PRA RESPONSE DOCUMENT:

Summary:

The Centers for Medicare & Medicaid Services (CMS) received a number of comments on the material published in support of the August 1, 2008, Federal Register (FR) Notice (CMS-10265 at 73 FR 45013). This Notice is a "...summery of proposed collections for public comment," more commonly referred to as a Paperwork Reduction Act (PRA) Notice. The supporting information for the PRA Notice is titled "Supporting Statement for the Medicare Secondary Payer (MSP) Mandatory Insurer Reporting Requirements of Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (P.L. 110-173). See 42 U.S.C. 1395(b)(7) and (8)." The Supporting Statement can be found through the link published in the August 1, 2008, PRA FR Notice and as a download on CMS' dedicated web page for Section 111 MSP Reporting at http://www.cms.hhs.gov/MandatoryInsRep/.

Comments on the August 1, 2008, PRA package and CMS' responses are labeled as either "GHP," "NGHP," or "GHP/NGHP". GHP is used for comments and responses relating to reporting for Group Health Plan arrangements. NGHP is used for comments and responses relating to Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Worker's Compensation. (Liability Insurance (including self-insurance), no-fault insurance, and workers' compensation are sometimes referred to collectively as Non-GHP or NGHP.)

The information originally published regarding data elements in Attachments C and D for the Supporting Statement was relatively general and abbreviated. Subsequent to the issuance of the PRA Notice on August 1, 2008, CMS issued the GHP User Guide as well as an Interim Record Layout document for NGHP. To the extent that these documents contain information which already covers comments received on the PRA Notice and supporting documents, CMS' responses to various comments refers the reader to these documents. Copies of these two documents are available as downloads through the link provided at http://www.cms.hhs.gov/MandatoryInsRep/. **Note:** All official CMS instructions for implementation of Section 111 reporting are being disseminated through CMS' dedicated web page (www.cms.hhs.gov/MandatoryInsRep) as either an article on the web page or as a download from the web page. The GHP User Guide and the NGHP Interim and Final User Guides for RREs will continue to be updated. The public is advised to consult the dedicated web page for the most recent version of all documents and instructions.

I. GHP and NGHP:

Comment: GHP and NGHP Section 111 Burden -- Staff Cost Estimates.
A number of comments argued that the hourly wage for support staff that CMS used to estimate the personnel costs that will be generated by compliance with Section 111 reporting (including data collection and analysis, the preparation of working documents, business process programming, etc.), is greatly underestimated. Other comments suggested that the implementation costs to both the government and the insurance industry should be re-estimated based on more realistic cost estimates provided by the commenters, that gathering

the extensive list of data required would cost far more than CMS projects, and that CMS has underestimated the amount of time required to gather and process the required data.

Response: GHP and NGHP Section 111 Burden – Staff Cost Estimates.
The CMS used personnel rates made available to Federal agencies for such estimates. Additionally, CMS used its and other agencies' experience in developing comparable programs and systems as part of CMS' estimate. The CMS acknowledges that experience with the implementation of Section 111 reporting may show some cost estimates to have been too low (and some to have been too high), and the agency will incorporate the new information in future program cost estimates.

Comment: GHP and NGHP Section 111 Burden -- Business Process Cost Estimates.
One comment suggested that CMS did not correctly estimate the volume of information that NGHP Responsible Reporting Entities (RREs) will be required to report, and that, as a consequence, reporting what is required will be unduly burdensome. Other comments questioned the utility of individual data elements. Additionally, there were a large number of comments that CMS had greatly underestimated the number of potential NGHP RREs, and that the much larger number of potential reporters would place unanticipated additional costs and technical burdens on CMS and on its COBC contractors.

Response: GHP and NGHP Section 111 Burden -- Business Process Cost Estimates.
The CMS acknowledges that if an RRE has not reported MSP data previously, new participation in a reporting process will require new resource allocations by the RRE. In response to comments about the utility of individual data elements CMS, as reported elsewhere, has reduced the number of data elements required for NGHP reporting, and will phase in the reporting of others. We believe these steps will help reduce business process costs and reporting burdens for NGHP RREs. Although comments indicating that CMS has underestimated the potential number of NGHP RREs are essentially outside the scope of the PRA and its Supporting Statement, CMS appreciates having received them. In response, CMS has reexamined its estimates of potential NGHP reporters and has taken steps both to manage a larger number of input files than originally estimated, and to strengthen its systems that will support the activities of the NGHP RREs.

