective dates in the regulations.

Accordingly, this rule proposes to set forth in regulations the framework for automation that State systems must have in place by the October 1, 2000, deadline. Our approach in developing these proposed rules was to adhere as closely as possible to the statute. We believe this approach is essential to ensuring that the proposed rules are well received, allowing the final regulation to be issued by the statutory deadline of August 22, 1998. The State deadline for completing these systems enhancements is delayed by one day for each day, if any, that we miss the statutory deadline for regulating. We believe this would be an unconscionable position—PRWORA compliant systems are intended to have a substantial impact on States' ability to protect the support rights of children, and it is essential that these changes are made without delay.

In addition, we believe the statute provides a proper and straight-forward