

the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IV. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final 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 duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process

to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

V. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 12, 2000.

James Jones,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

§ 180.242 [Amended]

2. In § 180.242, amend the entry for "Lentils" in the table under paragraph (b) by revising "4/30/00" to read "12/31/01".

[FR Doc. 00-10041 Filed 4-25-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001, 1003, 1005 and 1006

RIN 0991-AA90

Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting From Public Law 104-191

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

ACTION: Final rule.

SUMMARY: This final rule revises 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 final rulemaking codifies 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 also codifies a number of technical corrections to the regulations governing OIG's sanction authorities.

EFFECTIVE DATE: These regulations are effective on April 26, 2000.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. The Health Insurance Portability and Accountability Act of 1996

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191, included a number of changes 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 programs funded by the Department of Health and Human Services (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 the OIG's CMP authority, HIPAA (1) increased the maximum penalty amounts per false claim from \$2,000 to \$10,000; (2) allowed CMPs to be

assessed for incorrect coding, medically unnecessary services, and offering remuneration to beneficiaries to influence their choice of a particular provider or supplier; and (3) established a new CMP for physicians' 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 Social Security Act (the Act) were effective on January 1, 1997,¹ these provisions did allow the Department some policy discretion in their implementation. As a result, we developed proposed rulemaking to address these HIPAA CMP 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.

B. Summary of the Proposed Rule

On March 25, 1998, the Department published proposed rulemaking (63 FR 14393) addressing new and revised CMP authorities in accordance with HIPAA, in addition to a number of proposed technical and corrections to 42 CFR parts 1003, 1005 and 1006. Set forth below is a brief summary of the regulatory provisions contained in that proposed rule—

1. Extension of Current CMP Authority

Section 231(a) of HIPAA expanded the scope of the CMP authorities beyond programs funded by the Department, to include application to other Federal agencies' health care programs. The statute may now be used to address violations involving other Federal health care programs such as Tricare, Veterans Affairs, and the Public Health Service programs which are involved with the funding or provision of health care items and services (42 U.S.C. 1320a-7b(f)). We proposed amending the basis and purpose sections of 42 CFR part 1003, as well as the current definitions for the terms "claim" and "exclusion" in § 1003.101, to extend CMP coverage to other applicable Federal health care programs.

2. Increased CMP Amounts

In accordance with section 231(c) of HIPAA, we proposed amending § 1003.103(a) of the regulations to increase the CMP maximum amount from \$2,000 to \$10,000 per false item or service or prohibited practice, and amending § 1003.104 to raise the amount of authorized assessments from double to triple the amount claimed.

These amounts are consistent with the penalty and damage amounts contained in the False Claims Act (FCA) (31 U.S.C. 3729(b)).

3. CMPs for Excluded Individuals Retaining Ownership or Control Interest in a Participating Entity

A major loophole existed under the law prior to HIPAA whereby an excluded individual was able, without sanction, to continue to gain benefits from the Medicare and the State health care programs by retaining a direct or indirect ownership or control interest in a health care entity that participates in Medicare or any State health care program. Revised OIG regulations, in accordance with section 231(b) of HIPAA, were proposed to codify a new CMP designed to deter such affiliations. Specifically, the rule proposed a new § 1003.102(b)(11) (now being designated as (b)(12)), and other conforming revisions, to establish a CMP of up to \$10,000 for each day that an excluded individual retains a prohibited ownership or control interest in an entity participating in Medicare or any State health care program. The penalty provision would apply to excluded individuals, having an ownership or control interest in a participating entity, who know, or should know, of the action constituting the basis for the exclusion. It also applies to any excluded persons who remain as officers or managing employees of a participating entity.

4. CMPs for Upcoding Claims and Medically Unnecessary Services

While the OIG has historically viewed upcoding medical procedure codes and the submission of claims for medically unnecessary services as warranting the imposition of a CMP, section 231(e) of HIPAA expressly identifies a "pattern" of these practices as violations of the CMP statute. The regulations proposed revising § 1003.102(a)(1) to reflect that a CMP and assessment may be imposed for submitting, or causing to be submitted, claims that the person knows or should know will result in greater payment than the code applicable to the item or service actually provided. A new § 1003.102(a)(6) was also proposed for purposes of imposing CMPs and assessments for submitting or causing to be submitted claims for medically unnecessary items or services.

5. CMPs for Offering Inducements to Beneficiaries

A new § 1003.102(b)(12) (now being designated as (b)(13)), and conforming changes, were proposed in accordance with section 231(h) of HIPAA to address

the new CMP authority imposing sanctions against individuals or entities that offer remuneration to a program beneficiary that they know, or should know, will influence the beneficiary's decision to order or receive items or services from a particular provider, practitioner or supplier reimbursable by Medicare or the State health care programs. Under the statute and the proposed regulations, remuneration would include both the waiver of all or part of deductible and coinsurance amounts, and the transfer of items and services for free or for other than fair market value.

Congress enacted statutory exemptions to the definition of "remuneration" under this CMP provision to encompass deductible and coinsurance waivers that meet certain conditions, certain differentials in coinsurance amounts as part of a benefit plan design, and incentives to promote the delivery of preventive care. Specifically, Congress exempted:

- Waivers of coinsurance and deductible amounts that are not advertised or solicited, are not routine, and are made either after a good faith, individualized determination of financial need or after reasonable collection efforts have failed;
- Any waiver of coinsurance or deductible amounts made in accordance with a "safe harbor" to the anti-kickback statute or other regulations issued by the Secretary;²
- Differentials in coinsurance and deductible amounts as part of a benefit plan design where the differentials have been disclosed in writing to all beneficiaries, third party payers, and providers, to whom claims are presented and where the differentials meet standards set forth in regulations issued by the Secretary; and
- Incentives given to individuals to promote the delivery of preventive care, as determined by the Secretary.

We proposed defining "remuneration" consistent with the above provisions.

6. CMPs for the False Certification of Home Health Services Eligibility

The regulations proposed the addition of § 1003.102(b)(13) (now being

² In HIPAA, this exception was originally contained in the general waiver of co-payment exception. This provision has since been made a separate exception under section 4331(e) of the Balanced Budget Act of 1997, and has been further modified by the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (Pub. L. 105-277) to expand this exception from co-payment waivers protected by an anti-kickback statute safe harbor to any payment practice that meets an anti-kickback statute safe harbor.

¹ Section 232 of HIPAA, setting forth the CMP for false certification of Medicare home health benefit eligibility, applies to certifications made on or after August 21, 1996, the enactment date of the statute.

designated as (b)(14)), and conforming changes, to address the new CMP authority set forth in section 232 of HIPAA imposing sanctions against a physician who falsely certifies the necessity of Medicare-covered home health services when he or she knows that such care is not necessary. Under this authority and the proposed rule, the physician could be subject to a CMP of the greater of \$5,000 or 3 times the amount of Medicare payments made for the home health services.

7. Clarification of the CMP Knowledge Standard

Section 1128A of the Act and the implementing OIG regulations have applied a “knows or should know” standard of proof with regard to false claims and other prohibited acts. The “should know” standard historically placed a duty on providers to use reasonable diligence to ensure that claims submitted to the government are true and accurate. However, to make the knowledge standard consistent with the FCA, section 231(d) of HIPAA clarified the applicable standard of proof. Under the proposed revised definition for “should know or should have known” in § 1003.101, the proposed regulations indicated that individuals and entities would only be liable under the CMP authority if they acted with actual knowledge, or with reckless disregard or deliberate ignorance of information supporting the truth or falsity of a claim or other fraud. No specific intent to defraud would be required. The rule also proposed adding a new § 1003.102(e) to clarify, in accordance with the legislative history of HIPAA, that the term “knowingly” will be applied to the presentment of a claim under the CMP statute consistent with the standard of knowledge set forth in the FCA.

8. Other Technical Corrections

In addition to a number of conforming changes to the CMP provisions in part 1003 required by HIPAA, the regulations proposed to revise certain procedures applicable to the appeal of OIG exclusions, CMPs and assessments in 42 CFR part 1005. These included—

- Clarification of the scope of an administrative law judge’s (ALJ) authority to issue subpoenas at a hearing in § 1005.9(b) to indicate that the ALJ is authorized to issue a subpoena to any individual to attend the hearing and to provide documentary evidence at or prior to that hearing. (The existing language has been misconstrued in some situations as only authorizing the production of documents at the hearing itself.)

- A proposed revision to § 1005.7(e) to provide for motions to compel discovery once a request for production of documents has been received. The proposed revision was intended to clarify 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.

- A revision to § 1005.21(d) was proposed to allow for interlocutory appeal to the Departmental Appeals Board (DAB) of the timeliness of the filing of a hearing request. The proposed rule indicated that without this proposed change, a final DAB ruling that a hearing request was untimely filed can be meaningless, since the hearing has often taken place before appeal of an ALJ’s ruling on timeliness can occur.

II. Response to Comments and Summary of Revisions

In response to the notice of proposed rulemaking, the OIG received a total of 31 timely-filed public comments from various health care providers and organizations, professional medical societies and associations, and other interested parties. The comments included both broad concerns about the issuance of these CMP regulations, and more detailed comments on specific aspects of the HIPAA CMP provisions. Set forth below is a synopsis of the various comments and recommendations received, our response to those concerns, and a summary of the specific revisions and clarifications being made to the regulations at 42 CFR parts 1003, 1005 and 1006 as a result of the proposed HIPAA CMP rule and the public comments.

General Comments

Comment: One commenter raised concern over how the Government’s anti-fraud activities under this new rule would be coordinated with private sector efforts. The commenter believed that increased enforcement efforts in the public sector might cause fraud perpetrators to shift their illegal activities to programs not covered by these regulations, such as the Federal Employees Health Benefits Program (FEHBP), causing these programs to lose money. The commenter believed that there appeared to be little opportunity for private health insurance plans to receive restitution for their losses.

Response: The OIG is equally concerned about the spread of potential fraud in all health care programs not

covered by these regulations, such as the FEHBP. The statute, however, created an exception for that program under the CMP provisions, excluding the FEHBP from the definition of a Federal health care program. Overall, we believe the OIG’s anti-fraud efforts should serve to identify and sanction those health care providers that are in a position to defraud both the Federal health care and private sector health care programs.