Comment: GHP and NGHP – Existing Obligations Pursuant to the Medicare Secondary Payer Provisions.
Several comments asked how the new MMSEA provisions at 42 U.S.C. 1395y(b)(7) & (8) relate to existing MSP provisions. Others indicated their belief that the MMSEA provisions changed some of the existing MSP law and regulations.

Response: GHP and NGHP – Existing Obligations Pursuant to the Medicare Secondary Payer Provisions.
The amendments added by 42 U.S.C. 1395y(b)(7) & (8) are distinct from and in addition to existing MSP requirements. They do eliminate or alter any of those requirements. For example:

- Beneficiaries (and/or their representatives) who are involved in liability insurance (including self-insurance), no-fault insurance, or workers' compensation matters

should continue to self-identify such situations to CMS' COBC. CMS cannot begin to develop a conditional payment amount until it receives this information.

- Multi-employer/Multiple Employer GHPs (or their authorized insurer) will continue to be responsible for applying for the Small Employer Exception for the working aged if the plan wishes to be granted this exception for specified Medicare beneficiaries for specific employers.
- Obligations set forth in the applicable regulations at 42 CFR. Part 411, including 42 CFR 411.22 and 411.25 still apply.

Comment: GHP and NGHP – Compliance.
CMS received a number of questions concerning compliance with the requirements of Section 111. Almost all fell into these general categories: What places an RRE at risk of noncompliance? What is the process for the imposition of penalties? May the RRE to be held harmless for any data element it is unable to obtain? Is there a standard of substantial compliance, or of "good faith effort?"

Response: GHP and NGHP – Compliance.
CMS is currently in the process of developing the body of information that will answer these and similar questions. CMS will publish that information on http://www.cms.hhs.gov/MandatoryInsRep/ when those procedures have been finalized. But in this context, we do wish to state that CMS' primary focus is quality reporting for 42 U.S.C. 1395y(b)(7) & (8).

Comment: GHP and NGHP – Record Retention.
Several comments expressed concern about the CMS recommended ten (10) year record retention period mentioned in the original Supporting Statement.

Response: GHP and NGHP – Record Retention.
The provisions at 42 U.S.C. 1395y(b)(7) & (8) impose no new or specific record retention requirements. With the recommendation, CMS only intended to raise awareness of various other statutory provisions that RREs may wish to take into consideration in determining how long they will maintain their records. Nonetheless, CMS has removed any statement regarding record retention from the revised Supporting Statement.

II. GHP Only

Comment: GHP – General Rules for the use of Agents for Section 111 reporting.
A number of comments expressed confusion regarding the authority of agents, as well their scope of responsibility.

Response: GHP – General Rules for the use of Agents for Section 111 reporting.
General rules regarding the use of agents for Section 111 reporting are set forth below. These will be included in an updated version of the GHP User Guide at a later date.

- Agents are not Responsible Reporting Entities (RREs) for purposes of the MSP reporting responsibilities for 42 U.S.C. 1395y(b)(7) & (8). However, the applicable RRE may contract with an entity to act as an agent for reporting purposes.

- Agents may include, but are not limited to, data service companies, consulting companies or similar entities that can create and submit Section 111 files to the COBC on behalf of the RRE.

- Registration for reporting and file submission with the COBC must be completed by the RRE. During registration, the RRE may designate an agent. An agent may not register on behalf of an RRE.

- An RRE may not shift its Section 111 reporting responsibility to an agent, by contract or otherwise. The RRE remains solely responsible and accountable for complying with CMS instructions for implementing Section 111 and for the accuracy of data submitted.

- CMS does not sponsor or partner with any entities that can be agents. CMS has not and will not endorse any entity as an agent for Section 111 reporting purposes and has no approved list of agents. Entities that are potential agents do not register with CMS or pay CMS a fee in order to become an agent.

Comment: GHP – General File Submission Rules for Section 111 Reporting.
Some comments indicated confusion regarding what an RRE may or may not combine when submitting files.

Response: GHP – General File Submission Rules for Section 111 Reporting.
General file submission rules are set forth below. These will be included in an updated version of the GHP User Guide at a later date.

