VI. Do Executive Orders 12875 and 13084 Require EPA to Consult With States and Indian Tribal Governments Prior to Taking the Action in this Notice?

A. Executive Order 12875

Under Executive Order 12875, entitled ''Enhancing Intergovernmental Partnerships'' (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. As explained in more detail in Unit IV. of this document, the statutory waivers provided for States and local governments are being extended to Indian Tribes. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

B. Executive Order 13084

Under Executive Order 13084, entitled ''Consultation and Coordination with Indian Tribal Governments'' (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. As explained in more detail in Unit IV. of this document, the statutory waivers provided for States and local governments are being extended to Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VII. How Do Other Regulatory Assessment Requirements Apply to this Action?

The applicability of various regulatory assessment provisions to this action are discussed in the preamble to the corresponding final rule published elsewhere in the Rules section of this issue of the **Federal Register**, and summarized below.

Under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), it has been determined that this rule is not ''significant'' and is not subject to OMB review. This rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et. seq.*, or impose any enforceable duties on State and local governments or impose private sector exependitures of $100 million or more annually so as to trigger applicablity of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). In addition, this action does not involve any standards that would require Agency consideration pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (Pub. L. 104–113).

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. This certification is based on an analysis that the Agency prepared for this action, which indicates that the rule should not place undue burden on small business. Information relating to this determination will be provided to the Chief Counsel for Advocacy of the Small Business Administration upon request. This information is also included in the public record for this action as a part of the economic analysis.

List of Subjects in 40 CFR Part 745

Environmental Protection, Fees, Hazardous Substances, Lead poisoning, Reporting and recordkeeping requirements.

Dated: August 25, 1998.

Carol M. Browner,

Administrator.

[FR Doc. 98–23454 Filed 8–31–98; 11:24 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001, 1002, and 1003

RIN 0991–AA95

Health Care Programs: Fraud and Abuse; Revised OIG Sanction Authorities Resulting From Public Law 105–33

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

ACTION: Notice of proposed rulemaking.

SUMMARY: This rulemaking proposes revisions to the OIG's exclusion and civil money penalty authorities set forth in 42 CFR parts 1001, 1002 and 1003, resulting from the Balanced Budget Act of 1997, Public Law 105–33. These proposed revisions are intended to protect and strengthen Medicare and State health care programs by increasing the OIG's anti-fraud and abuse authority through new or revised exclusion and civil money penalty provisions.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on November 2, 1998.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–30–P, Room 5246, 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–30–P.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. The Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104–191, was enacted on August 21, 1996 and set forth a number of significant amendments to the OIG's exclusion and civil money penalty (CMP) authorities. Among the various provisions related to program exclusion authority, HIPAA: (1) expanded the OIG's minimum 5-year mandatory exclusion authority to cover any felony conviction under Federal, State or local law relating to health care fraud, even if governmental programs were not involved; (2) established minimum periods of exclusion from 1 to 3 years for certain permissive exclusions from Medicare and the State health care programs; and (3) established a new permissive exclusion authority applicable to individuals who have a majority ownership in, or have significant control over the operations of, an entity that has been convicted of a program-related offense. Proposed regulations addressing these revised or expanded OIG exclusion authorities were published in the **Federal Register** on September 8, 1997 (62 FR 47182).

In addition, HIPAA revised and strengthened the OIG's existing CMP authorities, and extended the application of the CMP provisions beyond those programs funded by the Department to include all Federal health care programs. The revised or expanded CMP provisions resulting from HIPAA are being addressed in a separate OIG proposed rulemaking.

B. The Balanced Budget Act of 1997

In conjunction with many of the HIPAA fraud and abuse authorities, the Balanced Budget Act (BBA) of 1997, enacted on August 5, 1997, contained a number of provisions designed to further preserve and protect the integrity of Medicare, Medicaid and all other Federal health care programs for current and future beneficiaries, and combat fraudulent and abusive program activities. Specifically, the fraud and abuse provisions of BBA serve to strengthen the OIG's exclusion and CMP authorities with respect to Federal health care programs.

The new exclusion and CMP authorities under BBA are effective for violations occurring on or after August 5, 1997. As the new statutory provisions allow the Department some policy discretion in their implementation, we are developing this proposed rulemaking and soliciting public comments. The proposed regulation text changes reflected in this rule are designed to address statutory revisions resulting from BBA. As indicated above, revisions to 42 CFR chapter V resulting from the HIPAA fraud and abuse provisions are being published and addressed through separate proposed rulemakings. All final regulation text changes resulting from the HIPAA and BBA fraud and abuse proposed rules will be coordinated and collectively addressed in a final rulemaking document that will amend OIG's exclusion and CMP authorities.

