aromatic hydrocarbons (PAHs), co-planar and non-coplanar polychlorinated biphenyls (PCBs), persistent organochlorine pesticides, carbamate pesticides, dioxins and furans, and phytoestrogens.

Future editions of the ''Report'' will provide detailed assessments of exposure levels among different population groups defined by sex, race or ethnicity, age, urban or rural residence, educational level, income, and other characteristics. Over time, CDC will be able to track trends in exposure levels. Future editions may also include additional exposure information for special-exposure populations (*e.g.*, children, women of childbearing age, the elderly) from studies of people through localized or point sources, and from studies of adverse health effects resulting from exposure to varying levels of environmental chemicals.

Dated: September 30, 2002.

Verla S. Neslund,

Director, Executive Secretariat, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–25374 Filed 10–4–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4050–NR]

Medicare Program; Changes in Medicare Appeals Procedures Based on Section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of CMS ruling.

SUMMARY: This notice announces a CMS Ruling that sets forth our policy regarding implementation of the new appeals provisions in section 1869 of the Social Security Act, as amended by section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106–554. The Ruling identifies changes that will take effect on October 1, 2002 and provides notice of the administrative procedures that CMS contractors, administrative law judges, and the Departmental Appeals Board are to follow in processing Medicare claims appeals.

FOR FURTHER INFORMATION CONTACT: Michele Edmondson (410) 786–6478.

SUPPLEMENTARY INFORMATION: The CMS Administrator signed Ruling CMSR–02–01 on September 12, 2002. The text of the CMS Ruling is as follows:

Changes in Medicare Appeals Procedures Under Section 521 of BIPA

Summary: Section 521 of BIPA states that ''the amendments made by [section 521] shall apply with respect to initial determinations made on or after October 1, 2002.'' BIPA § 521(d), Pub. L. 106–554 (2000). The statute includes a series of structural and procedural changes to the existing appeals process, including revised time limits for filing appeals, reduced decision-making time frames throughout all levels of the Medicare administrative appeals system, and the establishment of new entities known as qualified independent contractors (QICs) to conduct reconsiderations of contractors' initial determinations or redeterminations. However, CMS is unable to immediately implement many of these far-reaching changes. The primary purpose of this Ruling is to explain CMS' progress to date in implementing section 521 of BIPA and identify those provisions that will be implemented effective October 1, 2002. Additionally, the Ruling will clarify our policies with respect to the provisions that cannot be implemented by October 1, 2002, and provides notice of the administrative procedures that CMS contractors, administrative law judges (ALJs) and the Departmental Appeals Board (DAB) will follow in processing Medicare claim appeals until we are able to fully implement section 521 of BIPA.

Citations: Sections 1154, 1869 and 1879 of the Social Security Act and section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554.

I. Background

Section 1869 of the Act establishes a Medicare beneficiary's right to dispute initial determinations made by contractors that result in the denial of claims, in whole or in part, for services received under the Medicare Part A and Part B Programs. Section 1879(d) extends these appeal rights, under certain circumstances, to providers and suppliers who accept assignment.

For initial determinations made before October 1, 2002, an appeal of an initial claim decision generally follows one of two distinct processes, depending on whether it is a Part A or a Part B claim. For Part A claims, ''reconsiderations'' under section 1816(f)(2)(A) of the Act are carried out by Medicare contractors, known as fiscal intermediaries (FIs), who issue the initial determination. If an initial determination is upheld at the reconsideration level, the appellant may request a hearing before an ALJ, if the amount in controversy is $100 or more. If the ALJ upholds the FI's reconsideration decision, the appellant may request a review by the DAB. An appellant's next level of appeal is to a Federal District Court. For Part B claims, reviews under section 1842(b)(2)(B)(i) of the Act are carried out by Medicare contractors known as carriers. If the amount in controversy is at least $100, carrier reviews are subject to ''fair hearings'' under section 1841(b)(2)(B)(ii) of the Social Security Act, which are carried out by the same Medicare contractor that conducted the review. Subsequently, these appeals may proceed to the ALJ hearing level, provided that the amount in controversy is $500, after which the appeals process for Part B claims mirrors the Part A appeals process. In addition, Quality Improvement Organizations (QIOs—formerly Peer Review Organizations) make initial determinations and reconsiderations with respect to certain hospital discharges under sections 1154 and 1155 of the Act. These decisions are also subject to ALJ hearings, if the amount in controversy is at least $200.