- CMS' COBC will be responsible for the technical aspects for reporting and for the management of all file submissions.

- RRE GHP file submissions may not be mixed with RRE NGHP (liability insurance [including self-insurance], no-fault insurance, and workers' compensation) file submissions.

- An RRE may arrange for multiple submissions within the same submission window. The COBC will accommodate such requests where feasible from a COBC workload standpoint.

- An agent may not mix data for multiple RRE clients in the agent's file submission. (However, CMS is working on a process that would permit an agent to submit information on multiple RRE clients in a single file submission through the use of RRE specific headers/trailers. Please note that this process still would not allow an RRE to submit NGHP and GHP records in the same file.)

- Each registered RRE will be assigned a COBC EDI representative (EDI Rep). The EDI Rep will manage all testing and production file exchanges.

- All reporting is to be through electronic file exchanges. CMS presently has no plans for direct data entry by RREs. (RREs who believe that their volume is too small to report electronically directly may wish to contract with an agent for file submission.)

Comment: GHP – Reporting Age Threshold

Several respondents asked why GHP Responsible Reporting Entities (RREs) were being required to report all individuals age 45 and older who are covered by group health plans. A number of respondents remarked that reporting all active covered individuals age 45 and older would be a significant administrative and technical burden.

Response: GHP – Reporting Age Threshold

CMS has required a "reporting age threshold" in other data exchange programs and will continue to do so with Section 111 GHP RRE reporting. MSP law and regulation require that GHP RRE reporters provide CMS with information about all active covered individuals (and dependents) who are also Medicare beneficiaries or who the RRE should know are Medicare beneficiaries. Oftentimes an RRE may not be aware that an active covered individual (or dependent) is also a Medicare beneficiary. If an RRE reports all active covered individuals above a certain age to CMS the likelihood of identifying the majority of covered Medicare beneficiaries the RRE should know about is greatly increased.

Many large insurers argue that the CMS requirement for reporting all active covered employees age 45 and above could conceivably produce millions of input records in order to identify relatively few previously unknown Medicare beneficiaries. CMS believes that this is a concern with some validity. A number of insurers have suggested that CMS permit use of an initial input "finder" file through which CMS would identify any Medicare beneficiaries, and return these positive identifications to the sending RRE. The RRE could then submit standard input files to include all identified Medicare beneficiaries.

In response to these "age threshold" concerns, CMS will make the "finder file" option available to GHP RREs. However, CMS points out that use of a "finder file" is not a foolproof method of identifying all active covered individuals that should be reported. CMS believes that use of a finder file is functionally less precise than routine reporting of all Active Covered Individuals above a particular age. Consequently, use of the "finder file" option may increase an RRE's probability of underreporting all active covered individuals who are Medicare beneficiaries, including spouses and dependents, putting the RRE in jeopardy of noncompliance with the Section 111 reporting requirements. This possibility should be carefully weighed by any RRE considering the "finder file" reporting option.

In further response to these "age threshold" concerns, CMS will allow RREs that do not use the "finder file" option to use an age reporting threshold starting at age 55 through December 31, 2010. However, starting January 1, 2011, all GHP RREs will use the age 45 reporting threshold.

Comment: GHP – Data Elements and Definitions

During the first Section 111 PRA Comment Period, the current Section 111 GHP User Guide was not available for review. Many of the comments and suggestions CMS received regarding the RRE GHP data elements and definitions were generated based on the limited information available to respondents at the time.

Response: GHP – Data Elements and Definitions

The first version of the Section 111 GHP User Guide was posted on October 14, 2008, and in the period since we have received assurances that many of the original questions raised about data elements and definitions have been answered.

Those that appear to have been adequately addressed through the information now available in the Section 111 GHP User Guide (and other more recently posted documents) can be sorted into the following categories: Further clarification of the data elements, such as Transaction Type; data element definitions including Late Submission Indicator and Document Control Number; and conventions for describing data values. If you had a question or comment about any of these subjects we believe you are already aware that you can find the answer in the Section 111 GHP User Guide.

Comment: GHP – Discrepancy Resolution

An inquiry was received concerning how CMS will resolve discrepancies between data obtained and reported by RREs on the GHP MSP Input File and data reported by the COBC on the GHP MSP Response File.