II. Provisions of the Proposed Rule

A. Revised Exclusion Authorities Resulting from BBA

1. OIG Authority to Direct Exclusions From State Health Care Programs, and to Extend the Application of OIG Exclusions to all Federal Health Care Programs

Prior to the enactment of BBA, a program exclusion imposed by the OIG was applicable to Medicare and State health care programs, as defined in section 1128(h) of the Social Security Act (the Act). As part of the fraud and abuse provisions set forth in HIPAA, section 231 of Public Law 104–191 amended the criminal and CMP provisions in sections 1128A and 1128B of the Act to encompass acts occurring with respect to a ''Federal health care program,'' as defined in section 1128B(f) of the Act.[1] With the enactment of HIPAA, however, this extension of coverage was not replicated with respect to the Secretary's program exclusion authority as set forth in section 1128 of the Act. In addition, prior to BBA, the OIG was authorized to impose exclusions from participation in Medicare, but only to direct State health care programs to impose parallel exclusions from State health care programs such as Medicaid. The practical result of this bifurcated exclusion implementation process was that States frequently failed to implement exclusions in a timely or otherwise appropriate manner.

To ensure that the OIG's program exclusion authority is consistent with other sanction authorities set forth in sections 1128A and 1128B, section 4331(c) of BBA specifically amended sections 1128(a) and (b) of the Act to provide that the scope of an OIG exclusion extends beyond Medicare and the State health care programs to all Federal health care programs, as defined in section 1128B(f) of the Act, and to enable the OIG to impose exclusions from all Federal health care programs directly. As a result, we propose to add a definition for the term ''Federal health care program'' in § 1001.2, and make conforming revisions in §§ 1001.1(a), 1001.1901, 1001.3003, 1001.3005 and 1002.2(a).

Section 1001.1901, Scope and effect of exclusion, would be amended by revising paragraph (a) to reflect the revised scope of exclusions under title XI of the Act. As indicated above, under section 4331(c) of BBA, exclusions imposed by the OIG under title XI of the Act are now directly to indicate the Secretary, through the OIG, would have the authority to direct the imposition of exclusions from all Federal health care programs. Section 1001.1901 would be amended to indicate that the Secretary, through the OIG, now has the direct authority to impose exclusions from all Federal health care programs. The reference in this section to an exclusion's effect with respect to other Federal agency procurement and nonprocurement programs and activities is being deleted. The effect of an exclusion on such programs (other than Federal health care programs) is specifically addressed in the Federal Acquisition Regulation at 48 CFR 9.405 and the HHS Common Rule at 45 CFR part 76.

With regard to program agency notification, since all affected agencies within the Department, as well as all Federal health care programs outside of the Department, must now effectuate an OIG decision to exclude an individual or entity, we intend to provide notice to these program agencies regarding any action taken by the OIG. Since we believe that it would not be practical to send program agencies an individual notice on every case, we are proposing to inform all affected agencies through the OIG's web site (http://www.dhhs.gov/progorg/oig) every month. The OIG web site will also advise the public of all individuals and entities excluded from program participation. We are advising program

[1] Section 1128B(f) of the Act defines the term ''Federal health care program'' to encompass any plan or program providing health care benefits, whether directly through insurance or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the Federal Employees Health Benefits Program).

agencies to check the web site and to take action, as appropriate, to exclude individuals and entities from their programs.

Broadening factors for the circumstances and length of exclusion—We are also proposing to amend the mitigating and aggravating factors for length of exclusion in §§ 1001.201(b)(3)(iii)(A), 1001.301(b)(2)(ii) and (b)(3)(ii)(A), 1001.401(c)(2)(ii) and (c)(3)(i)(A), 1001.1301(b)(2)(iii), 1001.1401(b)(1) and (b)(4), and 1001.1501(a)(3) to incorporate consideration of all Federal health care programs, not just Medicare and the State health care programs, in determining an appropriate period of exclusion. We believe that since the OIG's authority to exclude individuals and entities has been broadened under section 4331(c) of BBA to encompass all Federal health care programs, it is reasonable for the OIG to consider the impact of exclusion with respect to all of these health care programs.

Effect of exclusion on employment and the reimbursement of items and services in the Federal health care programs—The effect of an exclusion as a result of this authority remains the same as it had been prior to the BBA expansion, i.e., with limited exceptions, no payment may be made for any health care item or service furnished, ordered or prescribed by an excluded individual. There is one significant difference, however, that results from broadening the scope of an exclusion to encompass all Federal health care programs. An individual who was excluded from Medicare and the State health care programs prior to BBA could be employed by another agency which funded a Federal health care program, such as the Department of Defense (which funds the CHAMPUS health care program). In addition, while other Federal agencies were instructed to give government-wide affect to the OIG exclusion, each agency retained some discretion as to whether it would debar that individual or entity from its programs. Such Federal agencies no longer have the discretion to permit excluded individuals and entities to remain in their programs. With the expanded scope of the OIG's exclusion authority, no agency which funds a Federal health care program may reimburse excluded individuals for items and services they provide, nor may any such agency pay the salaries or expenses of such persons using Federal dollars. As a result, an agency which funds a Federal health care program may only employ an excluded individual in limited situations, where the program is able to pay the individual with private grant funds or other non-Federal funding sources. In most instances, the effect of an OIG exclusion will preclude the employment of an excluded individual in any capacity by a Federal or State agency, or other entity, where reimbursement is made by any Federal health care program.

2. Permanent Exclusions for Individuals Convicted of 3 or More Health Care Related Crimes, and 10 Year Exclusions for Individuals Convicted of 2 Health Care Related Crimes

Prior to the enactment of BBA, section 1128(a) of the Act directed the Secretary to impose mandatory exclusions of individuals and entities from participation in the Medicare and State health care programs upon conviction of certain criminal offenses, including Medicare and Medicaid program-related crimes, patient abuse crimes, health care fraud felonies and felonies relating to controlled substances. While such mandatory exclusions were, in most cases, for a minimum period of 5 years, no established mechanism was in place to require a fixed exclusion period for repeat offenders.

