

Complainant alleges that the goods were loaded on a Wan Hai Lines (Singapore) PTE Ltd. ("Wan Hai") vessel, under a Wan Hai bill of lading naming Henan Huatai as Shipper, and Complainant as Consignee; and that the cargo arrived at the port of discharge, Long Beach, CA, mid-June 2008. Complainant further alleges that it paid the full amount of the ocean freight and other charges to Wan Hai. Complainant claims that Shipper, Henan Huatai, went out of business in June 2008, and Respondent, acting as a freight forwarder in China on behalf of the Shipper, is unlawfully holding the original bill of lading, alleging debts owed by Shipper to Respondent.

Complainant alleges that Respondent's refusal to provide the original bill of lading to Complainant, unless Complainant paid to Respondent the amount owed by the Shipper, constitutes an unreasonable regulation or practice related to the delivery of property in violation of 46 U.S.C. 41102(c) (formerly § 10(d)(1) of the Shipping Act of 1984). Complainant claims injury in the form of demurrage charges in the amount of \$16,944.00; loss of its funds held in an escrow account required by Wan Hai in the amount of \$47,801.42; and liquidated damages imposed by Wal-Mart for lost sales in the amount \$106,115.00; for a total of \$170,860.42, with liquidated damages continuing to accrue.

Complainant requests that the Commission issue as relief, an Order: (1) Compelling Respondent to answer the charges in the subject complaint, and scheduling a hearing in Washington, DC; (2) finding that Respondent's activities were unlawful and in violation of the Shipping Act; (3) compelling Respondent to pay reparations of \$170,860.42 plus interest, costs, and attorney's fees; and (4) requiring Respondent to provide Complainant with the original bill of lading to allow Complainant to secure release of its escrow deposit from Wan Hai and stop other liquidated damages from accruing. Additionally, Complainant requests that the Commission issue further relief as it deems just and proper.

This proceeding has been assigned to the Office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper

showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by August 26, 2009, and the final decision of the Commission shall be issued by December 24, 2009.

**Karen V. Gregory,**

*Assistant Secretary.*

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**BILLING CODE 6730-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Common Formats for Patient Safety Data Collection and Event Reporting

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), DHHS.

**ACTION:** Notice of Availability—Common Formats for Safety Data Collection and Event Reporting.

**SUMMARY:** The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) provides for the formation of Patient Safety Organizations (PSOs), which would collect and analyze confidential information reported by healthcare providers. The Patient Safety Act (at 42 U.S.C. 299b-23) authorizes the collection of this information in a standardized manner, as explained in the related Notice of Proposed Rulemaking published in the **Federal Register** on February 12, 2008: 73 FR 8112-8183. As requested by the Secretary of DHHS, AHRQ has coordinated the development of a set of common definitions and reporting formats (Common Formats) which would facilitate the voluntary collection of patient safety data and reporting of this information to PSOs. The purpose of this notice is to announce the initial release of the Common Formats, Version 0.1 Beta, and the process for development of future versions.

**DATES:** Ongoing public input.

**ADDRESSES:** The Common Formats can be accessed electronically at the following Web site of the Department of Health and Human Services: <http://www.pso.ahrq.gov/index.html>.

#### FOR FURTHER INFORMATION CONTACT:

Susan Grinder, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: [psoc@ahrq.hhs.gov](mailto:psoc@ahrq.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

The Patient Safety Act establishes a framework by which doctors, hospitals, and other health care providers may voluntarily report information on a privileged and confidential basis regarding patient safety events and quality of care. The Patient Safety Act provides for voluntary formation of PSOs, which can be public or private organizations, that collect, aggregate, and analyze information regarding the quality and safety of care delivered in any healthcare setting. Information that is assembled and developed by providers and PSOs—called "patient safety work product"—is privileged and confidential; it can be used to identify patient safety events and unsafe conditions that increase risks to patients.

The Patient Safety Act requires PSOs, to the extent practical and appropriate, to collect patient safety work product from providers in a standardized manner in order to permit valid comparisons of similar cases among similar providers.

One of the goals of the legislation is to allow aggregation of sufficient data to identify and address underlying causal factors of patient safety problems. In order to facilitate standardized data collection, the Secretary of DHHS requested AHRQ to coordinate the development of Common Formats for patient safety events.

Definitions and other details about PSOs and patient safety work product have been prepared for publication at 42 CFR Part 3; a Notice of Proposed Rulemaking was published in the **Federal Register** on February 12, 2008, as noted above, and a final regulation implementing the Patient Safety Act is under review.

##### Definition of Common Formats

The term Common Formats is used to describe technical requirements developed for the uniform collection and reporting of patient safety data, including all supporting material:

- Descriptions of patient safety events and unsafe conditions to be reported,
- Delineation of data elements to be collected for specific types of events,

- Examples of patient safety population reports,
- A metadata registry with data element attributes and technical specifications,
- Paper forms to allow immediate implementation, and
- A users guide.

Common Formats delineate definitional and reporting specifications that will allow healthcare providers to collect and submit standardized information regarding patient safety events. The Common Formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research related reporting system, or other reporting/recording systems.

### Scope of Common Formats

The scope of Common Formats will apply to all patient safety concerns including:

- Incidents—patient safety events that reached the patient, whether or not there was harm,
- Near misses or close calls—patient safety events that did not reach the patient, and
- Unsafe conditions.