Response: GHP – Discrepancy Resolution

In the case of the key beneficiary identifiers, consisting of SSN or HICN, first name, last name, date of birth and gender, used to determine if the individual submitted is a Medicare beneficiary, CMS utilizes enrollment data received from the Social Security Administration.

For CMS to confirm an individual's Medicare entitlement, the following minimum set of data elements must be submitted by the RRE: the individual's HICN or SSN, plus the following personal information: (1) the first initial of the first name; (2) the first 6 characters of the last name; (3) the date of birth; and (4) gender. Three of the four personal information data elements must match to a corresponding SSN or HICN, or it is not considered a match by the system. When CMS determines that there is a match to an

existing Medicare beneficiary, on the response record CMS will update any non-matching personal information it received on the input record. If an RRE disputes this corrected personal information, only the Medicare beneficiary can update this information with the Social Security Administration, which would then send updates to CMS.

In the case of disputed or other conflicting coverage information received from other sources or other RREs, CMS is discussing the development of an internal hierarchy which would resolve conflicting information. RREs will be notified if beneficiary information they report is updated by other information received by the COBC.

Comment: GHP – Reporting Requirements

During the first Section 111 PRA Comment Period the current Section 111 GHP User Guide was not available for review. Many of the comments and suggestions CMS received regarding the RRE GHP data reporting requirements were generated based on the limited information available to respondents at the time.

Response: GHP – Reporting Requirements

The first version of the Section 111 GHP User Guide was posted on October 14, 2008, and in the period since we have received assurances that many of the original questions raised about reporting requirements have been answered.

Those that appear to have been adequately addressed through the information now available in the Section 111 GHP User Guide (and other more recently posted documents) can be sorted into the following categories. What is the definition of Group Health Plan for reporting purposes; when will the file layouts be available; what TINs or EINs are to be reported, and how are they to be reported; how is employer size counted; are there separate GHP and NGHP reporting requirements; is employer VDSA reporting different from Section 111 reporting; how will the COB Secure Website (COBSW) function; and what are the rules for registering through the COBSW. If you had a question or comment about any of these subjects we believe you are already aware that you can find the answer in the Section 111 GHP User Guide.

Comment: GHP - Changing From Basic to Expanded Data File Exchanges

A number of respondents asked if RREs would be permitted to change from the Basic data file exchange Reporting Option to the Expanded Reporting Option after they were in production data exchange status.

Response: GHP - Changing From Basic to Expanded Data File Exchanges

CMS would encourage such a change. Please note, however, that an RRE switching from the Basic to the Expanded Reporting Option will have to test the Expanded Option reporting process before production file exchanges can begin.

Comment: GHP - FSAs, HSAs, HRAs

We received a number of comments and questions regarding whether Flexible Savings Accounts (FSAs), Health Savings Accounts (HSAs), and Health Reimbursement Accounts (HRAs) qualify as GHP coverages under Section 111.

Response: GHP - FSAs, HSAs, HRAs

Following we provide short definitions of these types of health care payment plan options in relations to Section 111 reporting. We suggest interested parties consult other HHS and IRS materials for in-depth discussions of these options.

- A Flexible Savings Account product is not considered to be GHP coverage for MSP purposes. RREs are not required to include FSA programs in Section 111 reporting.
- A Health Savings Account is typically associated with a high deductible GHP product. Under current law, Medicare beneficiaries may not make further contributions to the savings portion of an HSA, although they retain access to previous contributions, both their own and those made by an employer. The CMS will not consider HSAs to be reportable under Section 111 as long as Medicare beneficiaries may not make a current year contribution to an HSA. However, if the law should change to allow such contributions, HSAs may be reportable.

- The CMS considers a Health Reimbursement Account to be a GHP product for MSP purposes. RREs are required to include HRA programs in Section 111 reporting.

CMS notes that while the Medicare Part D program may treat certain of these coverage arrangements as if they were GHP products, for Section 111 MSP reporting RREs should be guided by the descriptions above.

Comment: GHP – Taft-Hartley Multiple Employer/Multi-Employer plans

We received a number of comments expressing concern that CMS had not adequately addressed how Section 111 should be done for certain multiple employer/multi-employer plans (typically Taft-Hartley plans using an “hours bank” arrangement) covering individuals who routinely work for multiple employers in a single Section 111 reporting period.