Comment: In light of the fact that CMPs can now reach \$10,000 per claim, one commenter urged the OIG, as well as the Department of Justice, to review and investigate preliminary findings carefully before accusing a health care provider of fraud and abuse.

Response: We understand and agree with the commenter’s concerns with regard to increased maximum CMP amounts. The OIG has stressed, and will continue to stress, the importance of investigating specific allegations against a provider thoroughly and completely before taking any action.

Specific Comments

Section 1003.102(a)(1) and (a)(6), Claims for Upcoding and for Medically Unnecessary Services

Comment: Several commenters expressed concern that physicians not be prosecuted for honest coding mistakes and legitimate differences of opinion over medical necessity or the use of appropriate billing codes. Commenters suggested that failure to document the medical basis for a claim may be an oversight rather than proof of a medically unnecessary claim. Other commenters believed that the OIG needs to clarify both that CMPs will not be imposed before intent is established, and that CMPs will only be imposed commensurate with the harm to the Federal Government and not as a bargaining tool.

One organization urged the OIG, in implementing this CMP authority, to work with the medical profession to educate physicians regarding proper billing procedures, in order to minimize potential fraud and abuse violations. Still another commenter believed that peer review should be mandatory before a physician can be subject to a penalty for upcoding or providing services deemed to be not medically necessary. This commenter believed that because of the serious consequences associated with improper coding, it is imperative that judgment on the appropriateness of these claims rest essentially with physicians.

Response: Sanctions may only be imposed against those who act in

“deliberate ignorance” or with “reckless disregard” of the truth or falsity of information specified on claims. A physician whose documentation fails to support the level of service submitted for a service code would not be subject to CMP liability unless he or she specifically acted in “deliberate ignorance” or “reckless disregard” of the truth or falsity of the claim. As a result, the OIG would not consider as a basis for CMP action the submitting of a claim for a service found upon review to be medically unnecessary, without evidence that the issue of medical necessity was deliberately ignored or recklessly disregarded. Honest or inadvertent billing or coding mistakes will not be the basis for the imposition of CMPs. In addition, CMPs may be imposed only where a “pattern” of improper claims with upcoded procedures or unnecessary services exists. Sanctions will be imposed only in appropriate cases where a “pattern” of upcoding or billing for unnecessary services has been identified.

Comment: One commenter believed the proposed § 1003.102(a)(6) raised a number of issues for laboratories since laboratories do not determine medical necessity or actually order laboratory services. The commenter believed that it would be inappropriate for the OIG to allege this provision was violated if the laboratory merely submitted a claim for services with an ICD-9 code that the carrier did not recognize as demonstrating the medical necessity of the services. The commenter cited several reasons why the laboratory might submit such claims. Specifically, the commenter indicated that the beneficiary has a right to ask that the claim be submitted to obtain the denial, and that laboratories often disagree with carriers’ coding determinations and may submit a claim to obtain the denial so that it can pursue further appeal rights. As a result, the commenter believed that the regulations should emphasize that the mere submission of a claim with an ICD-9 code that is not acceptable to the carrier should not constitute a violation.

Response: Consistent with the statute and the legislative history, the OIG does not intend this penalty provision to apply when providers submit claims that they know will not be considered reimbursable as medically necessary, but that are required to be submitted because their patients need to document that the Medicare program will not cover the service. However, as explained in the legislative history to this statutory provision, in submitting such claims providers must explicitly notify Medicare carriers that a claim is being submitted not for payment, but

solely for the purpose of seeking reimbursement from secondary payers.

Comment: Proposed § 1003.106(a)(6) provided that CMPs may be imposed if a claim is submitted for “an item or service that is medically unnecessary, and which is part of a pattern or practice of such claims.” Several commenters indicated that the proposed language in § 1003.102(a)(6), regarding the submission of claims for services that are medically unnecessary, should be amended to include the “knows or should know” standard found in the statute and in the proposed revision to § 1003.102(a)(1). Commenters believed that absence of a “knows or should know” standard for all errors pertaining to medical necessity will place the OIG in the position of subjecting legitimate medical decisions to CMPs, and believed that the “know or should know” language is critical to ensuring that physicians are not prosecuted for inadvertent billing mistakes or legitimate disagreements over medical necessity of items or services. Another commenter also stated that the conjunctive re-phrasing of § 1003.102(a)(6) of the proposed regulation (an item or service that is medically unnecessary *and* part of a pattern or practice) could alter the meaning of the statutory language.

In addition, one commenting organization stated that the language in proposed § 1003.102(a)(6) was identical to section 231(c)(4) of HIPAA, except that the words “or practice” were not included in the HIPAA language. The commenter indicated that HIPAA requires an actual pattern of medically unnecessary claims as a prerequisite to CMPs, while the regulation, as drafted, would allow CMPs for a single claim.

Response: The knowledge standard in the statute requires that providers assume responsibility for appropriate billing of their services. It is not our intent, however, to subject physicians to penalties for legitimate disagreements over the medical necessity of items and services, or for honest mistakes or errors. The OIG intends to impose CMPs only after establishing that a provider knew that a billed item or service was not medically necessary, or that he or she deliberately ignored or recklessly disregarded such information. In response to comments, we are revising § 1003.102(a)(6) by adding the words “knows or should know” to read as follows: “An item or service that a person *knows or should know* is medically unnecessary, and which is part of a pattern of such claims” (emphasis added).

We are also amending the proposed § 1003.102(a)(6) by deleting the words

“or practice” from this section in order to be consistent with language set forth in HIPAA.

Section 1003.102(b)(12), Retaining Ownership or Control Interest While Excluded

Comment: Two commenters believed that the regulations do not adequately allow for the timely divestiture of an excluded person’s interest in a health care entity. One commenter indicated, for example, that continuing care of patients might be harmed by the failure to allow an excluded individual to divest his or her interest in a health care entity over a period of time. A second commenter indicated that, given the complexity of business arrangements, it may not be possible to immediately divest an ownership or controlling interest, and that a CMP should not be imposed until the individual has been given adequate time to dispose of his or her interest in the entity.

Response: The use of this CMP authority remains discretionary, with the OIG taking into full consideration the effect on program beneficiaries of any sanctions action. The OIG would refrain from imposing an exclusion normally if it believed that such action would jeopardize patient care. However, where we have deemed a particular provider unfit to participate in the Medicare and other Federal health care programs, and to provide items or services for which these programs will pay (by virtue of a program exclusion), we believe that, ordinarily, immediate exclusion will protect, rather than harm, program beneficiaries. With respect to allowing a sufficient time period to permit excluded individuals to divest themselves of an ownership or controlling interest in a health care entity once excluded, the OIG is cognizant of the complex nature of some business arrangements involving ownership or controlling interests in health care entities, and will remain flexible in its imposition of a CMP if it receives adequate assurances from the excluded individual that he or she is taking concrete steps to dispose of an ownership or controlling interest in a timely manner.

Section 1003.102(b)(13), Offering Inducements to Program Beneficiaries

a. Waivers of Coinsurance and Deductibles

Congress exempted from the prohibition on persons offering inducements to beneficiaries certain waivers of Federal health care program copayments that are not advertised, that are not routine, and that are either made

after an individualized determination of financial need or the failure of reasonable collection efforts. Congress also exempted copayment waivers that are exempt from the anti-kickback statute in accordance with the safe harbor or other regulations.

Comment: While supporting the exception for waivers of coinsurance and deductible amounts in cases where the beneficiary is indigent or reasonable collection efforts have failed, several commenters requested guidance as to what constitutes "financial need" and "reasonable collection efforts." At a minimum, commenters asked that we incorporate the text of the statutory definition of remuneration into the regulations, instead of merely incorporating it by reference.

Response: We agree with the commenters and are incorporating the language of the statutory definition of "remuneration" in the final regulations in full text form. We are not specifying any particular method of determining financial need because we believe what constitutes "financial need" varies depending on the circumstances. What is important is that providers make determinations of financial need on a good faith, individualized, case-by-case basis in accordance with a reasonable set of income guidelines uniformly applied in all cases. The guidelines should be based on objective criteria and appropriate for the applicable locality. We do not believe that it is appropriate to apply inflated income guidelines that result in waivers of copayments for persons not in genuine financial need. "Reasonable collection efforts" are those efforts that a reasonable provider would undertake to collect amounts owed for items and services provided to patients.

If the patient has an insurer providing secondary coverage that refuses to pay a copayment amount, the provider should attempt to collect from the patient, unless the provider has contractually agreed with the insurer not to balance bill the patient. In that case, the insurer remains liable for the copayment.

Comment: One commenter also sought clarification as to whether section 231(h)(6)(B) of HIPAA, which exempts any "permissible waiver" as specified in an anti-kickback statute safe harbor, applies to items or services covered by a health plan that are protected from anti-kickback liability under the safe harbor for reduced cost-sharing amounts at § 1001.952(l).

Response: In accordance with an amendment contained in section 5201(a) of the Omnibus Consolidated and Emergency Supplemental

Appropriations Act of 1999, Public Law 105-277, prohibited remuneration under section 231(h) of HIPAA does not include "any permissible practice described in any subparagraph of section 1128B(b)(3) of the Act or in regulations issued by the Secretary" (with the exception of certain premium payment arrangements described in the statute). In other words, payment practices that are protected by a safe harbor to the anti-kickback statute are also protected from sanction under section 231(h) of HIPAA.

b. Differentials in Coinsurance and Deductibles as Part of a Benefits Plan Design

Congress exempted from the definition of remuneration differentials in coinsurance and deductible amounts as part of a benefits plan design where the differentials are disclosed to beneficiaries, providers and third-party payers, and otherwise conform to standards promulgated by the Secretary. We stated in the preamble to the proposed rule that we do not interpret this exemption as authorizing any benefits plan design that directly or indirectly operates to waive deductible or coinsurance amounts required by any Federal health care program. Thus, for example, a private plan's "coordination of benefits" provision may not relieve a provider or a plan that is secondary to Medicare from its respective obligations to bill and pay Medicare copayments. We solicited comments regarding how to best define differentials in coinsurance and deductibles that are part of a plan design.