As a result of the ability of some health care providers to re-enter participation in the Federal and State health care programs after a minimum exclusion period, section 4301 of BBA imposes a mandatory exclusion of not less than 10-years on individuals who have been twice convicted of mandatory exclusion offenses (including program-related crimes, patient abuse, health care fraud and convictions relating to controlled substances) under section 1128(a) of the Act. In addition, a mandatory permanent program exclusion would also be imposed against those individuals who have been convicted on 3 or more occasions for conduct relating to a Federal health care program under section 1128(a) of the Act. Accordingly, we propose to amend § 1001.102 by adding a new paragraph (d) to reflect these new mandatory lengths of exclusion. An exclusion of not less than 10 years, in the case of a second conviction, or a permanent exclusion, in the case of three or more convictions, will be mandatory where the final conviction has occurred on or after August 5, 1997—the date of enactment of BBA. We are also proposing to add a new paragraph (b)(7) to § 1001.102, the provision governing the length of mandatory exclusions, to include as a new aggravating factor consideration of whether prior criminal offenses involved same or similar circumstances.

3. Exclusion of Entities Controlled by Family or Household Members of Sanctioned Individuals

Under section 1128(b)(8) of Act, the OIG may exclude entities that are owned at least 5 percent, or controlled, by an individual who has been convicted of a health care related offense, or who has been sanctioned by the OIG. This authority enables OIG to enforce its exclusions by ensuring that health care companies operated by excluded individuals, in addition to the individuals themselves, do not continue doing business and receiving reimbursement from Government health care programs. Some excluded health care providers, however, have been able to circumvent the impact of a sanction by expediting transfers on paper of their ownership and control interests in health care entities to a family or household member. These individuals have thus been able to retain silent control of health care businesses that participate in Medicare, Medicaid and all other Federal health care programs despite their exclusion from these same programs. To address this concern of ''paper transfers'' of ownership or control interest by excluded individuals who still retain control of the health care business, section 4303 of BBA amended section 1128(b)(8) of the Act by expanding existing exclusion authority to include entities owned or controlled by the family or household members of excluded individuals when the transfer of ownership or control interest was made in anticipation of, or following a conviction, assessment of a CMP, or exclusion.

We propose to amend § 1001.1001(a)(1)(ii) to reflect this new statutory authority. With regard to an individual excluded under section 1128(b)(8) of the Act, and consistent with the statute, § 1001.1001(a)(2) would also be amended by adding definitions for the terms ''Immediate family member'' and ''Member of household.''

B. Revised Civil Money Penalty Authorities Resulting from BBA

1. CMPs Against Institutional Health Care Providers That Employ or Enter in Contracts for Medical Services With Excluded Individuals

The OIG has been made aware of situations where individuals who have been excluded from Medicare or State health care program participation have, nonetheless, been able to obtain (or retain) employment, staff privileges or other affiliation with various health care entities, and to render services that are ultimately paid for by the programs.

Providers, such as hospitals, that hire excluded practitioners have often failed to investigate or query available sources such as the National Practitioner Data Bank (NPDB) or the OIG's cumulative Sanction Report on the internet (as discussed in section II.A.1. of this preamble), that would have informed them of an individual's exclusion status [2]. While CMP authority has existed for health maintenance organizations that employ or contract with excluded individuals, there was no parallel CMP authority in situations where a group medical practice, hospital, nursing home, home health agency, hospice or other provider continues to bill the programs for services rendered by excluded individuals.

Section 4304(a) of BBA, amending section 1128A(a) of the Act, added a new provision authorizing the imposition of a CMP against any provider that submits, or causes to be submitted, claims for health care items or services rendered by employees or other individuals under contract, whom they know or should know have been excluded from participation in the Federal health care programs. Accordingly, paragraph (a)(2) of § 1003.102 and paragraph (a) of § 1003.103 of the OIG regulations would be revised to implement this new CMP of up to $10,000 against any entity that submits, or causes to be submitted, claims for health care services rendered by employees or other individuals under contract whom they know, or should know, have been excluded from participation in the Federal health care programs.

In determining the appropriate amount of the penalty for each violation, we propose to amend § 1003.106(a)(1) to include the following five criteria: (1) The degree of culpability of the contracting provider; (2) whether the contracting provider knew or should have known of the exclusion; (3) the harm to patients or any Federal health care program which resulted or could have resulted from the provision of care by a person or entity with which the contracting provider is expressly prohibited from contracting under section 1128A(a)(6) of the Act; (4) the history of prior offenses by the contracting provider or principals of the contracting provider, including whether at any time prior to the determination of the current violation(s) the contracting provider or any of its principals were convicted of a criminal charge or were held liable for civil or administrative sanctions in connection with a Federal, State or private health care program; and (5) such other matters as justice may require.