Response: GHP – Taft-Hartley Multiple Employer/Multi-Employer Plans

For Taft-Hartley plans, GHP RREs should report the name, address, and EIN/TIN of the plan sponsor rather than the employer in the fields indicated for employer information. So that CMS can identify such situations, the RRE must place the following designation “(PS)” after the name of the plan sponsor in the employer name field.

Comment: GHP – Data Submission Consideration

A correspondent suggested that there are only a limited number of claims involving Medicare beneficiaries that are actually processed, that being required to send data on all beneficiaries would be burdensome, and that the reporting requirement should apply only to beneficiaries that have had paid claims within a prescribed reporting period.

Response: GHP – Data Submission Consideration

CMS replies that processing COB information after a claim has been paid is not consistent with the MSP requirement to establish correct payment order prior to claims processing.

Comment: GHP – Reporting of Medicare Advantage Organization Information

A number of respondents asked whether COB data originating with Medicare Advantage Organization (MAO) plans is reportable under Section 111 requirements.

Response: GHP – Reporting of Medicare Advantage Organization Information

An MAO plan is not a GHP for Section 111 reporting. MAO program management data (including COB data) will continue to be reported and processed using the established procedures already in place.

Comment: GHP - COBRA Coverage

A number of respondents asked if a Medicare beneficiary receiving ongoing GHP coverage through the COBRA program was to be reported by the RRE.

Response: GHP - COBRA Coverage

With one exception, coverage through COBRA is not considered GHP coverage. The exception involves active dialysis treatment or has had a kidney transplant. To the extent COBRA coverage overlaps the 30-month ESRD MSP coordination period, Medicare is secondary payer for benefits that a GHP is required to keep in effect under the COBRA continuation requirements where Medicare entitlement occurs first.

Except for this one exception, an RRE will not report on beneficiaries if the beneficiary has coverage through the COBRA program.

Comment: GHP – "Stand Alone" Dental and Vision Care Coverage

We received a number of questions about how – or whether – RREs should report dental and vision case insurance that is often provided in conjunction with GHP coverage.

Response: GHP – "Stand Alone" Dental and Vision Care Coverage

Routine dental services, and dentures, are not covered benefits in the Medicare program although Medicare does cover inpatient hospital services required in dental services.

"Routine" vision care is also not a covered Medicare benefit, although Medicare does cover periodic eye exams to check for the presence of diabetic retinopathy and will pay for one pair of glasses after one particular type of cataract surgery. When offered as "stand alone" products, dental and vision care GHP coverage will not be subject to Section 111 GHP reporting. However, RREs are responsible for being aware of situations where dental or vision care services *are* covered by Medicare and paying primary, where appropriate, for all active covered individuals who have such stand alone coverage.

Comment: GHP – Other Benefit Coverage Variations

One respondent asked if a number of other coverage types are to be included in Section 111 reporting. The list included stand alone (a) outpatient prescription drug coverage; (b) reimbursements for deductibles and coinsurance; (c) and fixed hospital indemnity (payment) or other limited benefit fixed indemnity coverages.

Response: GHP – Other Benefit Coverage Variations

To the extent that such coverages are part of the package of benefit coverages sponsored by or contributed to by an employer, they are subject to all MSP rules, including reporting for purposes of 42 U.S.C. 1395y(b)(7) unless otherwise specifically exempted.

Comment: GHP – Timeline Information and Questions

A number of commenters asked questions about the timeline for implementing the Section 111 reporting requirements.

Response: GHP – Timeline Information and Questions

These issues are addressed in the Section 111 GHP User Guide and in the "Implementation Timeline." Both documents have been available on the dedicated Section 111 Website for a number of months. If you had a question or comment on this subject, it should be covered in these two documents. There are two specific categories of subject area comments, however, that CMS will address here.

Time to Collect and Report SSNs: Many respondents suggested that the required collection of SSNs for certain active covered individuals would take more time than seemed to be available prior to the start of reporting. CMS agrees, and has structured the reporting process to permit additional time to gather the required SSNs. Please see the Section 111 GHP User Guide for more information. It can be found at http://www.cms.hhs.gov/MandatoryInsRep/.