Comment: Commenters expressed three major concerns in response to our statement that the exception for plan coinsurance differentials did not authorize any benefit plan design that directly or indirectly operates to waive deductible or coinsurance amounts required by any Federal health care program. The first concern expressed by several physicians' organizations is that the practice is not uncommon and that many health care plans require physicians to enter into contracts that limit payment for services to the plan's specified fee schedule (which is usually lower than Medicare's fee schedule) and prohibit physicians from billing beneficiaries for any amounts. These plans include enrollees who are Medicare beneficiaries for whom Medicare is the primary payer (on a fee-for-service basis) and the plan is the secondary payer. The commenters indicated the following sequence of events for physicians: (i) The physician bills Medicare for a service at the physician's "actual charge" and is paid

80 percent of the lower of the charge or the Medicare fee schedule amount; (ii) the physician bills the secondary plan for the 20 percent Medicare copayment; (iii) the secondary plan denies payment for all or part of the copayment on the ground that the physician has already received full payment under the contract, because the amount paid by Medicare (80 percent of the lower of the charge or Medicare fee schedule amount) is more than the applicable amount in the plan's fee schedule; and (iv) the physician, barred from billing the beneficiary for any amounts, must forego the unpaid copayment amount. These commenters stated that the effect of this is to waive routinely the Medicare copayment, since neither the secondary plan nor the beneficiary has paid it.

The second major concern that was expressed by the same physician groups is that, because physicians join multiple managed care plans and agree to different discounted rates with each one, often physicians do not know the plans' reimbursement rates. They indicated that, in some cases, plans do not provide fee schedules to their physicians, and that plan payment schedules are often changed unilaterally and retroactively, sometimes without notification to participating physicians. Moreover, the commenters stated that the exact amount of plan reimbursement is often contingent on bonus and withhold pools.

The third concern expressed by commenters was that secondary insurer contracts that operate to waive Medicare copayments do not implicate the statute, since section 231(h) of HIPAA only precludes remuneration that is likely to influence the choice of a particular provider. In situations where all providers participating in a particular plan are equally restricted from billing beneficiaries for copayments, the commenters believed that the waiver will not influence a patient's choice of provider. Alternatively, some commenters urged that the definition of "remuneration" as used in this CMP provision exclude routine waivers of coinsurance where a secondary insurer contract prohibits physicians from billing either the plan or the beneficiary for the full Medicare copayment amount. Similarly, some commenters requested that a section 231(h) "safe harbor" regulation be established for physician waivers of copayments in circumstances where Medicare requirements conflict with physician contractual arrangements with secondary insurers, arguing that in these circumstances physicians do make reasonable collection efforts and

therefore fall within the exemption for waivers of coinsurance. Finally, some other commenters advocated a contrary view; they suggested that the regulations should prohibit the contractual waiver of copayments and require that all secondary carriers (including Medigap insurers) cover the full Medicare copayment and deductible amounts.

Response: We agree that differentials in copayments or coinsurance amounts paid out of pocket by beneficiaries as part of plan designs that are properly disclosed to beneficiaries, providers and third party payers are not remuneration within the meaning of section 231(h) of HIPAA and do not violate the prohibition in section 231(h). However, as explained below, this practice implicates other Federal laws including, most notably, the anti-kickback statute. The Department is actively developing a safe harbor for waivers of coinsurance incidental to fee schedules for employer plans in which ten percent or less of the enrollees have primary coverage under Medicare.

Our statement in the preamble to the proposed regulation that the benefits plan design exception does not authorize any plan design that directly or indirectly operates to waive statutory coinsurance obligations for any Federal health care program was somewhat misconstrued by the commenters. Our original statement was only intended to make clear that plan designs that operate to waive Federal health care program statutory coinsurance obligations so that they are not satisfied by anyone may implicate other Federal laws, including the anti-kickback statute. Since the inception of the Medicare program and continuing to the present, the Social Security Act has imposed cost-sharing obligations on program beneficiaries, including beneficiaries enrolled in Medicare HMOs. However, most of these coinsurance obligations are imposed in conjunction with Medicare fee-for-service reimbursement. These coinsurance requirements help cover the total cost of health care, and they control overutilization by encouraging beneficiaries to be prudent purchasers. For most benefits covered under the Part B program, Medicare pays 80 percent of the lower of the physician's actual charge or the Medicare fee schedule. Providers are legally obligated to make reasonable efforts to collect the remaining 20 percent from the beneficiary. Part A also has certain coinsurance and deductible requirements. Private contracts cannot waive or defeat these Federal statutory obligations.

Supplemental Medicare insurance is very important to many program beneficiaries. Approximately ninety percent of all beneficiaries have some form of supplemental Medicare insurance coverage. Approximately thirty percent of beneficiaries purchase separate Medigap insurance which can cost \$100 per month or more without any prescription drug benefit. Another 15 percent cover the coinsurance through joining Medicare HMOs; in these plans, the actuarial cost of the coinsurance obligation is covered either by the beneficiary's copayments and premiums or by the plan in lieu of returning profits to the Medicare program. Approximately 12 percent of beneficiaries have Medicaid coverage.

Approximately 30 percent of beneficiaries have supplemental coverage from their former employers. Generally, Medicare is the primary insurer and the employer-sponsored plan is secondary. For retirees in these plans, Medicare pays the plan's providers on a fee-for-service basis. The comments we received indicate that an increasing number of these plans are utilizing contracts with their participating providers that purport to release the plans and their enrollees from some or all of the applicable Medicare coinsurance obligations. This result is achieved through a combination of: (i) A fee schedule that is below the Medicare fee schedule; (ii) a prohibition on a provider billing enrollees more than a token copayment; and (iii) a "coordination of benefits" provision that obligates the plan to pay providers only to the extent that payments from the primary insurer (including Medicare) are less than the contract fee schedule.

For example, an employer establishes a retiree plan that requires no copayments by the retirees if the retirees utilize certain "preferred providers." The contracts between the employer (or more likely a third party administrator) and the providers establish a fee of \$80 for a procedure for which Medicare will allow \$100; a "coordination of benefits" clause that limits plan liability if the provider has received the contract fee (*i.e.*, \$80) from another insurer; and a prohibition on balance billing enrollees. The net result is that Medicare pays the \$80 (80% of \$100); the plan refuses to pay any copayment because the provider has already received the \$80 plan contract fee amount; and the beneficiary pays nothing. In other words, the employer plan receives a substantial financial benefit equal to the coinsurance obligations it does not pay.

The employer in this example is "free riding" on the Medicare program. The

practice is unfair and inequitable to the roughly 60 percent of Medicare beneficiaries who must pay the coinsurance obligations out of their own pockets or purchase Medigap insurance at considerable personal expense. It is also unfair to beneficiaries in Medicare HMOs, who must either pay the coinsurance obligation through their premiums or copayments or forgo other desirable benefits, such as enhanced prescription drug coverage, which an HMO might have offered if it had not applied its surplus profit to pay the beneficiaries' premiums. Simply stated, liabilities imposed by Federal law should not turn on happenstance of a beneficiary's employer benefit plan.

Routine waivers of Medicare copayments and deductibles in accordance with a contract between an insurer and a plan also implicate the anti-kickback statute. This practice presents a significant risk of overutilization of services and increased program costs to Medicare. Since neither plans nor beneficiaries pay for services where the copayment is waived, they have no incentive to control costs or utilization. We have repeatedly expressed our concern that such agreements between providers and health plans can result in kickbacks from providers to health care plans in exchange for Federal health care program business.³

We recognize that the interplay between Medicare and employee-sponsored supplemental plans is complex. As indicated above, the Department is developing a safe harbor for waivers of coinsurance incidental to fee schedules that would protect employer plans in which ten percent or less of the plan enrollees have primary coverage under Medicare.

Absent a safe harbor, plans that prohibit participating physicians from balance billing enrollees for whom Medicare is the primary insurer are responsible for those enrollees' outstanding Medicare copayments. Accordingly, to avoid receiving prohibited remuneration, the secondary plan must pay the Medicare copayment in full if physicians bill Medicare an amount higher than the plan's fee schedule amount. Medicare would pay 80 percent of the Medicare fee schedule amount and the plan would pay the 20 percent copayment, resulting in physicians receiving 100 percent of the Medicare fee schedule amount.

³ See, for example, 42 CFR 1001.952(k)(1)(iii) (hospital waiver of inpatient deductible or coinsurance not protected by safe harbor regulation if part of an agreement between hospital and third party payer, including a health plan) and OIG Advisory Opinion 98-5 (April 17, 1998).

Alternatively, the physicians must bill Medicare the lower amount they agreed to accept from the plan. For example, if the Medicare fee schedule amount for a given service is \$100 and the plan fee schedule for the service is \$80, the physician would submit a claim to Medicare for \$80, receive \$64 from Medicare (80 percent of \$80), and the secondary plan would pay \$16 (the twenty percent copayment obligation). We understand that physicians currently may have difficulty in identifying the payment amount they will receive under a particular contract. However, that is an issue between them and the plans and can be addressed by developing with a plan a fixed fee schedule for plan participants that have primary coverage under Medicare. If a plan is denying payment on the ground that the provider has already received the full amount the plan is obligated to pay, the plan must necessarily know how much it is obligated to pay.

In sum, properly disclosed benefit plan designs that utilize differentials in coinsurance and deductible amounts paid by an enrollee are *not* remuneration within the meaning of section 231(h) of HIPAA. However, when such differentials are coupled with other provisions to achieve a waiver of Medicare coinsurance obligations, they implicate other Federal laws, including the anti-kickback statute.

Comment: One commenter requested guidance with regard to a physician's obligation to seek payment from a beneficiary when the beneficiary's health plan capitates payment to the physician, and the physician has been paid a capitation for the beneficiary.

Response: From Medicare's perspective, if the beneficiary is a fee-for-service patient, the physician is obligated to collect the full amount of the Medicare coinsurance, unless a waiver of the copayment would comply with the requirements for the exemptions under section 231(h) of HIPAA for waivers of coinsurance and deductibles. Where the capitation amount has been actuarially determined to equate with the expected copayment, no further payment amount would be required.

Comment: Two commenters believed that the policy position taken by the OIG on physician billing of copayments was an attempt to use the fraud and abuse laws to effectuate a "most favored nation" Medicare payment policy (for which there is no statutory authority), requiring physicians to limit their Medicare fees to levels established by private payers. One commenter stated that section 1848 of the Act explicitly

exempts the Medicare physician fee schedule from the comparability rules that are applicable to many other services under Part B of the Medicare program.