2. New CMP for Failure to Report Information to the Healthcare Integrity and Protection Data Bank

Section 1128E of the Act, as added by section 221 of HIPAA, established a national health care fraud and abuse data collection program, the Healthcare Integrity and Protection Data Bank (HIPDB), for the reporting of final adverse actions against health care providers, suppliers and practitioners. This authority mandated that private health plans [3], as well as certain State and Federal entities such as medical licensing boards, report information to the national fraud and abuse data collection program concerning certain final adverse actions taken against a health care provider, supplier or practitioner. However, while the Health Care Quality Improvement Act of 1986, which established the NPDB, provided sanction authority against those who do not report required information to the NPDB, the HIPAA authority for the HIPDB set forth no parallel provision to induce health care plans' compliance with the reporting requirements.

Section 4331(d) of BBA added a provision to the health care fraud and abuse data collection program to provide for the imposition of a CMP against any health plan that fails to report information on an adverse action required to be reported under this program. In accordance with section 1128E(b)(6) of the Act, § 1003.102(b)(5) would be amended to add a new subparagraph addressing violations by any health plan that fails to report information on an adverse action required to be reported under this authority. In addition, a new § 1003.103(g) would be added to impose a CMP of not more than $25,000 for each such adverse action not reported. In determining the penalty amount for each occurrence, we are proposing five criteria for consideration that would be set forth in an amended § 1003.106(a)(2): (1) the nature and circumstances of the failure to report any adverse actions taken against a health care provider; (2) the degree of culpability of the health plan in failing to provide timely and complete data; (3) the materiality or significance of omission of the information to be reported to the Data Bank; (4) any prior history of the individual or plan with respect to these occurrences; and (5) in general, other matters required by justice.

3. CMPs for Health Care Providers who Violate the Anti-Kickback Statute

Prior to the enactment of BBA, the only remedies available to the Federal Government to combat kickback violations involving the Federal health care programs were criminal penalties (section 1128B(b) of the Act), and exclusion from participation in Medicare and the State health care programs (section 1128(b)(7) of the Act) against individuals and entities that offer or receive improper remuneration in return for the referral of business paid for by Federal health care programs. Enforcement in the kickback area has been constrained since the two existing remedies were quite severe.

To create an alternative intermediate remedy, section 4304 of BBA amended section 1128A(a) of the Act, specifically authorizing a CMP of up to $50,000 and an assessment of up to three times the total amount of the kickback for any violations of the anti-kickback statute. A new § 1003.102(b)(11) would be added to codify this new CMP authority. Additionally, a new § 1003.103(h) is being proposed in accordance with section 4304 of BBA, setting forth $50,000 as the amount of penalty to be imposed for each kickback violation under section 1128B(b) of the Act, and an assessment (reflected in a new paragraph (b) in revised § 1003.104) of up to 3 times the total amount of remuneration offered, paid, solicited or received without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose.

4. Notification, Effectuation and Appeal Procedures

With respect to all 3 new proposed CMPs, violators of these provisions would be subject to the same notification, effectuation and appeal procedures as other CMP violations under section 1128A(a) of the Act and 42 CFR part 1003 of the OIG regulations.

[2] Under the Health Care Quality Improvement Act of 1986, hospitals are required to query the National Practitioner Data Bank when hiring or granting clinical privileges to a practitioner, and must perform follow-up checks on all such practitioners every two years.

[3] Section 1128E of the Act defines the term ''health plan'' consistent with the definition set forth in section 1128C(c) of the Act; that is, a plan or program that provides health benefits whether directly, through insurance, or otherwise, and includes (1) a policy of health insurance; (2) a contract of a service benefit organization; and (3) a membership agreement with a health maintenance organization or other prepaid health plan.

C. Additional Technical and Other Revisions to 42 CFR Parts 1001 and 1003

1. Technical Revisions

A number of proposed technical revisions consistent with the policy provisions resulting from BBA and these regulatory amendments are also being set forth. Specifically, we propose to amend the authority citation cites for parts 1001 and 1003, §§ 1001.302 (Basis for reinstatement), 1003.100 (Basis and purpose), and 1003.114 (Collateral estoppel) to reflect the above-cited revisions being proposed in accordance with revised OIG exclusion and CMP authorities.

In addition, we are revising § 1003.109(a)(3) by deleting the phrase ''the amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable).'' This language appears in paragraph (a)(4) of this section, and appears inadvertently in paragraph (a)(3).

2. Proposed Revision to OIG Exclusion Reinstatement Considerations

We are proposing to add two new elements to § 1001.3002(b) that would pertain to the OIG's review of an individual's or entity's request for reinstatement in the Federal health care programs after the individual's or entity's exclusion period. The first new proposed element would address the OIG's expectation that excluded parties adequately and promptly inform all their clients or patients of the exclusion so that the clients or patients will have a clear understanding that items and services provided by that individual or entity will not be paid for under any Federal health care program. Section 1001.1901(b) of the regulations authorizes Medicare reimbursement to a beneficiary for the first claim submitted for an item or service provided by the excluded party, at which time the beneficiary is notified that future claims will be denied due to the provider's excluded status. We do not believe that notification only *after* the submission of a claim provides adequate protection for program beneficiaries. By stating in regulations that the OIG, in making its reinstatement decisions, will consider whether a provider has adequately and promptly informed clients or patients of an exclusion, we hope to offer an incentive for providers to give the earliest possible notification to beneficiaries of any exclusion.