Compliance Timeline Extensions: Given that Section 111 reporting will be a new process for many RREs, a number of respondents suggested extending the overall timelines established for RREs to move into Section 111 reporting. CMS is permitting longer timeframes for the gathering and reporting of certain data elements. However, in

order to adhere to the mandates that are the core of Section 111 CMS believes it cannot alter the general reporting timelines and schedules already established. Detailed information on this subject is also in the Section 111 GHP User Guide.

III. NGHP Only

Comment: NGHP -- Who is the Responsible Reporting Entity (RRE).
A number of comments asked for clarification on exactly who/what entity is the RRE for purposes of 42 U.S.C. 1395y(b)(8) in various situations.

Response: NGHP -- Who is the Responsible Reporting Entity (RRE).
CMS is aware that for NGHP, an accident/illness/injury may involve multiple types of coverage and may involve multiple insurers and/or workers' compensation. Consequently, CMS has addressed the issue of "who is the RRE" in various situations in the "Interim Record Layout for Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers' Compensation" (which is available as a download on CMS' dedicated web page at www.cms.hhs.gov/MandatoryInsRep). This record layout document was not available at the time the PRA Notice and supporting documents were published in the Federal Register on August 1, 2008. Please refer to this document for specifics on who/what entity is the RRE in various situations such as stop loss insurance, multiple defendants, insurance guaranty funds, etc.

Comment: NGHP – General Rules for the use of Agents for Section 111 reporting.
A number of comments expressed confusion regarding the authority of agents, as well their scope of responsibility.

Response: NGHP – General Rules for the use of Agents for Section 111 reporting.
CMS is aware of the need for clarity regarding the use of agents for Section 111 reporting purposes. General rules for the use of Agents for Section 111 reporting are available in the "Interim Record Layout for Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers' Compensation" (which is available as a download on CMS' dedicated web page at www.cms.hhs.gov/MandatoryInsRep). This record layout document was not available at the time the PRA Notice and supporting documents were published in the Federal Register on August 1, 2008. Please refer to the section on general rules for agents in the record layout document.

Comment: NGHP – General File Submission Rules for Section 111 Reporting.
Some comments indicated confusion regarding what an RRE may or may not combine when submitting files.

Response: NGHP – General File Submission Rules for Section 111 Reporting.
General file submission rules were developed in connection with developing the User Guide for liability insurance (including self-insurance), no-fault insurance, and workers' compensation Section 111 reporting. There is a section addressing these rules in the "Interim Record Layout for Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers' Compensation" (available as a download on CMS' dedicated

web page at www.cms.hhs.gov/MandatoryInsRep), which was not available at the time the PRA Notice was published on August 1, 2008.

- An NGHP RRE may include liability insurance (including self-insurance), no-fault insurance, and workers' compensation files in a single submission if it has responsibility for multiple lines of business; however, there is no requirement to do so.

- An NGHP RRE is to report the assumption or termination of "ongoing responsibility" situations along with the reporting of payments where ongoing responsibility is not assumed.

- The number of submissions per quarter made by a particular NGHP RRE will be a consequence of how many lines of business it chooses to report separately; for a GHP RRE the number of submissions per quarter will be dependent upon how the RRE wishes to split its client base. An RRE may register separately for different lines of business and/or different client bases (including identifying a different agent for data submission for each registration). This could include registering at the parent company level vs. registering at a subsidiary level.

Comment: NGHP -- Definitions and Data Elements.
Comments asked for definitions of the General list of data elements provided in Attachments C and D to the Supporting Statement for the PRA Notice published on August 1, 2008. Comments also inquired why certain data elements were being required or disputed the need for certain data elements and questioned some of CMS' definitions.

Response: NGHP -- Definitions and Data Elements.
The "Interim Record Layout for Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers' Compensation" (which is available as a download on CMS' dedicated web page at www.cms.hhs.gov/MandatoryInsRep) was not available at the time the PRA Notice and supporting documents were published in the Federal Register on August 1, 2008. Please refer to the record layout document for detailed information regarding NGHP definitions and data elements.