Response: We do not believe that anything in these regulations requires physicians to limit their Medicare fees to private payer levels. However, it should be noted that section 1128(b)(6)(a) of the Act prohibits charges that are "substantially in excess" of a provider's "usual charges." Therefore, provider charges to Medicare should be comparable (and not "substantially in excess") of charges to private payers. In circumstances where plans and providers contract so as to prohibit physicians from seeking payment of coinsurance from Medicare beneficiaries and where plans decline to pay the coinsurance on behalf of beneficiaries, it is the plan and physicians that impose the lower fee amount for the plan's Medicare-covered members.

Comment: Several commenters asked that we clarify that this CMP provision does not affect the ability of physicians to be reimbursed for beneficiary copayments and deductibles through Medigap insurance.

Response: As discussed above, the exemption for differentials in coinsurance amounts that are part of a plan design includes arrangements where a beneficiary's copayments are paid by a secondary insurer, provided there is proper disclosure as required by the statute. Our main concern is with situations where nobody is obligated to pay the copayment amounts for beneficiaries for whom Federal health care payment is made on a fee-for-service basis (as is the case for many retirees in employer plans). In those circumstances, there is no one with an economic interest in controlling utilization of reimbursable services. We caution, however, that a secondary insurer's refusal to pay a claim for a copayment amount does not obviate the physician's obligation to engage in reasonable efforts to collect the copayment, including reasonable efforts to collect directly from the beneficiary in circumstances in which there is no contractual prohibition on billing beneficiaries.

Comment: One commenter questioned the applicability of the differentials exemption in the context of Medicare risk- and cost-based managed care contractors, who are permitted by HCFA to waive coinsurance and deductibles and whose waivers are exempt from section 231(h) of HIPAA by virtue of the anti-kickback safe harbor for reduced cost-sharing amounts at § 1001.952(l).

Response: Differentials in coinsurance and deductible amounts by Medicare managed care contractors disclosed to, and approved by, HCFA do not implicate section 231(h) of HIPAA.

Comment: One commenter requested that the Secretary exercise her discretion under section 231(h)(6)(B) of HIPAA to promulgate regulations identifying other permissible copayment waivers, including "professional courtesy" waivers offered by physicians to fellow physicians and family members.

Response: At this time, we are not identifying other permissible copayment waivers, but reserve the right to do so in the future. With respect to "professional courtesy," we note that traditionally the term means free care (*i.e.*, no charge is made to anyone), not care provided on an "insurance only" basis. Generally, a routine practice by a physician of waiving the entire fee for services provided to other physicians without regard to the potential for referrals is not a problem under section 231(h) of HIPAA or the anti-kickback statute. However, waivers of Medicare or other Federal health care program copayments for non-indigent persons, whether physicians or any other groups, are problematic.

Comment: One national association, commenting on what constitutes acceptable payment differentials under benefits plans, proposed that it should be acceptable for health plans to impose one deductible for a supplier that participates in the plan network and a different deductible for a comparable supplier that does not participate. The association also recommended that acceptable plan designs should include copayment or deductible differentials based on whether a beneficiary chooses brand name or generic drugs, and whether the beneficiary chooses drugs that are (or are not) on the relevant drug formulary. The association asserted that such differentials have legitimate economic bases and do not raise fraud concerns. On the other hand, the association asked that the OIG deem unacceptable differentials that exist between two suppliers that participate equally in the plan, such as a community pharmacy and a mail order pharmacy.

Response: We believe that Congress intended section 231(h) of HIPAA to be broadly construed to permit plans maximum flexibility to structure their financial incentives within their benefits packages, so long as the resulting arrangement does not have the effect of waiving payment of the Medicare copayment to the provider and is properly disclosed.

c. Applicability of Section 231(h) of HIPAA to Managed Care Organizations

Comment: Several managed care organizations and associations commented that section 231(h) should not apply to managed care organizations. These commenters stated that the OIG's interpretation of the statute set forth in the proposed rule was expansive and inappropriate on the grounds that the OIG's interpretation presumed that offering an incentive to enroll in a *particular health plan* is equivalent to offering an incentive to use a *particular provider*. Although the incentives may influence a beneficiary's choice of health plans, the commenters stated that such choice is not the same as influencing the choice of a particular provider. Another commenter remarked that limiting incentives provided by managed care organizations for Medicare and Medicaid enrollees was unfair to those populations, as such incentives are commonly offered in the commercial managed care market to those who are not Medicare or Medicaid enrollees. In addition, the commenter indicated that one effect of the regulation would be to terminate certain benefits that Medicare and Medicaid enrollees of employee benefit plans had been receiving before becoming eligible for Medicare or Medicaid. One commenter stated that even if managed care plans were not covered by section 231(h) of HIPAA, the OIG would still have the authority to oversee inducements by managed care plans under the anti-kickback statute.

Response: After having reviewed all of the comments, we agree that health plans that provide incentives to Federal health care program beneficiaries to enroll in a plan are not offering remuneration to induce the enrollees to use a particular provider, practitioner, or supplier. Accordingly, we are indicating that health plans that provide incentives to enroll in a plan will not be subject to sanctions under this provision. However, incentives provided by health plans to induce a Federal health care program beneficiary to use a particular provider, practitioner, or supplier once the beneficiary has enrolled in a plan are within the purview of this provision and are prohibited if they do not meet an exception. For example, coinsurance differentials for out-of-network providers fall within the prohibition of this statute, although they fit within the exception for differentials of coinsurance and deductibles, as long as the other requirements of the exception are met.

We remain concerned that health plans may use inducements in a manner that leads to enrollment of only healthy beneficiaries, such as offering memberships to exercise clubs for purposes of patient screening. However, such "cherry picking" is prohibited under separate CMP provisions that are unaffected by this provision. Additionally, incentives provided by health plans remain subject to the anti-kickback statute.

Many other comments were submitted that raised issues with regard to health plans. These comments were all premised on inducements to enroll in health plans falling within the provisions of the statute (section 1857 of the Act). Since such inducements will not be subject to section 231(h), these comments are no longer relevant.

d. Incentives To Promote the Delivery of Preventive Care

The statutory exception for preventive care, as defined in the proposed rule, exempted from the definition of remuneration incentives given to individuals to promote the delivery of preventive care. In the preamble to the proposed rule, we indicated that such incentives did not include the direct rendering of preventive medical care. Specifically, the exception included the provision of incentives to individuals eligible for benefits under a Federal health care program where the incentives are provided for the purpose of inducing individuals to obtain preventive care.

For purposes of the exception, we proposed defining in § 1003.101 the term "preventive care" 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. In addition, the proposed rule listed examples of permissible and impermissible incentives under this provision. Specifically, we stated that impermissible incentives would include items or services related to the promotion of general health and fitness (excluding annual physicals), such as health club memberships, nonprescription vitamins, nutritional supplements and beauty aids. In

addition, cash and cash equivalents would not be permissible incentives.

In the section discussing this exception we also reiterated the conference report statement that made clear that section 231(h) does not preclude the provision of items and services of nominal value, including, for example, refreshments, medical literature, complimentary local transportation services or participation in free health fairs. We interpreted the conference report to mean that the provision of items and services to an individual is not prohibited if the aggregate value of such items and services is nominal. However, it should be recognized that the frequent rendering of items or services to any individual may preclude such items and services from being classified as nominal in value.

Comment: We received a number of comments addressing the exception for incentives to promote the delivery of preventive care. Commenters expressed concern about the proposed definition of "preventive care." Some commenters found the proposed definition too narrow and confusing. One commenter, for example, questioned whether pharmacy care is included in the definition. Other commenters urged that preventive care include care related to general health and fitness and care associated with acute and chronic illnesses and diseases. Some commenters urged us to adopt a broad definition of preventive care, noting, for example, that preventive care promotes healthier patient populations, leads to increased productivity by patients, and results in lower health care costs.

Commenters also raised objections to the proposed scope of permissible incentives. These commenters requested clarification of permissible and impermissible incentives under the preventive care exception. For example, several commenters objected to the statement that the direct rendering of preventive medical care was not a permissible incentive, urging that the provision of free or discounted preventive care should fall within the exception for incentives to promote the delivery of preventive care. Other commenters noted that health plans often give patients, particularly Medicaid patients, gifts to encourage the use of health care services, such as diabetes management programs and prenatal care. These incentives include, among other things, coupons, gift certificates, Thanksgiving turkeys, amusement park tickets, books on caring for babies, baby blankets and medicine droppers. Several commenters noted that the examples of permissible

incentives provided in the proposed regulation were all non-medical items or services and requested clarification that permissible incentives could also include incentives that were health care related.

Some commenters suggested that lists of permissible and impermissible incentives be included in the text of the regulation. Commenters also suggested that the OIG add limiting factors to the definition of permissible incentives, such as a requirement that permissible incentives be offered to all similarly situated persons in a given community. Further, commenters requested clarification of the meaning of the term "cash equivalent" set forth in the proposed regulation. Two commenters suggested that a cash equivalent be defined as "an item easily convertible to cash."

Several commenters recommended that incentives that promote general health and fitness be allowed under the preventive care exception. The commenters argued that such incentives encourage healthy behavior, even though they are not tied to prevention of a specific illness, complaint, or injury. According to commenters, permissible incentives that promote general fitness should include items such as health club memberships, nonprescription vitamins, nutritional supplements and beauty aids. Specific examples offered by commenters included discounts for completion of a weight watchers program, a discounted price for an American Red Cross CPR course, and free YMCA visits for postpartum mothers.

Response: Based on our review of the public comments and after further consideration of the statutory language and public policy, we have concluded that the regulations should be revised to accord more fully with the statutory language of section 231(h) and the scope of coverage of preventive care by existing Federal health care programs. The following discussion addresses three key elements of the preventive care exception: The meaning of "preventive care," the scope of permissible incentives, and the requirement that incentives promote the delivery of preventive care. Some additional issues are addressed in separate comments and responses below.

• *Definition of Preventive Care*

Our review of the public comments disclosed considerable uncertainty about the proposed definition of preventive care for purposes of the preventive care exception. Moreover, it became apparent, based on an internal

review, that the proposed definition did not comport with the scope of preventive care services reimbursed by Medicare or the State health care programs. For these reasons, we concluded that it would be preferable to replace our proposed definition with an objective, "bright line" rule.