A second proposed reinstatement element would codify existing OIG policy which, in making reinstatement decisions, considers whether the individual or entity has, during the period of exclusion, submitted claims or caused claims to be submitted, or payments to be made by any Federal health care program for items or services the excluded party furnished, ordered or prescribed, including health care administrative services. Such conduct is impermissible and is a basis for a CMP under section 1128A(a)(1)(D) of the Act. By setting forth this regulatory clarification, we hope to make clear that the submission of claims for payment to any Federal health care program during a provider's period of exclusion will jeopardize the provider's chances for reinstatement into the programs.

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 substantial number of small entities the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

As indicated above, the provisions set forth in this proposed rulemaking implement new or revised OIG statutory requirements set forth in Public Law 105–33. These provisions are designed both to broaden the scope of the OIG's authority to exclude individuals and entities from Medicare, Medicaid and all other Federal health care programs, and strengthen current legal authorities pertaining to the imposition of CMPs against individuals and entities engaged in prohibited actions and activities. The proposed regulations would implement the new statutory requirements by (1) expanding the application of the OIG's exclusions to all Federal health care programs; (2) implementing permanent exclusions for individuals convicted of 3 or more offenses for which an exclusion can be imposed under section 1128(a) of the Act, and 10 year exclusions for individuals convicted of two or more such offenses; (3) allowing for the exclusion of entities controlled by family or household members of sanctioned individuals; and (4) establishing new CMPs in three specific areas.

With regard to the OIG's new exclusion authorities, the process for excluding individuals and entities who are convicted in accordance with these new provisions remains essentially the same, even though the types of convictions requiring mandatory exclusions have been broadened. While there may be a resulting increase in the number of mandatory and permissive exclusions imposed as a result of the expanded scope of the OIG's exclusion authority, we do not believe these increases will be significant. The clarification of exclusion authority in § 1001.1001 regarding a sanctioned individual's transfer of ownership or control interest to a family or household member, for example, should not result in a significant increase in exclusion actions in accordance with section 1128(b)(8) of the Act since the provision is likely to act as an effective deterrent against the occurrence of such transfer arrangements. In addition, we do not foresee significant increases resulting from the implementation of section 4301 of BBA, and proposed regulations at § 1001.102, regarding the permanent exclusion of individuals convicted of 3 or more health care related crimes. The authority for promulgating this exclusion is clear cut, and should limit the total number of repeat exclusions effectuated by the OIG against such fraudulent providers.

The proposed regulations addressing the new OIG CMPs also remain consistent with the congressional intent of BBA and with the OIG's existing CMP authority which allows for imposition of civil money penalties against individuals and entities who commit fraud. These CMPs are targeted to a limited group of individuals and entities; that is, those institutional health care providers that employ or enter into medical service contracts with excluded individuals, health care plans that fail to report information to the Healthcare Integrity and Protection Data Bank, and health care providers who violate the anti-kickback statute.

As indicated, these proposed regulations are narrow in scope and effect, comport with congressional and statutory intent, and strengthen the Department's legal authorities against those who defraud or otherwise act improperly against the Federal and State health care programs. Since the vast majority of individuals, organizations and entities involved in delivering health care do not engage in the

prohibited activities and practices described in this rulemaking, we believe that the aggregate economic impact of these regulations will not be economically significant. Since there is minimal economic effect on the industry as a whole, there would be little likelihood of effect on Federal or State expenditures to implement these regulations.

With regard to the effect of these proposed regulations on a substantial number of small entities, the provisions are targeted specifically to those individuals and entities who would defraud or abuse the health care programs, rather than to the health care industry as a whole. While some of the perpetrators of fraud effected by this rule may be small entities, it is the nature of the violation and not the size of the entity that will induce action on the part of the OIG.

In summary, we have concluded, and the Secretary certifies, that since this proposed rule should not have a significant economic impact on Federal, State or local economies and expenditures, nor have a significant economic impact on a substantial number of small entities, a regulatory flexibility analysis would not be required.

Paperwork Reduction Act

The provisions of these proposed regulations impose no new reporting or recordkeeping requirements necessitating clearance by OMB.

IV. Public Inspection of Comments

Comments will be available for public inspection September 16, 1998 in Room 5518 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, D.C., on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m., (202) 619–0089.

List of Subjects

42 CFR Part 1001

Administrative practice and procedure, Fraud, Health facilities, Health professions, Medicaid, Medicare.

42 CFR Part 1002

Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping.

42 CFR Part 1003

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

Accordingly, 42 Parts 1001, 1002 and 1003 would be amended as set forth below:

PART 1001—[AMENDED]

A. Part 1001 would be amended as follows:

1. The authority citation for part 1001 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(h), 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub.L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

2. Section 1001.1 would be amended by revising paragraph (a) to read as follows:

§ 1001.1 Scope and purpose.

(a) The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in Medicare, Medicaid and all other Federal health care programs. They also state the effect of exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing notices of exclusions, and the process by which an excluded individual or entity may seek reinstatement into the programs.

* * * * *

3. Section 1001.2 would be amended by revising the definition for the term *Exclusion*; and by adding a definition for the term *Federal health care program* to read as follows:

§ 1001.2 Definitions.