In the interest of supporting PSO data collection from the outset, AHRQ is releasing Version 0.1 Beta of the Common Formats, which have a defined focus on patient safety reporting for hospital inpatients. It should be noted, however, that the Patient Safety Act confers both privilege and confidentiality on all patient safety work product developed under the aegis of a PSO with respect to healthcare in any setting. AHRQ anticipates expanding future versions of the Common Formats to include other settings such as: Nursing homes and other bedded facilities; ambulatory surgery centers; other ambulatory care settings, including community health centers, rehabilitation centers, and hemodialysis centers; physician and practitioner offices; and retail establishments such as pharmacies.

### Common Formats Development

AHRQ has established a process to develop Common Formats that: (1) Is evidence based; (2) harmonizes across governmental health agencies; (3) incorporates feedback from the private sector, including professional associations/organizations, those who use the formats, and the public; and (4) permits timely updating of these clinically-sensitive formats. It is planned that updated versions of the formats will be released annually by AHRQ as guidance. While the

development and release of Common Formats is outside the scope of the regulations implementing the Patient Safety Act, AHRQ described its proposed development process in the Notice of Proposed Rulemaking referenced above and sought public comment. There were a significant number of strongly supportive comments about the process; there were no negative comments.

In anticipation of the need for Common Formats, AHRQ began their development in 2005 by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provides an evidence base to inform construction of the Common Formats. The inventory now numbers 64 and includes many systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (e.g., from the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems are included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

AHRQ convened an interagency Patient Safety Work Group (PSWG) to develop draft formats. Included in the PSWG are major health agencies within the Department—CDC, Centers for Medicare and Medicaid Services (CMS), FDA, Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), the National Institutes of Health (NIH), the Office of the National Coordinator for Health Information Technology (ONC)—as well as the DoD and the VA.

The PSWG reviewed the AHRQ inventory, created draft Common Format data sets, harmonized individual data elements where possible, and created new data elements where necessary. From February through May of 2008, the draft Common Formats underwent two pilot tests in a significant number of healthcare facilities within DoD, IHS, and VA. These pilot tests were designed to provide guidance to refine the draft formats prior to their release as Version 0.1 Beta. The PSWG, acting as the focus for original development and continuing upgrading/maintenance will assure consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues.

The PSWG aligned the formats, to the extent practicable, with World Health Organization (WHO) concepts,

framework, and definitions contained in their draft International Classification for Patient Safety (ICPS). The ICPS is currently under development.

AHRQ's initial construction of Common Formats thus draws on information from systems in both the public and private sectors, but was completed by a work group comprising only Federal agencies. To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ has engaged the National Quality Forum (NQF) to solicit comments and advice to guide future versions, as described below. It should be noted that the Common Formats Version 0.1 Beta can be implemented now, using AHRQ paper forms and the users guide. Other supporting materials will be made available shortly via the AHRQ Web site.

### Commenting on Common Formats Version 0.1 Beta

AHRQ is committed to continuing refinement of the Common Formats. The Agency is specifically interested in obtaining feedback from both the private and public sectors—particularly from those who use the Common Formats—and it has established a process to receive initial feedback that will guide rapid improvement of the formats.

AHRQ has contracted with the NQF, a non-profit organization focused on healthcare quality, to assist with gathering and analyzing feedback on the Common Formats. In this role, the NQF will assist AHRQ in updating future versions of the formats by: Soliciting public comments from providers, professional organizations, the general public, and PSOs; triaging comments in terms of immediacy of importance; setting priorities; and convening expert panel(s) to offer advice on suggested improvements to the formats. This process will be a continuing one, guiding periodic updates of the Common Formats and, most importantly, reflecting the feedback of those using the formats. This latter group, the users, will be the most sensitive to and aware of needed updates and improvements to the formats.

### Future Releases

While AHRQ's Version 0.1 Beta has been developed based on evidence, consensus of the PSWG, and results from initial testing, this version does not reflect the refinement that will come from large-scale use and repeated revision. We anticipate that we may get much helpful guidance from early users of the formats. For this reason, AHRQ

plans to release a second version of the formats in six to nine months, or perhaps sooner, depending on the nature of initial feedback. Once the formats are stabilized, AHRQ plans to release new versions annually. The Agency will follow the same process for formats developed for other settings.

AHRQ realizes that using Version 0.1 Beta paper forms is not the optimal way to collect patient safety data. Over time, computer software (developed in the private sector) will make use of the formats much more efficient. However, because the Agency plans an early second release of the Common Formats, it cautions software developers to understand that the first release of the formats will likely be substantially enhanced.

More information on the feedback process can be obtained through AHRQ's PSO Web site: <http://www.pso.ahrq.gov/index.html>.

Dated: August 21, 2008.

**Carolyn M. Clancy,**

*Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-65]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in Final Peer Review Organizations Sanction Regulations—42 CFR 1004.4, 1004.50, 1004.60, and 1004.70; *Use:* The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act (the Act), creating the Utilization and Quality Control Peer Review Organization Program. Section 1156 of the Act imposes obligations on health care practitioners and others who furnish or order services or items under Medicare. This section also provides for sanction actions, if the Secretary determines that the obligations as stated by this section are not met. Quality Improvement Organizations (QIOs) are responsible for identifying violations. QIOs may allow practitioners or other entities, opportunities to submit relevant information before determining that a violation has occurred. The information collection requirements contained in this information collection request are used by the QIOs to collect the information necessary to make their decision. *Form Number:* CMS-R-65 (OMB# 0938-0444); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 53; *Total Annual Responses:* 53; *Total Annual Hours:* 14,310.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *October 28, 2008*:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development,

Attention: Document Identifier/OMB Control Number \_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 22, 2008.

**Michelle Shortt,**

*Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0313]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Inspection Under the Inspection by Accredited Persons Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by September 29, 2008.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to [baguilar@omb.eop.gov](mailto:baguilar@omb.eop.gov). All comments should be identified with the OMB control number 0910-0569. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.