Section 521 of BIPA amends section 1869 of the Act to revise the Medicare administrative appeals process. Section 521's structural and procedural changes include:

- Establishing a uniform process for handling Medicare Part A and B appeals, including the introduction of a new level of contractor appeal.
- Revising the time frames for filing a request for a Part A and Part B appeal.
- Imposing a 30-day timeframe for certain ''redeterminations'' made by the contractors who made the initial determination.
- Requiring the establishment of a new appeals entity, the qualified independent contractor (QIC), to conduct ''reconsiderations'' of contractors' initial determinations or redeterminations, and allowing appellants to escalate the case to an ALJ hearing, if reconsiderations are not completed within 30 days.
- Establishing a uniform amount in controversy threshold of $100 for appeals at the ALJ level.
- Imposing 90-day time limits for conducting ALJ and DAB appeals of lower-level decisions and allowing appellants to escalate a case to the next level of appeal if ALJs or the DAB do not meet their deadlines.

• Imposing ''de novo'' review when the DAB reviews an ALJ decision made after a hearing.

Revised section 1869 also requires that the Secretary establish a process by which an individual may obtain an expedited determination if he/she receives a notice from a provider of services that the provider plans to terminate services or discharge the individual from the provider. Currently, this right to an expedited review only exists with respect to hospital discharges (under sections 1154 and 1155 of the Act).

As discussed in detail below, CMS is unable to immediately implement some of these provisions for initial determinations made on or after October 1, 2002. The primary purpose of this Ruling is to discuss the progress we have made to date in implementing the various section 521 provisions, describe the criteria used to evaluate our ability to implement the provisions at this time, and explain which requirements will be implemented effective October 1, 2002. Additionally, it clarifies our policies with respect to the provisions that cannot be implemented by October 1, 2002, and provides notice of the administrative procedures that CMS contractors, ALJs and the Medicare Appeals Council (MAC) at the DAB will follow in processing Medicare claims appeals until we are able to fully implement the procedures set forth in section 521 of BIPA.

II. Implementation of the New Appeals Requirements

CMS is fully committed to improving the administrative appeals process by implementing section 521 of BIPA and we have made significant progress toward full implementation of BIPA section 521. Consistent with the statute, we recently issued a Program Memorandum to our carriers and intermediaries instructing them to implement the revised filing deadlines for requesting an appeal of a reconsideration or review and the lower amount in controversy requirement for Part B ALJ hearings. We have completed development of the Requests for Proposals needed to solicit bids for the QIC contracts, including full statements of work (SOWs) for these contracts. We are releasing the draft SOWs for industry comment simultaneously with issuing this CMS ruling. We are also completing development of the notice of proposed rulemaking (NPRM) needed to establish implementing regulations for the provisions contained in section 521 of BIPA, and we expect to release the NPRM this fall for public display and comment. Additionally, CMS is near completion of the first phase of a contract to develop a central appeals case tracking system, and is working on revising the various appeals forms. Finally, we have taken steps within the agency to ensure that our denial messages from the initial determination phase through to reconsideration, review and fair hearing levels are more informative to potential appellants.

Despite these efforts, however we believe it is in the public interest to implement only some of section 521's provisions beginning October 1, 2002. The primary reason is that the new appeals provisions require additional policy development that can be best accomplished through notice and comment rulemaking. Only with the issuance of final regulations can we achieve the uniformity and consistency needed for proper implementation of the BIPA 521 provisions. (See, for example, the Inspector General's January 2002 report: ''Medicare Administrative Appeals—The Potential Impact of BIPA'', OEI–04–01–00290, in which CMS'' auditors, the OIG, concur that immediate implementation of section 521 presents significant challenges due to large-scale structural changes and the lack of guidance or resources to ensure a smooth transition to the new system.) Among the key issues that have been identified by CMS and other observers as requiring additional policy guidance prior to implementation are:

• How CMS can balance its responsibilities to reduce Medicare fraud and abuse with the need to comply with the shorter BIPA time frames and escalation provisions.

• The proper amount-in-controversy threshold for QIC reconsiderations.

• The rules that should apply during the transition period to the new appeals system and whether it is possible or prudent to operate dual appeals systems depending on the date of an initial claim determination.

• Whether the existing availability of phone and in-person ''fair hearings'' can be accommodated under the new QIC reconsideration process.

• Whether and how CMS should be represented at the upper levels of the appeal process.

• How will case docketing, record keeping, case file management and transmission, and case effectuation responsibilities be divided between the existing contractors and the QICs.

• Who will conduct expedited determinations, how will the process work, and what if any financial protections will be involved.