* * * * *

Exclusion means that items and services furnished by a specified individual or entity will not be reimbursed under Medicare, Medicaid and all other Federal health care programs.

Federal health care program means any plan or program providing health care benefits, whether directly through insurance or otherwise, that is funded directly, in whole or part, by the United States Government (other than the Federal Employees Health Benefits Program), or any State health care program as defined in this section.

* * * * *

4. Section 1001.102 would be amended by revising paragraphs (b)(5) and (b)(6); and by adding new paragraphs (b)(7) and (d) to read as follows:

§ 1001.102 Length of exclusion.

* * * * *

(b) * * *

(5) The convicted individual or entity has a prior criminal, civil or administrative sanction record;

(6) The individual or entity has at any time been overpaid a total of $1,500 or more by Medicare, Medicaid or any other Federal health care programs as a result of improper billings; or

(7) The individual or entity has previously been convicted of a criminal offense involving the same or similar circumstances.

* * * * *

(d) In the case of an exclusion under this subpart, based on a conviction occurring on or after August 5, 1997, an exclusion will be—

(1) For not less than 10 years if the individual has been convicted on one other occasion of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act (The aggravating and mitigating factors in paragraphs (b) and (c) of this section can be used to impose a period of time in excess of the 10-year mandatory exclusion); or

(2) Permanent if the individual has been convicted on two or more other occasions of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act.

5. Section 1001.201 would be amended by revising paragraph (b)(3)(iii)(A) to read as follows:

§ 1001.201 Conviction relating to program or health care fraud.

* * * * *

(b) *Length of exclusion.* * * *

(3) * * *

(iii) * * *

(A) Others being convicted or excluded from Medicare, Medicaid or any of the other Federal health care programs, or

* * * * *

6. Section 1001.301 would be amended by revising paragraphs (b)(2)(ii) and (b)(3)(ii)(A) to read as follows:

§ 1001.301 Conviction relating to obstruction of an investigation.

* * * * *

(b) *Length of exclusion.* * * *

(2) * * *

(ii) The interference or obstruction had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or on the Medicare, Medicaid or other Federal health care programs;

* * * * *

(3) * * *

(ii) * * *

(A) Others being convicted or excluded from Medicare, Medicaid or any of the other Federal health care programs, or

* * * * *

7. Section 1001.401 would be amended by revising paragraphs (c)(2)(ii) and (c)(3)(i)(A) to read as follows:

§ 1001.401 Conviction relating to controlled substances.

* * * * *

(c) *Length of exclusion.* * * *

(2) * * *

(ii) The acts that resulted in the conviction or similar acts had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or the Medicare, Medicaid or other Federal health care programs;

* * * * *

(3) * * *

(i) * * *

(A) Others being convicted or excluded from Medicare, Medicaid or any of the other Federal health care programs, or

* * * * *

8. Section 1001.1001 would be amended by revising paragraph (a)(1)(ii); and by amending paragraph (a)(2) by adding definitions for the terms *Immediate family member* and *Member of household* to read as follows:

§ 1001.1001 Exclusion of entities owned or controlled by a sanctioned person.

(a) *Circumstances for exclusion.* * * *

(1) * * *

(ii) Such a person——

(A)(i) Has a direct or indirect ownership interest (or any combination thereof) of 5 percent or more in the entity;

(ii) Is the owner of a whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the entity or any of the property assets thereof, in which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity;

(iii) Is an officer or director of the entity, if the entity is organized as a corporation;

(iv) Is partner in the entity, if the entity is organized as a partnership;

(v) Is an agent of the entity; or

(vi) Is a managing employee, that is, an individual (including a general manager, business manager, administrator or director) who exercises operational or managerial control over the entity or part thereof, or directly or indirectly conducts the day-to-day operations of the entity or part thereof, or

(B) Was formerly described in paragraph (a)(1)(ii)(A) of this section, but is no longer so described because of a transfer of ownership or control interest to an immediate family member or a member of the person's household as defined in paragraph (a)(2) of this section, in anticipation of or following a conviction, assessment of a CMP, or imposition of an exclusion.

(2) * * *

Immediate family member means, a person's husband or wife; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother or stepsister; father-, mother-, daughter-, son-, brother- or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild. * * *

Member of household means, with respect to a person, any individual with whom they are sharing a common abode as part of a single family unit, including domestic employees and others who live together as a family unit. A roomer or boarder is not considered a member of household.

* * * * *

9. Section 1001.1301 would be amended by revising paragraph (b)(2)(iii) to read as follows:

§ 1001.1301 Failure to grant immediate access.

* * * * *

(b) *Length of exclusion.* * * *

(2) * * *

(iii) The impact of the exclusion on Medicare, Medicaid or any of the other Federal health care programs, beneficiaries or the public; and

* * * * *

10. Section 1001.1401 would be amended by revising paragraphs (b)(1) and (b)(4) to read as follows:

§ 1001.1401 Violations of PPS corrective action.