Section 231(h) of HIPAA prohibits remuneration paid to an eligible beneficiary to influence him or her to order or receive from a particular provider, practitioner, or supplier *any item or service for which payment may be made by Medicare or a State health care program* (as defined in 42 U.S.C. 1320a-7(h)). In other words, section 231(h) generally bars incentives paid to influence the choice of provider, practitioner, or supplier for *covered* items or services.

We believe that in enacting the preventive care exception, Congress recognized that in some circumstances it may be prudent to allow providers to encourage beneficiaries to obtain covered preventive care services through payment of remuneration linked to the delivery of such services. Well-recognized benefits from appropriate preventive care include, among other things: Healthier patient populations, lower health care costs, and reduced morbidity and mortality. For these reasons, it is especially important that Medicare and Medicaid beneficiaries access appropriate preventive care services.

Accordingly, for purposes of the preventive care exception to section 231(h) of HIPAA, we are interpreting preventive care to mean preventive care covered by Medicare or the State health care program in the applicable State. We have decided to define "preventive care" as any service that is a prenatal service or a post-natal well-baby visit or is a specific clinical service described in the then current U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services*.⁴ If such services are covered by Medicare or the applicable State health care program, they fall within the preventive care exception to section 231(h) of HIPAA.

The *Guide to Clinical Preventive Services* addresses preventive care services provided to asymptomatic individuals in a clinical setting, classifying a number of preventive care services into three broad categories: screening tests, counseling interventions, and immunizations and chemoprophylaxis. For purposes of this regulation, to be considered as

preventive care the service in question must be described in the *Guide* (e.g., listed in the table of contents) to fall within the exception. The mere fact that a service involves screening, counseling, or immunization will not suffice to qualify the service for the preventive care exception. The *Guide* also includes measures of the effectiveness of preventive care services when performed on a routine basis. For purposes of determining whether a service is preventive under this regulation, these effectiveness measures will not be taken into account. By way of example, the second edition of the *Guide* includes "screening for visual impairment" as a preventive care service, but does not recommend certain kinds of screening for all elderly patients. Notwithstanding, any screening for visual impairment, if covered by the applicable Federal health care program, is a preventive care service within the meaning of the exception.

For beneficiaries enrolled in Medicare or Medicaid managed care programs, covered preventive care services would be those services included in the managed care organization's annual contract with HCFA or a State health care program.

Remuneration paid to influence the selection of a provider for non-covered preventive care services falls outside the scope of the statutory proscription. We are concerned, however, about arrangements that purport to provide patients with incentives to obtain non-covered items or services, where the true purpose of the incentives is to influence the selection of a provider for covered services. We are similarly concerned about arrangements where an incentive to obtain covered preventive care services is, in reality, an incentive paid to patients to induce them to obtain other covered services. Any tie between provision of an exempt covered preventive care service and a covered service that is not preventive would vitiate the preventive care exception and might constitute a violation of section 231(h), the Federal anti-kickback statute, or other legal authorities.

• *Scope of Permissible "Incentives"*

Many commenters sought clarification regarding the meaning of "incentives" for purposes of the preventive care exception. Because Congress intended the scope of permissible incentives under the preventive care exception to be reasonably broad, except for the limitations noted below, we are not imposing any particular limitations on the type or value of incentives that may qualify under the preventive care

⁴ U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services*, 2nd ed. Baltimore: Williams and Wilkins, 1996.

exception. Examples of permissible incentives include health care items or services (e.g., blood sugar screenings, cholesterol tests, medic alert jewelry) and non-health care items or services (e.g., gift certificates, t-shirts, infant car seats, Thanksgiving turkeys). Because of the large variety of permissible incentives, we decline to list permissible incentives in the regulation.

A price reduction is likely to be an effective means of encouraging beneficiaries to obtain preventive care services. Providers can offer a price reduction for a *covered* service for Medicare and Medicaid beneficiaries in one of two ways: (1) By waiving all or part of a copayment obligation, or (2) by offering care as a free community service and forgoing billing Medicare or Medicaid, as well as beneficiaries. Thus, notwithstanding our long-held and continuing concern with routine waivers of copayments, we are permitting providers to waive copayments as an incentive to promote the delivery of preventive care. We believe a copayment waiver in these limited circumstances comports with congressional intent in enacting the preventive care exception.

We are imposing two limitations on permissible incentives. First, we are concerned that excessively valuable incentives may be intended to induce a beneficiary to select a provider for more than just the covered preventive care service. Therefore, we are providing that the value of the incentive must bear a reasonable relationship to the value of the preventive care service (*i.e.*, to the service itself or to future health care costs reasonably expected to be avoided as a result of the preventive care). A disproportionately large incentive gives rise to an inference that at least part of the incentive is being provided to induce beneficiaries to obtain additional services beyond the preventive care that is the predicate for the incentive. Such incentives for additional services are not covered by the preventive care exception to section 231(h) of HIPAA. An incentive that is disproportionately small in comparison to the value of the preventive care service does not raise similar concerns and is permissible.

Second, we proposed excluding cash and cash equivalents from the scope of permissible incentives. Several commenters indicated confusion regarding the meaning of the term "cash equivalents." We agree that the term may not have clearly captured our intent. Accordingly, we are excluding from the scope of permissible exceptions cash payments and instruments convertible to cash. Thus, for example, it would not be permissible

to provide an incentive in the form of a check.

Finally, we note that section 231(h) of HIPAA only prohibits incentives that are likely to influence a beneficiary's choice of a provider for particular services. Such influence is only possible if the beneficiary knows about the incentive before making his or her choice. Thus, incentives that are not advertised or otherwise disclosed to a beneficiary before the beneficiary selects a provider for services do not come within the statutory proscription, and therefore need not qualify under any of the exceptions, including the preventive care exception. For example, discounted CPR courses or home visits offered to women who have delivered a child at a particular hospital are not prohibited under section 231(h), if the availability of the discounted CPR course or home visits is not made known to the mother until after she enters the hospital to deliver her child.

• *Promoting the Delivery of Preventive Care*

We interpret the phrase "to promote the delivery of preventive care" to mean that the incentives must be designed to encourage individuals to avail themselves of preventive care services, as defined above. Thus, the exception requires that a nexus exist between the incentive and the delivery of specific preventive care services. The preventive care must be care that is delivered by a person qualified to provide or furnish such services under State licensure laws and Federal health care program requirements (including conditions of participation and billing requirements). Moreover, as discussed above, there must be a rational relationship between the value of the incentive and the value of the preventive care service.

Comment: Several commenters urged the OIG to expand the definition of preventive care to include items or services designed to prevent the deterioration of, or complications from, an acute or chronic illness, such as hemophilia or diabetes. These commenters argued that preventive care should include care aimed at managing and preventing the exacerbation of chronic conditions, such as disease management programs.

Response: As indicated above, the final rule defines preventive care with reference to those services that are both described in the then current U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (as well as pre-natal and well-baby care visits) and covered by Medicare or a State health care program for the particular patient. The *Guide to Clinical*

Preventive Services is limited to certain primary and secondary preventive care services provided to asymptomatic individuals in a clinical setting. Primary preventive care measures prevent the onset of a targeted condition (e.g., routine immunization of healthy children). Secondary preventive measures identify and treat asymptomatic persons who have developed risk factors or preclinical disease, but in whom the condition has not become clinically apparent (e.g., screening for high blood pressure).

An expansion of the preventive care exception to include tertiary preventive care (that is, preventive care that is part of the treatment and management of persons with clinical illnesses), as suggested by the commenters, would understandably be desirable from the perspective of those individuals afflicted with acute or chronic illness, but would create an exception that would swallow the general prohibition. Most medical services provided to a symptomatic patient can arguably be characterized as designed to prevent the patient from getting worse or developing complications. We do not believe that Congress intended the preventive care exception to be so broadly construed. Given the large number of possible chronic and acute conditions, we also do not believe it is feasible or fair to craft a rule that would apply only to some diseases or illnesses (such as hemophilia or diabetes), but not to others.

Comment: One commenter noted that HCFA and the Health Resources and Services Administration (HRSA) have promoted programs to enlist the support of the business community to provide incentives to encourage medically uninsured populations to receive needed health care services or obtain available health insurance coverage. The commenter questioned the effect of these regulations on such outreach programs.

Response: We do not believe anything in this final rule is inconsistent with the HCFA and HRSA outreach programs. As explained above, incentives to encourage an individual to enroll in a particular health plan or program are outside the scope of the statutory provision, as are incentives provided to individuals not covered by Medicare or a State health care program.

Comment: One commenter questioned whether permissible incentives include incentives designed to promote the delivery of services that can lead to preventive care, such as early detection tests. The commenter asked whether it would be permissible for a hospital to offer free blood sugar screenings, which

are not covered by Medicare, at health care fairs or as part of a National Diabetes Awareness Week campaign. The purpose of the screenings would be to increase diabetes awareness and to identify diabetic individuals who are not receiving treatment. The screenings might also identify individuals eligible for Medicare-covered diabetes self-management education programs.

Response: Under the final rule, certain early detection tests may themselves qualify as preventive care if they are enumerated in the *Guide to Clinical Preventive Services* and covered by Medicare or an applicable State health care program. With respect to the hypothetical posed by the commenter, provision of a free non-covered screening test would not violate section 231(h) of HIPAA so long as the test is not tied to the provision of other services by the hospital. Thus, for example, the screening test would be permissible where the hospital provides an individual who tests positive for diabetes with general information or literature and a recommendation that the individual contact his or her personal physician. If, on the other hand, as part of the screening program, the hospital makes appointments for individuals with one of its physicians, offers individuals discounts for additional covered services, or otherwise promotes its particular diabetes programs, an inference may be drawn that the free screening test was an inducement to choose the hospital as a provider of other services. Finally, we note that some early detection tests may be of such nominal value as not to come within the scope of the statutory prohibition, as discussed below.

Comment: One commenter suggested that the rule include a requirement that permissible incentives be offered to all similarly situated persons in a given community.

Response: We are not requiring in this rule that incentives to promote the delivery of preventive care be offered to all similarly situated persons in a given community. For example, a health plan may offer incentives designed to influence plan members' selections of particular participating providers for preventive services to plan members only. Requiring permissible incentives to be offered to all similarly situated persons might discourage providers from offering potentially beneficial preventive care to a limited number of individuals, for example, to the first x-number of individuals who show up. We do not believe that Congress intended to prohibit such arrangements.