Each year, more than 5 million Medicare claim appeals are filed with 54 CMS contractors—the FIs and carriers—and upper level appeals may be heard by any one of an estimated 1,000 SSA ALJs or by the MAC. The introduction of QICs into this process adds a new level of complexity, as the questions above demonstrate. As we transition to the new appeals process envisioned by BIPA, it is crucial that implementation be carried out uniformly and that our implementation plans be clear to the key stakeholders who will be affected by these changes in the claim appeals process, including not only the entities that adjudicate appeals, but also Medicare beneficiaries, providers, and suppliers. Attempting to resolve these types of issues and develop final regulations without public comment will clearly produce piecemeal public policy development. More importantly, it is unlikely to achieve the more efficient, more accurate appeals system that is the goal of the BIPA 521 provisions.

Thus, in view of the complex nature of the changes required by BIPA, we believe that it is essential to the public interest to carry out notice and comment rulemaking before implementing the new appeals provisions. This rulemaking effort is greatly complicated by the continuing uncertainty over resource availability and the possibility of further changes to the statutory appeals provisions. Moreover, we need to ensure that allocating scarce CMS resources to carry out this statutory mandate will not risk disruptions to other fundamental functions of the Medicare program, such as processing and payment of Medicare claims. Rather than risk disruptions to these core functions of the Medicare program, we believe that the more appropriate course is to continue to conduct appeals under the current system while simultaneously working toward effective BIPA implementation.

III. What Provisions Will Be Implemented on October 1, 2002?

While we cannot ignore the risks of proceeding directly to final regulations without public comment, CMS recognizes the urgent need for improvements to the Medicare claim appeals system. Additionally, we understand the benefits that the new appeals provisions afford to beneficiaries, providers, physicians and other suppliers of service. Therefore, we sought to determine the feasibility of implementing individual sections of 521 by evaluating each of the key BIPA provisions in terms of the following criteria:

• Do the new provisions fundamentally affect an individual's

right to appeal a denied claim, or do they primarily involve the applicable appeals procedures?

- Are the provisions clear and self-explanatory?
- Can the provisions be implemented by October 1, 2002, using existing CMS resources?
- Can the provisions be implemented appropriately under the existing appeals structure, that is, without the introduction of QICs into the administrative appeals process?
- In the short-term, will implementing a given provision on a stand-alone basis support, rather than undermine, Congress' statutory intent (and the Administration's shared goal) of producing more timely and accurate final decisions on Medicare claim appeals?

Our examination revealed three instances where all of these key questions could be answered affirmatively. Therefore, CMS will implement the following provisions on October 1, 2002:

We intend to implement the new 120-day deadline for filing requests for redeterminations, established under section 1869(a)(3)(C)(i). This change increases the existing 60-day deadline for requesting reconsiderations of Part A claims and decreases the 180-day deadline for requesting Part B reviews. This provision fundamentally affects an individual's right to appeal a denied claim, and its implementation is financially feasible. Therefore, CMS will implement these new filing deadlines for all initial determinations made on or after October 1, 2002 (*Note:* These deadlines do not apply to QIO determinations.)

We recognize that this change would establish a shorter deadline for Part B appeals, which could at least temporarily prove more difficult to meet for parties wishing to appeal Part B claims. We note though that it is generally in the best financial interest of an appellant to request an appeal and receive an appeal decision expeditiously. Also, particularly for beneficiary appellants, we believe that uniform appeals filing deadlines for Part A and B claims represents another positive aspect of this change. However, to alleviate any hardship associated with the possible need to gather documentation faster than in the past in order to comply with the new statutory filing deadlines, we are instructing CMS contractors, under these limited circumstances, to grant requests for extensions of up to 60 days in the filing deadline for Part B claims that are based on an explanation from the patient, provider, or supplier that the time was needed to gather the necessary supporting records.

Revised section 1869(b)(1)(E) specifies that the amount in controversy (AIC) threshold for requesting an ALJ hearing is $100, as opposed to the thresholds of $500 for Part B appeals and $200 for appeals of QIO determinations. It also stipulates the circumstances under which appellants may aggregate appeals to meet the AIC threshold. We believe that the reduced threshold is an unambiguous change that fundamentally affects an individual's right to appeal a denied claim. Therefore, CMS will implement the new amount in controversy requirements for Part B ALJ hearings and ALJ hearings for QIO initial determinations specified in section 521 of BIPA for initial determinations made on or after October 1, 2002. Contractors should continue to follow the existing instructions for aggregation of claims to meet the AIC threshold—thus the rules at 42 CFR 405.740 and 405.817 governing aggregation continue to apply. We note that the new statute does not establish an amount in controversy threshold for QIC reviews; and section 1842(b)(3), which was not repealed by section 521, sets a $100 AIC threshold for fair hearings. Thus, we believe it is appropriate to continue a $100 AIC threshold for carrier fair hearings.