* * * * *

(b) *Length of exclusion.* * * *

(1) The impact of the hospital's failure to comply on Medicare, Medicaid or any of the other Federal health care programs, program beneficiaries or other individuals;

* * * * *

(4) The impact of the exclusion on Medicare, Medicaid or any of the other Federal health care programs, beneficiaries or the public; and

* * * * *

11. Section 1001.1501 would be amended by revising paragraph (a)(3) to read as follows:

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) *Circumstance for exclusion.* * * *

(3) The OIG will take into account access of beneficiaries to physicians' services for which payment may be made under Medicare, Medicaid or other Federal health care programs in determining whether to impose an exclusion.

* * * * *

12. Section 1001.1901 would be amended by revising paragraphs (a), (b)(1), introductory paragraph (c)(3) and (c)(4)(i) to read as follows:

§ 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, Medicaid and any of the other Federal health care programs, as defined in § 1001.2 of this part.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Medicare, Medicaid and other Federal health care programs in accordance with subpart F of this part, no payment will be made by Medicare, Medicaid or any of the other Federal health care programs for any item or service furnished, on or after the effective date specified in the notice period, by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion.

* * * * *

(c) *Exceptions to paragraph (b)(1) of this section.* * * *

(3) Unless the Secretary determines that the health and safety of beneficiaries receiving services under Medicare, Medicaid or any of the other Federal health care programs warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

* * * * *

(4)(i) Notwithstanding the other provisions of this section, payment may be made under Medicare, Medicaid or other Federal health care programs for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services.

* * * * *

13. Section 1001.3002 would be amended by republishing introductory paragraph (b), removing existing paragraph (b)(5) and adding new paragraphs (b)(5) and (b)(6); and by revising paragraph (c)(1) to read as follows:

§ 1001.3002 Basis for reinstatement.

* * * * *

(b) In making the reinstatement determination, the OIG will consider—

* * * * *

(5) Whether the individual or entity, during the period of exclusion, has adequately and promptly informed its clients or patients that any items or services provided will not be reimbursable under any Federal health care program; and

(6) Whether the individual or entity has, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by any Federal health care program, for items or services the excluded party furnished, ordered or prescribed, including health care administrative services.

(c) * * *

(1) Has properly reduced his or her ownership or control interest in the entity below 5 percent;

* * * * *

14. Section 1001.3003 would be revised to read as follows:

§ 1001.3003 Approval of request for reinstatement.

(a) If the OIG grants a request for reinstatement, the OIG will—

(1) Give written notice to the excluded individual or entity specifying the date of reinstatement;

(2) Notify HCFA of the date of the individual's or entity's reinstatement;

(3) Notify appropriate Federal and State agencies that administer health care programs that the individual or entity has been reinstated into all Federal health care programs; and

(4) To the extent applicable, give notice to others that were originally notified of the exclusion.

(b) A determination by the OIG to reinstate an individual or entity has no effect if a Federal health care program has imposed a longer period of exclusion under its own authorities.

15. Section 1001.3005 would be amended by revising paragraphs (a) introductory text, (b) and (d) to read as follows:

§ 1001.3005 Reversed or vacated decisions.

(a) An individual or entity will be reinstated into Medicare, Medicaid and other Federal health care programs retroactive to the effective date of the exclusion when such exclusion is based on—

* * * * *

(b) If an individual or entity is reinstated in accordance with paragraph (a) of this section, HCFA and other Federal health care programs will make payment for services covered under such program that were furnished or performed during the period of exclusion.

* * * * *

(d) An action taken by the OIG under this section will not require any other Federal health care program to reinstate the individual or entity if such program has imposed an exclusion under its own authority.

PART 1002—[AMENDED]

B. Part 1002 would be amended as follows:

1. The authority citation for part 1002 would continue to read as follows:

Authority: 42 U.S.C. 1302, 1320a–3, 1320a–5, 1320a–7, 1396(a)(4)(A), 1396(p)(1), 1396a(30), 1396a(39), 1396b(a)(6), 1396b(b)(3), 1396b(i)(2) and 1396b(q).

2. Section 1002.2 would be amended by revising paragraph (a) to read as follows:

§ 1002.2 General authority.

(a) In addition to any other authority it may have, a State may exclude an individual or entity from participation in the Medicaid program for any reason for which the Secretary could exclude that individual or entity from participation in the Medicare, Medicaid and other Federal health care programs under sections 1128, 1128A or 1866(b)(2) of the Social Security Act.

* * * * *

PART 1003—[AMENDED]

C. 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, 1320a–7e, 1320b–10, 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c) and 11137(b)(2).

2. Section 1003.100 would be amended by revising paragraphs (a) and (b)(1)(iv), (viii), (x), (xi) and by adding (b)(1)(xii) to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1128E, 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–7e, 1320a–7(c), 1320b(10), 1395mm, 1395ss(d), 1396(m), 11131(c) and 11137(b)(2)).

(b) *Purpose.* This part—

(1) * * *

(iv)(A) 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, or

(B) Are health plans and fail to report information concerning sanctions or other adverse actions imposed on providers as required to be reported to the Healthcare Integrity and Protection Data Bank (HIPDB) in accordance with section 1128E of the Act;

* * * * *

(viii) Have submitted, or caused to be submitted, certain prohibited claims, including claims for services rendered by excluded individuals employed by or otherwise under contract with such person, under one or more Federal health care programs;

* * * * *

(x) Have collected amounts that they know or should know were billed in violation of § 411.353 of this title and have not refunded the amounts collected on a timely basis;

(xi) 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; or

(xii) Violate the Federal health care programs' anti-kickback statute as set forth in section 1128B of the Act.