Comment: A commenter questioned whether a managed care organization

violates section 231(h) of HIPAA if it provides transportation for Medicaid patients to and from health care services for diagnosed conditions. The commenter observed that transportation costs are often a barrier to care for this patient population and that some States require managed care organizations to provide such transportation as a covered benefit.

Response: We do not believe that section 231(h) is violated if a State requires a managed care organization to include transportation services as a covered benefit. Moreover, we do not believe that the statute is violated if the transportation is provided on an equal basis to all plan enrollees and transportation is available to any participating plan provider.

Comment: A number of commenters questioned whether incentives to promote the delivery of preventive care must be of nominal value.

Response: The incentives need not be of nominal value. As discussed below, incentives that are of nominal value may not be improper under section 231(h) of HIPAA.

Comment: One commenter believed that our proposed interpretation of the preventive care exception would conflict with the HCFA marketing guidelines, since vitamins, nutritional supplements and beauty aids valued at under \$10 would be permissible under HCFA's guidelines but prohibited by the OIG rule.

Response: No conflict exists between the HCFA marketing guidelines and this CMP provision. Vitamins, nutritional supplements and the like are permissible incentives if offered to promote the delivery of covered preventive care services or if they are of nominal value, as discussed below. Moreover, pre-enrollment incentives offered by health plans do not implicate section 231(h) of HIPAA for the reasons stated above under paragraph heading c., Applicability of section 231(h) to managed care organizations. Finally, a payment will not be considered impermissible remuneration if it falls into any one of the statutory exceptions.

Comment: Numerous commenters requested clarification as to the requirement that the preventive care must be provided, or directly supervised by, the medical provider that provided the incentive. Managed care organizations and associations commenting on the proposed rule raised concern over how this requirement would apply to them, since it is the managed care organization and not the provider that is offering the incentive. In addition, a physician association commented that the "directly

supervised" language was very restrictive, especially if it is given the same meaning as under the proposed Stark II regulations.

Response: As a result of these concerns and in light of our revised interpretation of this provision, we have amended the regulations to delete this requirement. In drafting the proposed rule, we did not intend to limit "medical providers" to physicians. Accordingly, we wish to clarify that preventive services may be provided by non-medical providers, including health plans, as long as all elements of the preventive care exception described above are satisfied.

e. Applicability to Items That Are of Nominal Value

Comment: Several commenters requested clarification as to whether items of nominal value also had to be related to preventive care. One commenter stated that if an item or service is preventive, it need not be nominal in value, and conversely, if the item is nominal it need not be preventive. One commenter suggested that if an item is of nominal value, it would not induce a beneficiary to choose a particular provider, practitioner, or supplier. In addition, two commenters asked that we incorporate a nominal value "exception" into the final regulations.

Response: Incentives that are only of a nominal value were not specifically exempted in the language of this CMP provision. However, we agree with the interpretation of the commenter who suggested that if an incentive is nominal in value, then the individual providing the incentive would not and should not know that the incentive is likely to induce a beneficiary to use a particular provider, practitioner or supplier. Accordingly, we believe that incentives that are only nominal in value are not prohibited by the statute, and therefore no exception is necessary. Further, we wish to clarify that the exception for preventive care is separate from the issue of whether an incentive is of nominal value. Consequently, incentives that meet the preventive care exception do not need to be nominal in value, and items of nominal value do not have to meet the preventive care exception.

Comment: The OIG was asked by commenters to clarify and take a flexible position as to what constitutes "nominal." Most of the commenters on this issue were not in favor of aggregating the value of items, suggesting that recordkeeping would be difficult and cumbersome. One commenter requested that the measure

of nominal value be greater for patients with chronic diseases because such patients receive items and services more frequently. The commenter suggested using the proposed Stark II definition⁵ of *de minimis* compensation as a basis for defining "nominal."

Response: For purposes of consistency with the HCFA national marketing guidelines, we are interpreting nominal value to be no more than \$10 per item, or \$50 in the aggregate on an annual basis.

Section 1003.102(b)(14), False Certification of Home Health Services Eligibility

Comment: While supporting efforts to prevent, investigate and eliminate fraud and abuse associated with the provision of home health services, one commenter expressed concern over any increased enforcement and investigative activities that would unfairly target physicians for authorizing appropriate home health services.

Response: These regulations are merely designed to implement new CMP authorities, consistent with the statute, for program violations related to the false certification of home health services eligibility. Only in those circumstances where there is evidence that the physician had actual knowledge that Medicare-covered home health services certified were medically unnecessary will the OIG seek to impose appropriate penalties. These situations will come to our attention from the OIG's normal investigative efforts focusing on all aspects of fraud and abuse in Medicare and other Federal health care programs.

Section 1003.106, Determining CMP and Assessment Amounts

Comment: Several commenters expressed concern that the guidelines set forth in § 1003.106(b)(2) fall below the level of intent required for CMPs established under section 321(d) of HIPAA. Specifically, commenters indicated that the mitigating circumstance under the degree of culpability—described in part as "unintentional and unrecognized" errors—is not consistent with the "knows or should know" standard set forth in HIPAA and § 1003.101 of the proposed regulations.

Response: We agree with the concerns expressed by the commenters and are modifying these guidelines by deleting this phrase from § 1003.106(b)(2) to more accurately reflect the level of intent required under HIPAA for the imposition of CMPs.

Comment: One commenter raised concern over health care providers' reliance on Medicare contractors and the contractors' responsibility for accurate guidance on Medicare reimbursement issues. As a result, the commenter requested that § 1003.106(b)(2), addressing the degree of culpability, be amended to include contractor error as a mitigating factor when determining whether, and how much, to penalize a health care provider.

Response: We do not believe the recommended change is necessary. The OIG already takes into account such factors as contractor error in determining the culpability of a health care provider.

Comment: One commenter believed that, with regard to determining penalty amounts, the factor relating to "prior offenses" should be expanded to include any item reported to the Health Care Fraud and Abuse Data Collection Program, established under section 221 of HIPAA. The Data Collection Program requires Government agencies and private health plans to report all final adverse actions against health care providers, suppliers and practitioners to the Healthcare Integrity and Protection Data Bank (HIPDB). The commenter suggested that § 1003.106(d) be amended to include as an aggravating circumstance any time a respondent has an action reported in the final adverse action database.

Response: "Prior offenses" will routinely be identified in the HIPDB. We do not believe respondents should be penalized twice by having the listing of a prior offense in the HIPDB constitute a separate aggravating factor. However, the HIPDB includes many sanction actions (such as loss of professional license) that would not typically be considered "prior offenses." Therefore, we are amending § 1003.106(d)(3) to state that, with respect to prior offenses, it would be an aggravating circumstance if there were evidence that at any time prior to the current violation(s) the respondent was identified in the HIPDB for any conduct not constituting a "prior offense" in accordance with the statute.

Comment: With regard to the "financial condition" circumstance set forth in § 1003.106(b)(5), some commenters objected to the proposed deletion of the mitigating circumstance under which "the imposition of the penalty or assessment without reduction will jeopardize the ability of the respondent to continue as a health care provider." One commenter believed that this factor should be maintained since it allows physicians and other providers

to retain important protections from loss of their profession and livelihood and, in the case of health professional shortage areas, protects against physician loss that could otherwise impair the delivery of health care services.

Response: We have indicated that the current factor does not represent a generally applicable standard since the 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. Accordingly, we believe this language change to § 1003.106 is appropriate and warranted. With regard to the concerns stated by several of the commenters, in health professional shortage areas where the loss of a provider could seriously impair the delivery of health care services, the OIG still retains the authority to waive any sanctions action that it believes would seriously impair the delivery of health care services. Our foremost responsibility is and remains the protection of program beneficiaries and the care they receive.

Section 1005.7, Discovery

Comment: One commenter indicated that the OIG needs to be sensitive to the fact that some evidentiary material may involve medical records for patients undergoing active medical treatment, and that discovery procedures should not impede the ongoing care of patients. In addition, the commenter expressed concern about discovery requests for records in the possession of private health insurance companies that need the documents for private fraud cases.

Response: With respect to medical records involving ongoing patient care and private health care cases, the OIG's current practice is to photocopy appropriate medical records, exercising all due precaution to protect records and not compromise patient care.

Comment: One commenter was concerned that the proposed regulatory changes to the discovery process would transform the administrative process into a formal judicial process.

Response: We disagree. The changes we proposed in the discovery section of the proposed rule have been designed to streamline the discovery process and to avoid protracted litigation over the failure to produce documents in a timely fashion. These changes are not intended to create a more formal administrative process, but rather are designed to protect against discovery abuses.

Comment: One commenter believed that the 15 days given to health care providers to comply fully with the request for documents is inadequate and

⁵ 63 FR 1659; January 9, 1998.

recommended expanded time frames. The commenter indicated that this provision makes no distinction between a request for information on a handful of claims and a request involving numerous claims, and fails to recognize that such information may be stored at different locations.

Response: The time frame set forth in § 1005.7(e) is intended to induce parties to produce discovery within a reasonable period of time. We believe that the 15-day period will be adequate in the majority of cases, and the ALJs have been amenable to granting extensions in appropriate circumstances. Also, we are amending § 1005.7 to indicate that, upon a showing of good cause, the period of time for fully responding to the request for discovery may be extended by the ALJ.

III. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the March 25, 1998 proposed rule. A brief description of the provisions of this final rule follow.

- We are amending §§ 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* in § 1003.101 is being deleted.
- We are amending the definition of the term *remuneration* in § 1003.101 by incorporating the language of the statutory definition of “remuneration” in the final regulations and reflecting the fact that incentives to promote the delivery of preventive care services are exceptions to the prohibition on inducements. We are also adding a new definition for the term *preventive care*.
- We are amending § 1003.103(a) to address the increase in the penalty amount from \$2,000 to \$10,000 per item or service improperly claimed or prohibited practice, and amending § 1003.104 to address the increase in the authorized assessment amount from double to triple the amount claimed.
- In § 1003.101, we are specifically defining the terms *should know* and *should have known*, and are making corresponding revisions in §§ 1003.100(b)(1)(i) and 1003.102(a) and (b). We are also adding a new paragraph (e) to § 1003.102, defining the term *knowingly*, to clarify congressional intent to apply the False Claims Act (FCA) standard of knowledge to the presentment of a claim under the CMP law.