Revised section 1869(a)(3) deals with redeterminations. Redeterminations under BIPA are to be conducted by the same CMS contractors that made the initial determinations. BIPA section 521 did not repeal either section 1816(f)(2)(A) or section 1842(b)(2)(B)(i), which currently set specific time frames for FI reconsiderations and carrier reviews, respectively. The general rules and limitations established under sections 1869(a)(3)(A) and (B) basically mirror current policy, for example, a contractor's review of the initial determination must precede a higher level appeal and that no redetermination may be made by an individual involved in the initial determination. Therefore, for initial determinations made on or after October 1, 2002, existing CMS contractors will continue to follow the provisions in sections 1816(f) and 1842(b) of the Social Security Act for both Part A reconsiderations and Part B reviews.

The remaining provisions in section 521 of BIPA, when evaluated using the criteria mentioned above, resulted in negative responses to all or most of the questions posed. We will discuss each of these below, in the order in which they appear in the revised section 1869 of the Act.

Section 1869(a)(2)(A) of the Act, as amended by BIPA, requires certain initial determinations to be concluded and notice provided no later than 45 days following receipt of the claim by the fiscal intermediary or carrier. Under the current process, providers are given 45 days to produce additional medical documentation. Thus, the imposition of a 45-day decision-making time frame creates substantial financial pressure on the existing medical review structure. Additionally, since providers, physicians, and other suppliers will receive significantly less time to respond to document requests, we believe that these entities will want an opportunity to comment on how these decision-making deadlines are to be implemented. Therefore, we will address this issue in the forthcoming proposed rule.

Section 1869(a)(3)(C)(ii) of the Act, as amended by BIPA, requires that all redeterminations of initial determinations made on or after October 1, 2002 be issued within 30 days. This reduction of the current timeframes established by sections 1816(f)(2) and 1842(b)(2) of the Act, creates a strain on the existing appeals structure and requires significant additional resources to implement. Given these considerations, we are unable to implement this requirement immediately. Instead, we will continue to hold contractors to the existing statutory standards in sections 1816(f)(2) and 1842(b)(2) of the Act, that is, 90 percent of Part A reconsideration decisions within 90 days, and 95 percent of Part B review decisions within 45 days.

Section 1869(b)(1) of the Act contains a series of new provisions concerning Medicare claim appeals, including the general rule under paragraph (b)(1)(A) that any individual who is dissatisfied with a redetermination decision can request a reconsideration of this decision by a QIC before proceeding to an ALJ hearing. As discussed in detail above, we do not believe it is feasible or consistent with other policy considerations to immediately implement this new level of appeal; thus we do not intend to introduce this change until QICs are in place to carry out these reconsiderations.

Sections 1869(b)(1)(B) and (C) address provider and supplier representation and assignment issues. To the extent that these provisions represent departures from existing requirements, we do not view them as self-explanatory and instead believe that they warrant notice and comment rulemaking before they can be implemented. Thus, we do not intend to make any changes in

existing regulatory appeal procedures based on these provisions effective October 1, 2002. The existing regulations regarding representation (at 20 CFR Subpart R, and 42 CFR 405.870 and 405.872) will continue in effect until full BIPA implementation.

Section 1869(b)(1)(D) addresses the time limits for filing upper level appeals. The statute charges the Secretary with establishing in regulations time limits for filing requests for ALJ hearings. We believe that the public, especially the beneficiary population, will want an opportunity to comment on the filing deadlines that will govern their ALJ hearing requests, and, therefore, we will address this issue in the forthcoming proposed rule.

Section 1869(b)(1)(F) establishes a new requirement for expedited determinations in the cases of individuals who are dissatisfied with provider decisions to terminate their care. There are many significant issues related to these new provisions, including who should conduct these determinations, to whom should these provisions apply, and related financial liability and notice requirements. Although Quality Improvement Organizations have performed a comparable function for hospital discharges for many years, the new expedited determination process is much broader in scope and will require substantial additional resources and new contractual obligations. We also believe that the beneficiary population and other stakeholders will be interested in commenting on any rules governing expedited determinations. In view of these considerations, we are unable to implement these provisions effective October 1, 2002. We will discuss these complex issues in detail in our upcoming proposed rule.