* * * * *

3. Section 1003.102 would be amended by revising paragraphs (a)(2) and (b)(5); and by adding a new paragraph (b)(11) to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

(a) * * *

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent, including a claim for any item or service furnished by an excluded individual employed by or otherwise under contract with that person;

* * * * *

(b) * * *

(5) Fails to report information concerning—

(i) A payment made under an insurance policy, self-insurance or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist or other practitioner in accordance with section 421 of Pub. L. 99–660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60; or

(ii) An adverse action required to be reported to the Healthcare Integrity and Protection Data Bank as established by section 221 of Public Law 104–191 and set forth in section 1128E of the Act.

* * * * *

(11) Has violated section 1128B of the Act by unlawfully offering, paying, soliciting or receiving remuneration in return for the referral of business paid for by Medicare, Medicaid or other Federal health care programs.

* * * * *

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

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b) and (d) through (h) of this section, the OIG may impose a penalty of not more than $10,000 for each item or service that is subject to a determination under § 1003.102.

* * * * *

(g) The OIG may impose a penalty of not more than $25,000 against a health plan for failing to report information on an adverse action required to be reported to the Healthcare Integrity and Protection Data Bank in accordance with section 1128E of the Act and § 1003.102(b)(5)(ii) of this part.

(h) For each violation of § 1003.102(b)(11) of this part, the OIG may impose—

(1) A penalty of $50,000, and

(2) An assessment of up to 3 times the total amount of remuneration offered, paid, solicited or received, as specified in § 1003.104(b) of this section.

5. 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 (except for § 1003.102(b)(11)), of not more than three times the amount claimed for each item or service which was a basis for the penalty. The assessment is in lieu of damages sustained by the Department or a State because of that claim.

(b) In accordance with § 1003.102(b)(11), the OIG may impose an assessment of not more than three times the total amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose.

6. Section 1003.105 would be amended by revising the section heading, introductory paragraph (a)(1) and paragraph (b)(1) to read as follows:

§ 1003.105 Exclusion from participation in Medicare, Medicaid and other Federal health care programs.

(a)(1) Except as set forth in paragraph (b) of this section, in lieu of or in addition to any penalty or assessment, the OIG may exclude from participation in Medicare, Medicaid and other Federal health care programs the following persons for a period of time determined under § 1003.107—

* * * * *

(b)(1) (i) With respect to determinations under § 1003.102(b)(2) or (b)(3), a physician may not be excluded if the OIG determines that he or she is the sole community physician or the sole source of essential specialized services in a community.

(ii) With respect to determinations under § 1003.102(b)(5)(ii) of this part, no exclusion shall be imposed.

* * * * *

7. Section 1003.106 would be amended by redesignating existing paragraph (a)(1)(vi) to read as new paragraph (a)(1)(ix); by adding new paragraphs (a)(1)(vi), (a)(1)(vii) and (a)(1)(viii); and by revising paragraphs (a)(1)(ii), (a)(1)(iii), (a)(1)(ix), (a)(2)(i), (a)(2)(ii) and (a)(2)(iii) to read as follows:

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

(a) *Amount of penalty.*

(1) * * *

(ii) The degree of culpability of the contracting provider, or the person submitting the claim or request for payment, or giving the information;

(iii) The history of prior offenses of the contracting provider (or principals of the contracting provider), or the person submitting the claim or request for payment, or giving the information;

* * * * *

(vi) The amount of financial interest involved with respect to § 1003.102(b)(10);

(vii) Whether the contracting provider knew of the exclusion when employing or otherwise contracting with an excluded individual or entity in accordance with § 1003.102(a)(2) of this part;

(viii) The harm to patients or any Federal or State health care program which resulted or could have resulted from the provision of care by a person or entity with which the contracting provider is expressly prohibited from contracting under section 1128A(a)(6) of the Act; and

(ix) Such other matters as justice may require.

(2) * * *

(i) The nature and circumstances of the failure to properly report information, or the improper disclosure of information, as required;

(ii) The degree of culpability of the person in failing to provide timely and complete data or in improperly disclosing, using or permitting access to information, as appropriate;

(iii) The materiality, or significance of omission, of the information to be reported, or the materiality of the improper disclosure of, or use of, or access to information, as appropriate;

* * * * *

8. Section 1003.109 would be amended by revising introductory paragraph (a) and paragraph (a)(3) to read as follows:

§ 1003.109 Notice of proposed determination.

(a) If the Inspector General proposes a penalty and, when applicable, an assessment, or proposes to exclude a respondent from participation in Medicare, Medicaid and any other 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—

* * * * *

(3) The reason why such claims, requests for payments or incidents subject the respondent to a penalty, assessment and exclusion;

* * * * *

9. Section 1003.114 would be amended by revising paragraph (a) to read as follows:

§ 1003.114 Collateral estoppel.

(a) Where a final determination pertaining to the respondent's liability under § 1003.102 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

* * * * *

Dated: February 6, 1998.

June Gibbs Brown,

Inspector General, Department of Health and Human Services.

Approved: April 6, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–23463 Filed 8–28–98; 4:23 pm]

BILLING CODE 4150–04–P