- In § 1003.102, we are adding a new paragraph (b)(12) to codify the new CMP authority for excluded individuals that retain ownership or control interests in a participating entity. Conforming revisions are also being made to § 1003.100 through the addition of a new paragraph (b)(1)(xi), and to § 1003.103 through the addition of a new paragraph (j). We are also making technical changes in §§ 1003.105 and 1003.106 to reflect this new authority.

- We are clarifying § 1003.102(a)(1) 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. We are also adding a new § 1003.102(a)(6) 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 of such claims.

- We are adding a new § 1003.102(b)(13) to codify the new CMP authority for the offering of inducements to beneficiaries, along with a conforming change through a new § 1003.100(b)(1)(xii). In addition, we are adding new §§ 1003.106(a)(1)(i), (a)(1)(vii) and (b)(2)(iv) to include the factors the OIG will take into account with respect to this authority in determining a penalty and assessment, including the degree of culpability and the amount of remuneration offered or transferred.

- We are adding a new §§ 1003.100(b)(1)(xiii), 1003.102(b)(14) and 1003.103(i), allowing for a CMP of the greater of \$5,000 or 3 times the amount of the Medicare payments made, against any physician who falsely certifies the medical necessity for Medicare-covered home health services, knowing that the care is not necessary. This provision applies to false certifications made on or after August 21, 1996.

- We are deleting § 1003.100(b)(1)(viii) and redesignating the remaining paragraphs accordingly, since many CMPs (including several new CMP authorities in HIPAA) do not involve the submission of claims as the prohibited conduct. The existing language in § 1003.100(b)(1)(viii) had provided for the imposition of CMPs and, as applicable, assessments against persons who have “submitted certain prohibited claims against the Medicare program.”

- We are deleting the language in §§ 1003.102(b)(2) and (b)(3) and are

reserving these paragraphs. The statutory freeze for actual charges exceeding the maximum allowed has expired, making CMPs for non-participating physicians billing for actual charges in excess of the maximum allowable actual charge in § 1003.102(b)(2) no longer valid. The CMP authority for billing for the services of an assistant at routine cataract surgery in § 1003.102(b)(3) has been delegated to the Health Care Financing Administration. We are making conforming changes through the deletion of § 1003.107(c) and (e).

- We are updating the language in §§ 1003.103(e) and 1003.105(a)(1), relating to patient anti-dumping provisions, to remove the knowledge and penalty provisions that are no longer applicable. With respect to the imposition of a CMP against hospitals and physicians under the patient anti-dumping statute (section 1867 of the Act), the statute imposes liability based upon the negligent violation of statutory requirements, and we are confirming that the new “should know” standard does not apply to CMPs for violations of the patient anti-dumping provisions.

- In § 1003.106, we are broadening the language in paragraph (a)(1) to include all existing and new CMP authorities. In addition, we are amending § 1003.106(b)(5), the factor addressing financial condition, by deleting the first sentence in this paragraph to clarify that 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). Section 1003.106(b)(2) is being revised, in part, by deleting the mitigating circumstance involving “unintentional and unrecognized errors” under the degree of culpability, to be consistent with § 1003.101.

- We are amending § 1003.107(b) to incorporate reference to the new CMP authorities being set forth in §§ 1003.102(b)(12) and (13).

- We are revising § 1005.1, Definitions, to include a definition for the term “Inspector General.”

- We are amending § 1005.7(e) to provide for motions to compel discovery once a request for production of documents has been received. The revision to § 1005.7(e) will 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 will have to be filed with

the opposing party within 15 days of receiving the discovery request, unless good cause is shown for an extension of time. The party seeking the production of documents may then file a motion to compel discovery within the next 15 days unless a lengthier time frame is set by the administrative law judge (ALJ).

- We are amending § 1005.9(b) to clarify that this provision is intended to authorize an ALJ to issue a subpoena to any individual to attend the hearing and to provide documentary evidence at or prior to the hearing. The language clarifies that an ALJ may issue a subpoena *duces tecum* requiring documents to be produced before the hearing.

- In § 1005.15(b), the language incorrectly used the term “respondent” to refer to several exclusion authorities. (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.) We are revising § 1005.15(b) to make the language in this paragraph consistent with the way parties are currently defined in § 1005.2(b).

- We are revising § 1005.21(d) to allow for interlocutory appeals to the Departmental Appeals Board (DAB) in one limited situation, the timeliness of filing of the hearing request. Absent this change, 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 ALJ’s ruling on timeliness can occur.

- We are making technical revisions in §§ 1003.126, 1003.128(b) and 1006.4(b)(2) by deleting the reference to “the Office of the General Counsel.” With the consolidation of the IG Division of Office of the General Counsel into the OIG, these regulatory revisions give the OIG exclusive authority to settle or compromise cases brought under these regulations, and to attend investigational inquiries.

- We are also making technical revisions to §§ 1003.109(b) and 1005.2 that were not previously addressed in the proposed rule. Specifically, § 1005.2 is being amended to provide that a request for an administrative appeal be to the DAB. In addition, § 1003.109(b) is being amended to provide that an administrative appeal be sent certified mail with a return receipt. These changes are being made to ensure that the appropriate adjudicating body, the DAB, receives the request for appeal. The certification requirement is being made to ensure that the Department has knowledge of the appeal and its receipt. These procedural clarifications should help avoid the improper filing of

requests for hearings with the OIG, as well as having to litigate timeliness issues.

IV. Additional Technical Revision

We are also making technical clarifications to §§ 1001.2003 and 1005.20 with regard to exclusion decisions made under section 1128(b)(7) of the Act. Under the current regulations, there appears to be some uncertainty as to when an exclusion under section 1128(b)(7) of the Act may be implemented. Section 1001.2003 currently states that the exclusion will not take effect unless the ALJ upholds the decision to exclude, while § 1005.20 indicates that the ALJ decision is final and binding 30 days from the date of the decision unless appealed to the DAB. This language would indicate that an appeal to the DAB on any case stays the effect of the ALJ decision until the DAB rules on the request. The intent of § 1001.2003 is to give the individual or entity an opportunity to have an ALJ hearing before the effectuation of an exclusion under section 1128(b)(7) of the Act. As it was never intended that the individual or entity would be able to exhaust all appeals before the exclusion could go into effect, the OIG believes that it is appropriate to implement the exclusion under section 1128(b)(7) once an ALJ makes a ruling. Accordingly, we are revising §§ 1001.2003(b)(2) and 1005.20(d) to conform these provisions and to clearly indicate that the OIG will be able to effectuate an exclusion under section 1128(b)(7) of the Act once an ALJ decision is rendered, even if an appeal is still pending.

V. Regulatory Impact Statement

The Office of Management and Budget (OMB) has reviewed this final 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). Section 202 of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) also requires that agencies assess anticipated costs and benefits before issuing any final rulemaking that may result in an expenditure by State, local or tribal government, in the aggregate, or by the private sector of \$100 million or

more in any given year. 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. Further, Executive Order 13132, Federalism, requires agencies to determine if a final rule will have a significant affect on States, on their relationship with the Federal Government, and on the distribution of power and responsibility among the various levels of government.

As indicated above, the provisions contained in this final rule 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 economic effect on Federal, State or local economies, nor will they have a significant economic effect on a substantial number of small entities. In addition, in accordance with the Unfunded Mandates Reform Act, there are no significant costs associated with this rule that will impose mandates on State, local or tribal governments or on the private sector that would result in an expenditure of \$100 million or more in any given year. 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 final 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 final 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 interests 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.

These final regulations implement congressional intent in the area of fraud and abuse in health care programs. The regulations target areas of health care fraud, not specific segments of the 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 little or 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 care 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.

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 final 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's legal authorities against those who defraud or otherwise act improperly against the Federal and State health care programs. 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. In addition, 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 final 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 concluded, and the Secretary certifies, that this final rule should not have a significant effect on Federal, State or local economies and expenditures, and would not have a significant economic impact on a substantial number of small entities that would require a regulatory flexibility analysis. We have also reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and we have determined that this final rule does not significantly affect the rights, roles and responsibilities of States.

List of Subjects

42 CFR Part 1001

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

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 1001, 1003, 1005 and 1006 are amended as set forth below:

PART 1001—[AMENDED]

A. Part 1001 is amended as follows:

1. The authority citation for part 1001 continues 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 1001.2003 is amended by revising paragraph (b)(2) to read as follows:

§ 1001.2003 Notice of proposal to exclude.

* * * * *

(b) * * *

(2) If the individual or entity makes a timely written request for a hearing and

the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant immediate exclusion, an exclusion will only go into effect, with the date of the ALJ's decision, if the ALJ upholds the decision to exclude.

* * * * *

PART 1003—[AMENDED]

B. Part 1003 is amended as follows:

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

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

2. Section 1003.100 is 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 or § 489.24 of this title;

(vii) Substantially fail to provide an enrollee with required medically necessary items and services; engage in certain marketing, enrollment, reporting, claims payment, employment or contracting abuses; or 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 § 411.353 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 that they know or should know are likely 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 is amended as follows:

A. By republishing the introductory text;

B. By revising the definition for the terms *Claim* and *Exclusion*;

C. By removing the terms *General Counsel* and *Program*; and

D. By adding, in alphabetical order, definitions for the terms *Preventive care*, *Remuneration* and *Should know*, or *should have known*. The republication, revisions and additions 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).

* * * * *

Preventive care, for purposes of § 1003.102(b)(13) of this part and the preventive care exception to section 231(h) of HIPAA, means any service that—

(1) Is a prenatal service or a post-natal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services*, and

(2) Is reimbursable in whole or in part by Medicare or an applicable State health care program.

Remuneration, as set forth in § 1003.102(b)(13) of this part, is consistent with the definition contained in section 1128A(i)(6) of the Act, and includes the waiver of coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The term "remuneration" does not include—

(1) The waiver of coinsurance and deductible amounts by a person, if the waiver is not offered as part of any advertisement or solicitation; the person does not routinely waive coinsurance or deductible amounts; and the person waives coinsurance and deductible amounts after determining in good faith that the individual is in financial need or failure by the person to collect coinsurance or deductible amounts after making reasonable collection efforts;

(2) Any permissible practice as specified in section 1128B(b)(3) of the Act or in regulations issued by the Secretary;

(3) Differentials in coinsurance and deductible amounts as part of a benefit plan design (as long as the differentials have been disclosed in writing to all beneficiaries, third party payers and providers), to whom claims are presented; or

(4) Incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program. Such incentives may include the provision of preventive care, but may not include—

(i) Cash or instruments convertible to cash; or

(ii) An incentive the value of which is disproportionately large in relationship to the value of the preventive care service (*i.e.*, either the value of the service itself or the future health care

costs reasonably expected to be avoided as a result of the preventive care).