As the statute provides under section 1869(b)(1)(G), we also will establish through rulemaking guidelines with respect to the reopening and revision of initial determinations and reconsidered determinations.

Section 1869(c) sets forth a series of requirements for conducting QIC reconsiderations. Until the Secretary enters into contracts with these new entities, we are unable to implement these provisions. As noted above, we believe it would be impractical to begin the formal procurement process until we have reasonable assurances that we can allocate adequate resources to commit to these contractual obligations. To the extent that we are unable to commit to future contractual obligations, we believe that it would be impractical at this time to begin the formal contract procurement process, and thus expect private-sector entities to expend resources preparing their proposals. Thus, carriers will continue to conduct fair hearings in accordance with section 1869 of the Act, prior to its amendment by BIPA, and existing regulations.

Section 1869(d) of the Act sets forth the remaining substantive changes to the Medicare administrative appeals procedures. These changes all involve the procedures and deadlines for upper level appeals, that is, hearings before SSA ALJs, reviews by the MAC at the DAB, and judicial review. Like the provisions set forth under new section 1869(c), we believe that these new requirements are clearly premised on, and build upon, the conduct of a previous reconsideration by the new QIC entities. In fact, section 1869(d)(1) which contains the deadlines for ALJ hearings specifically states that the deadlines apply for a ''hearing on a decision of a qualified independent contractor.'' Similarly, section 1869(d)(2), which contains the deadlines on DAB proceedings, puts those deadlines in the context of ''decisions on a hearing described in paragraph (1)''—that is, reviews of ALJ hearings on decisions made by QICs.

Without QICs, there is no reasonable expectation that the new 90-day deadlines for ALJ and DAB decisions can be met. With fully operational QICs, on the other hand, working in concert with other systemic improvements envisioned by the statute (such as, an appeal-specific data base) there is reason to believe that the volume of Medicare claims decisions that will reach these upper levels of the appeals system can be significantly reduced—eventually making attainable the new deadlines established under section 1869(d).

Much like section 1869(c)(3)(C)(ii) of the Act, section 1869(d)(3) contains provisions concerning the consequences of a failure by an ALJ or the DAB to meet the new 90-day deadlines for decision-making. In brief, the statute gives an appellant the option of escalating a case to the next level of appeal, and also to Federal district court, if a decision is not issued within the prescribed timeframe. These decision-making deadlines are premised in statute on the sequential introduction of QICs, under section 1869(c). Without QICs, we do not believe that these deadlines can be met. Thus, as a practical reality, implementing these escalation provisions has the potential to result in cases escalating to Federal court without benefit of the record developed during an ALJ hearing. Under a worst case scenario, the prospect would exist of Federal courts being inundated by more than 10,000 cases that now are heard annually by the MAC, or of the introduction of an endless loop where cases are remanded from the courts to the MAC to the ALJs in search of a timely decision. We do not believe that these prospects are consistent with statutory intent or responsible government, and thus we do not believe that these escalation provisions can be implemented effective October 1, 2002. The next section of this ruling discusses how contractors will be expected to implement all aspects of this ruling, including how to deal with escalation requests.

IV. Responsibilities of Medicare Contractors Under This Ruling

Until QICs are established and final regulations to implement section 521 of BIPA are issued, Medicare contractors (that is, FIs, carriers, and QIOs) generally should continue to follow current practices, consistent with section 1869 of the Act prior to its amendment by BIPA, and consistent with existing regulations, in making initial determinations and carrying out Medicare claim appeals and reviews of hospital discharges. As explained in Section III of this Ruling, the only substantive changes to these provisions involve the new 120-day deadline for filing for carrier reviews or FI reconsiderations and the reduction of the AIC threshold to $100 for an ALJ hearing for the Part B claim determinations or QIO determination appeals process. Contractors should not implement other provisions contained in section 521 of BIPA until further notice.

If an FI receives a request for a QIC reconsideration of a Part A claim denial that has been upheld on the FI's reconsideration, the contractor should treat the request as a request for a hearing before an ALJ and process it accordingly. After following the appropriate processing requirements, contractors should retain a copy of the request onsite and mail a copy of the request to: BIPA Lead, CMS, Mail Stop S1–05–06, 7500 Security Boulevard, Baltimore, MD 21244. If a carrier or FI receives a request for a QIC reconsideration of a Part B claim denial that has been upheld on review, the contractor should treat the request as a request for a fair hearing, and process it accordingly. After following the appropriate processing requirements, contractors should retain a copy of the request onsite and mail a copy of the request to: BIPA Lead, CMS, Mail Stop

S1–05–06, 7500 Security Boulevard, Baltimore, MD 21244.