With respect to comments which disputed the need for certain data elements:

- The applicable statutory provision at 42 U.S.C. 1395y(b)(8) provides for information necessary for coordination of benefits, including information necessary for MSP recoveries. Consequently, the required data elements include information necessary for CMS to pursue recoveries as well as information necessary for claims processing. The reporting obligation under 42 U.S.C. 1395y(b)(8) is not limited to placing CMS on notice of an actual or potential situations involving liability insurance (including self-insurance), no-fault insurance, or workers' compensation. CMS is limiting required data elements to those it requires for coordination of benefits, including claims payment purposes and recovery actions.

- After further consideration, CMS has eliminated some of the data elements originally listed in Attachment D to the Supporting Statement for the PRA Notice issued August 1, 2008. Additionally, CMS will permit free form text for a description of the incident/alleged harm until file submissions starting with the first calendar quarter in 2011. Finally, CMS is delaying implementing certain required data elements. CMS continues to evaluate the data elements required for product liability situations.

- CMS is aware that industry definitions differ from certain of CMS's definitions. However, CMS is constrained by the applicable statutory and regulatory definitions. The statutory language in 42 U.S.C. 1395y(b)(8) must be used in conjunction with the definitions set forth in "Attachment A -- Definitions and Reporting Responsibilities" to the Supporting Statement for the PRA Notice, particularly in determining who is a Responsible Reporting Entity for purposes of Section 111. (The definitions in Attachment A also provide further citations to MSP statutory provisions and applicable regulations.) Although comments expressed concern about CMS' definition of the term "Date of Incident" because some state and federal laws have a different definition for their programs, CMS is retaining its definition because it is must be used for purposes of determining its MSP recovery claim. Please note that the definition routinely used by the insurance industry/workers' compensation only differs from CMS' definition where the incident involves exposure, ingestion, or implantation. Finally, although CMS is aware that certain of the insurers/workers' compensation entities do not specifically track some of the required data elements, CMS is retaining those it requires to fulfill its MSP responsibilities.

Comment: NGHP – What Triggers Reporting.
There were a number of questions and comments regarding when an RRE is to report. The areas in question included whether or not a specific type of insurance is required to be reported, the frequency of reporting with respect to a particular Medicare beneficiary, the possibility of duplicative reporting by RREs, whether or not there is an age threshold for reporting purposes, whether or not the geographic location of the incident or the date of the incident affects the necessity of reporting, etc.

Response: NGHP – What Triggers Reporting.
CMS recognized the need for more detailed information regarding "what triggers NGHP reporting" because coverage for liability insurance (including self-insurance), no-fault insurance, and workers' compensation situations is incident specific rather than the type of ongoing coverage provided by GHP coverage. CMS has addressed this in some detail in the "Interim Record Layout for Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers' Compensation" (which is available as a download on CMS' dedicated web page at www.cms.hhs.gov/MandatoryInsRep). This record layout document was not available at the time the PRA Notice and supporting documents were

published in the Federal Register on August 1, 2008. Please refer to this document for specifics on "what triggers NGHP reporting."

Comment: NGHP – Privacy/Confidentiality.
Comments expressed concern about the interplay of state vs. federal law, confidentiality of data, the release of alleged proprietary information, the release of information subject to a confidentiality agreement agreed to by the parties, the use of reported data for other governmental purposes, and the possibility of being sued for reporting the required data.

Response: NGHP – Privacy/Confidentiality.
For a settlement involving a Medicare beneficiary, no party may legally agree to a confidentiality agreement limiting the release of information related to coordination of benefit issues with Medicare (see 42 CFR 411.23 and 411.24). Federal law supersedes state law where the state law in question would prohibit the reporting of the required data.

In terms of privacy issues, all CMS contractors are HIPAA compliant. For HIPAA purposes, CMS has worked to require only the minimum data elements necessary to fulfill its responsibilities. Finally, CMS will work with the industry to determine which, if any, of the required data elements should be considered proprietary and any limits on further release for any data elements that CMS agrees are proprietary.

Comment: NGHP – Out of Scope.
Numerous comments were received relating to CMS' MSP recovery processes. Such comments ranged from suggesting a new process to questions regarding Medicare set-aside arrangements, as well specific questions regarding the existing recovery processes (including how CMS will reconcile the data received through the mandatory reporting with data received from other sources). There were also comments which referenced possible reporting obligations with respect to Medicaid.

Response: NGHP – Out of Scope.
All of the above-referenced areas are outside of the scope of the PRA Notice for 42 U.S.C. 1395y(b)(7) & (8).