* * * * *

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 is amended as follows:

A. By revising introductory text paragraph (a) and paragraphs (a)(1) and (a)(3);

B. Republishing the introductory text of paragraph (a)(4) and revising paragraphs (a)(4)(iii) and (5);

C. Adding a new paragraph (a)(6);

D. Republishing the introductory text of paragraph (b) and revising paragraph (b)(1), introductory text;

E. Removing and reserving paragraphs (b)(2) and (b)(3);

F. Revising paragraphs (b)(4) and (b)(9); and

G. By adding new paragraphs (b)(12) through (b)(14) and (e). The revisions, additions and republications 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 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—

* * * * *

(2) [Reserved]

(3) [Reserved]

(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 of this part, 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.

* * * * *

(12) 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.

(13) Offers or transfers remuneration (as defined in § 1003.101 of this part) 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.

(14) 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)), that is, a person, with respect to information, has actual knowledge of information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information, and that no proof of specific intent to defraud is required.

5. Section 1003.103 is amended by revising paragraphs (a) and (e); and by adding new paragraphs (i) and (j) 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 if 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.

* * * * *

(i) For violations of § 1003.102(b)(14) of this part, 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.

(j) The OIG may impose a penalty of not more than \$10,000 per day for each day that the prohibited relationship

described in § 1001.102(b)(12) of this part occurs.

* * * * *

6. Section 1003.104 is 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 is amended as follows:

A. By revising the section heading and paragraphs (a)(1);

B. Removing existing paragraph (b)(1); and

C. By redesignating existing paragraphs (b)(2) and (b)(3) respectively as new paragraphs (b)(1) and (b)(2). The revisions read as follows:

§ 1003.105 Exclusion from participation in Medicare, Medicaid and all Federal 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 Federal 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)(12) or (b)(13); 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 is amended as follows:

A. By revising paragraph (a)(1);

B. Republishing the introductory text of paragraph (b) and revising paragraphs (b)(2) and (b)(5);

C. Revising the introductory text of paragraph (c) and paragraph (c)(3);

D. Redesignating existing paragraphs (d) and (e) as new paragraphs (e) and (f);

E. Revising the introductory text of the new redesignated paragraph (e); and
 F. By adding a new paragraph (d). The revisions, republication and additions read as follows:

§ 1003.106 Determinations 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)(14) of this part, 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)(12);

(vii) The amount of remuneration offered or transferred with respect to § 1003.102(b)(13); 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 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)(12), 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 of remuneration described in § 1003.102(b)(13) of this part would influence a beneficiary to order or receive from a particular provider, practitioner or supplier items or services reimbursable under Medicare or a State health care program.

* * * * *

(5) *Financial 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 in making 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 written acknowledgment from the individual (or his or her representative) prior to the individual's departure from the respondent hospital that he or she is leaving contrary to medical advice.

(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 publicly-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, directly or indirectly, 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 is amended as follows:

A. By revising paragraph (b);
B. Removing existing paragraphs (c) and (e);

C. Redesignating paragraph (d) as new paragraph (c) and revising it. The revisions 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)(12) or (b)(13) of this part, 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 of this part.

10. Section 1003.109 is amended by revising the introductory text of paragraph (a) and revising paragraph (b) 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—

* * * *

(b) Any person upon whom the Inspector General has proposed the imposition of a penalty, assessment or exclusion may appeal such proposed penalty, assessment or exclusion to the DAB in accordance with § 1005.2 of this chapter. The provisions of part 1005 of this chapter govern such appeals.

* * * *

11. Section 1003.126 is revised to read as follows:

§ 1003.126 Settlement.

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

12. Section 1003.128 is 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]

C. Part 1005 is amended as follows:

1. The authority citation for part 1005 continues 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 is 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 1005.2 is amended by revising paragraph (c) to read as follows:

§ 1005.2 Hearing before an administrative law judge.

* * * *

(c) The request for a hearing will be made in writing to the DAB; signed by the petitioner or respondent, or by his or her attorney; and sent by certified mail. The request must be filed within 60 days after the notice, provided in accordance with §§ 1001.2002, 1001.203 or 1003.109, is received by the petitioner or respondent. For purposes of this section, the date of receipt of the notice letter will be presumed to be 5 days after the date of such notice unless there is a reasonable showing to the contrary.

* * * *

4. Section 1005.7 is amended by revising paragraphs (e)(1) and (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.

* * * *

5. Section 1005.9 is 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 of this part at or prior to the hearing.

* * * *

6. Section 1005.15 is 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, in Peer Review Organization exclusion cases under part 1004, 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

* * * *

7. Section 1005.20 is amended by revising paragraph (d) to read as follows:

§ 1005.20 Initial decision.

* * * *

(d) Except for exclusion actions taken in accordance with § 1001.2003 of this chapter and as provided in paragraph (e) of this section, unless the initial decision is appealed to the DAB, it will be final and binding on the parties 30 days after the ALJ serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

* * * *

8. Section 1005.21 is 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]

D. Part 1006 is amended as follows:

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

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

2. Section 1006.4 is 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: April 19, 1999.

June Gibbs Brown,
Inspector General.

Approved: November 24, 1999.

Donna E. Shalala,
Secretary.

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BILLING CODE 4150-04-P

have been addressed in or rendered moot by action taken in other Commission orders. Other issues raised in the petitions are being considered in ongoing Commission proceedings. The Commission does, however, amend its rules to clarify the station identification requirements applicable to CMRS providers licensed under its private land mobile radio services rules.

DATES: Effective June 26, 2000.

FOR FURTHER INFORMATION CONTACT:

Wilbert E. Nixon, Jr., Policy and Rules Branch, Commercial Wireless Division, Wireless Telecommunications Bureau, at (202) 418-7240.

SUPPLEMENTARY INFORMATION: In this document released on April 7, 2000, the Commission, resolves various petitions for reconsideration of Implementation of Sections 3(n) and 332 of the Communications Act, Regulatory Treatment of Mobile Services, GN Docket No. 93-252, Third Report and Order, 59 FR 59945 (November 21, 1994) (CMRS Third Report and Order). The primary goal of the CMRS Third Report and Order was to establish the regulatory framework for implementing the mandate of the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, Title VI § 6002(b), 107 Stat. 312, 392 (1993) (1993 Budget Act), to treat “substantially similar” CMRS providers in a similar regulatory manner. In the five years since the release of the CMRS Third Report and Order, this task has been accomplished through the revision of scores of Commission rule sections in several Commission proceedings. In fact, the majority of the issues raised in the petitions have been addressed in or rendered moot by Commission action taken in Amendment of Part 90 of the Commission’s Rules to Facilitate Future Development of SMR Systems in the 800 MHz Frequency Band, PR Docket No. 93-144, Implementation of Sections 3(n) and 322 of the Communications Act—Regulatory Treatment of Mobile Services, GN Docket No. 93-252, Implementation of Section 309(j) of the Communications Act—Competitive Bidding, PP Docket No. 93-253, First Report and Order, Eighth Report and Order and Second Further Notice of Proposed Rulemaking, 61 FR 6212 (February 16, 1996) (800 MHz Report and Order), Amendment of Parts 0, 1, 13, 22, 24, 26, 27, 80, 87, 90, 95, 97, and 101 of the Commission’s Rules to Facilitate the Development and Use of the Universal Licensing System in the Wireless Telecommunications Service, WT Docket No. 98-20, Report and Order, 63 FR 68904 (December 14, 1998) (ULS Report and Order), and other Commission orders released subsequent

to the release of the CMRS Third Report and Order. Other issues raised in the petitions are being considered in ongoing Commission proceedings. For these reasons, with one exception, the Commission dismisses or denies all of the pending petitions for reconsideration. The Commission does, however, amend §§ 90.425 and 90.647 of our rules to clarify the station identification requirements applicable to CMRS providers licensed under part 90. The amended rule language appears below.

This Order (FCC 00-106), adopted March 17, 2000 and released on April 7, 2000, is available for inspection and copying during normal business hours in the FCC Reference Center, 445 Twelfth Street, SW, Washington, DC. The complete text may be purchased from the Commission’s copy contractor, International Transcription Service, Inc. 1231 20th Street, NW, Washington DC 20036 (202) 857-3800. The document is also available via the Internet at <http://www.fcc.gov/Bureaus/Wireless/Orders/>.

I. Final Regulatory Flexibility Certification

1. Final Regulatory Flexibility Certification. In this Memorandum Opinion and Order on Reconsideration, we amend §§ 90.425 and 90.647(d) of the Commission’s rules as set forth in the Rule Changes below. The amended rules clarify that all part 90 CMRS providers licensed by geographic area are exempt from station identification requirements, and that other part 90 CMRS providers need comply only with the streamlined station identification requirements of § 90.425(e). Specifically, the amendments clarify that station identification need only occur once an hour instead of once every 15 minutes and that the affected CMRS providers need not comply with other detailed technical requirements. We therefore certify, pursuant to the Regulatory Flexibility Act, that the rules adopted in this Order will not have a significant economic impact on a substantial number of small entities.

2. The Commission will send a copy of this Memorandum Opinion and Order on Reconsideration, including specifically a copy of this final certification, in a report to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, see 5 U.S.C. 801(a)(1)(A). In addition, the Memorandum Opinion and Order on Reconsideration and this certification will be sent to the Chief Counsel for Advocacy of the Small Business Administration, and will be

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[GN Docket No. 93-252, PR Docket No. 93-144, PR Docket No. 89-553; FCC 00-106]

Commercial Mobile Radio Service (CMRS)

AGENCY: Federal Communications Commission.

ACTION: Final rule; dismissing various petitions for reconsideration.

SUMMARY: This document dismisses or denies fourteen of the fifteen petitions for reconsideration filed against an earlier Federal Communications Commission (Commission) order. The Commission takes this action because most of the issues raised in the petitions