If a contractor receives a request to escalate an appeal to the ALJ hearing level (or the MAC level) because the contractor (or the ALJ) has not issued a timely decision on the appeal, the contractor should inform the appellant of the delay in implementation of the BIPA provisions, referencing this Ruling, and explain that the appeal will be processed under the existing appeals procedures. The contractor should note that the contractor (or the ALJ) will notify the appellant of its decision on the case and of any subsequent right the appellant may have to an ALJ hearing (or MAC review) on the decision. If the appellant makes such an appeal, a copy of the contractor's correspondence with the appellant should be sent to the ALJ (or the MAC), including a copy of the appellant's request for escalation.

If an ALJ or the MAC requests case files from a contractor in order to process a request to escalate an appeal, the contractor should notify the ALJ or the MAC, in writing, that the case file is currently being used to process a request for appeal at the review, reconsideration or fair hearing level, as appropriate. In that situation, contractors should indicate that the case file will be transmitted when the carrier, FI or hearing officer completes its review. Contractors should retain a copy of the request onsite and mail a copy of the request to: BIPA Lead, CMS, Mail Stop S1–05–06, 7500 Security Boulevard, Baltimore, MD 21244.

Finally, QIOs should continue to review hospital discharges in accordance with §§ 1154(a) and 1154(e) of the Act, with respect to time frames and financial liability.

Authority: Section 1154, 1869, and 1879 of the Social Security Act (42 U.S.C. 1395ff) and section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 12, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–25351 Filed 10–1–02; 4:05 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of New System

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of new System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records, called the ''Privacy Accountability Database (PAD),'' HHS/CMS/OIS No. 09–70–0540. The primary purpose of the system of records is to aid CMS in tracking, reporting, and accounting the disclosures made from all CMS system of records as permitted by the Privacy Act of 1974 and The Health Insurance Portability and Accountability Act of 1996 (HIPAA). Information retrieved from this system of records will be used to support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; support constituent requests made to a Congressional representative; and support litigation involving the agency.

We have provided background information about the proposed system in the **SUPPLEMENTARY INFORMATION** section, below. Although the Privacy Act requires only that the ''routine use'' portion of the system be published for comment, CMS invites comments on all portions of this notice. See ''Effective Dates'' section for comment period.

EFFECTIVE DATES: CMS filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on September 19, 2002. In any event, we will not disclose any information under a routine use until forty (40) calendar days after publication. We may defer implementation of this system of records or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comments to: Director, Division of Data Liaison and Distribution (DDLD), CMS, Room N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Kimberly Elmo, Division of Data Liaison and Distribution (DDLD), CMS, Room N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

SUPPLEMENTARY INFORMATION:

I. Description of the New System of Records

A. Statutory and Regulatory Basis for System of Records

42 CFR 401.101–401.148 and 1106(a) of the Social Security Act, 42 U.S.C. 1306(a), 45 CFR 552a(c) of the Privacy Act and 45 CFR 164.528 of the Health Insurance Portability and Accountability Act.

B. Background

CMS administers the Medicare, Medicaid, and the State Children's Health Insurance Program to accomplish its mission of ensuring health care security for beneficiaries. Accordingly, CMS possesses the nation's largest collection of health care data (consisting of over 60 system of records), with information on over 74 million Americans. Having in place adequate electronic and procedural controls to address confidentiality will protect this personally identifiable data.

Data files consisting of personally identifiable data are disclosed to various entities. These disclosures fall under exceptions of the Privacy Act, routine uses of the applicable system of record or are permitted by HIPAA. Privacy legislation requires CMS to track disclosures from each individual system of records. The PAD will provide the necessary tracking, reporting and accounting capabilities that CMS must have in place to be in compliance with the Privacy Act of 1974 and HIPAA.

II. Collection and Maintenance of Data in the System

A. Scope of the Data Collected

The PAD will contain information on disclosures of CMS data that fall under exceptions of the Privacy Act; routine uses of the applicable system of record or permitted by HIPAA that require tracking. This system may also contain the Medicare Health Insurance Claim Number, Social Security Number, or Railroad Retirement Board Number and a PAD tracking number for Medicare beneficiaries whose CMS data have been disclosed.

The PAD will be implemented in phases. The initial fielding, scheduled to coincide with the April 14, 2003