for new technology services that were not covered by the transitional pass-through payments provisions authorized by the Balanced Budget Refinement Act (BBRA) of 1999. Both the New Technology APC provision and the transitional pass-through provisions provide ways for ensuring appropriate payment for new technologies for which the use and costs are not adequately represented in the base year claims data on which the outpatient PPS is constructed.

CMS needs to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner. It is necessary that we continue to collect appropriate information from interested parties such as hospitals, medical device manufacturers, pharmaceutical companies and others that bring to our attention specific services that they wish us to evaluate for New Technology APC payment. We are making no changes to the information that we collect. The information that we seek to continue to collect is necessary to determine whether certain new services are eligible for payment in New Technology APCs, to determine appropriate coding and to set an appropriate payment rate for the new technology service. The intent of these provisions is to ensure timely beneficiary access to new and appropriate technologies. *Form Number:* CMS–10054 (OMB#: 0938–0860); *Frequency:* Annually; *Affected Public:* Private sector business or other for-profits; *Number of Respondents:* 15; *Total Annual Responses:* 15; *Total Annual Hours:* 180. (For policy questions regarding this collection contact Christina Smith Ritter at 410–786–4636. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* New collection; *Title of Information Collection:* State Plan Preprint for Medicaid Recovery Audit Contractors (RACs); *Use:* Under section 1902(a)(42)(B)(i) of the Social Security Act, States are required to establish programs to contract with one or more Medicaid RACs for the purpose of identifying underpayments and recouping overpayments under the State plan and any waiver of the State plan with respect to all services for which payment is made to any entity under such plan or waiver. Further, the statute requires States to establish programs to contract with Medicaid RACs in a manner consistent with State law, and generally in the same manner as the Secretary contracts with Medicare RACs. State programs contracted with Medicaid RACs are not required to be fully operational until after December 31, 2010. States may submit, to CMS, a State Plan Amendment (SPA) attesting that they will establish a Medicaid RAC program. States have broad discretion regarding the Medicaid RAC program design and the number of entities with which they elect to contract. Many States already have experience utilizing contingency-fee-based Third Party Liability recovery contractors; *Form Number:* CMS–10343 (OMB#: 0938–NEW); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 56. (For policy questions regarding this collection contact Mary Jo Cook at 410–786–3231 or Eva Tetteyfio at 410–786–3653. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address 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,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *February 14, 2011.* OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov*.

Martique Jones,

Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–736 Filed 1–13–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–268 and CMS–10328]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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:* CMS Survey Tool for *http://www.cms.gov* and *http://www.medicare.gov; Use:* The purpose of this submission is to continue to collect information from Internet users as they exit from the Web sites Medicare.gov and CMS.gov. To ensure that we gather information about user reactions to the Web sites, we have developed a survey tool that users can complete when they exit either site or by accessing a link on the bottom bar on the page. The responses on this survey tool will help CMS to make appropriate changes to the Web sites in the future. The survey tool contains questions about the information that visitors are seeking from the sites, the degree to which either site was useful to them, the improvements that they would like to see in the sites, and their general comments. *Form Number:* CMS–R–268 (OMB# 0938–0756); *Frequency:* Yearly; *Affected Public:* Individuals and households, Private sector—Business or other for-profit; *Number of Respondents:* 7,000; *Total Annual Responses:* 9,100; *Total Annual Hours:* 1,167. (For policy questions regarding this collection contact Matthew Aiken at 410–786–1029. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Medicare Self-Referral Disclosure Protocol; *Use:* Section 6409 of the ACA requires the Secretary to establish and post information on the CMS' public Internet Web site concerning a self-referral disclosure protocol (SRDP) that sets forth a process for providers of services and suppliers to self-disclose actual or potential violations of section 1877 of the Act. In addition, section 6409(b) of the ACA gives the Secretary authority to reduce

the amounts due and owing for the violations. This information collection request is necessary in order to inform the public of the process and the types of information needed to participate in the SRDP.

The SRDP is a voluntary self-disclosure instrument that will allow providers of services and suppliers to disclose actual or potential violations of section 1877 of the Act. CMS will analyze the disclosed conduct to determine compliance with section 1877 of the Act and the application of the exceptions to the physician self-referral prohibition. In addition, the authority granted to the Secretary under section 6409(b) of the ACA, and subsequently delegated to CMS, may be used to reduce the amount due and owing for violations. *Form Number:* CMS–10328 (OMB#: 0938–1106; *Frequency:* Once; *Affected Public:* Private Sector, Business and other for-profit and not-for-profit institutions; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 1,175. (For policy questions regarding this collection contact Ronke Fabayo at 410–786–4460. For all other issues call 410–786–1326.)

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,* 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 *March 15, 2011:*

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: January 7, 2011.

Martique Jones,

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

[FR Doc. 2011–737 Filed 1–13–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0021]

Prescription Drug Products Containing Acetaminophen; Actions To Reduce Liver Injury From Unintentional Overdose

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is taking steps to reduce the maximum dosage unit strength of acetaminophen in prescription drug products. This change will provide an increased margin of safety to help prevent liver damage due to acetaminophen overdosing, a serious public health problem. This notice explains the reasons for the reduction in dosage unit strength and describes how FDA is implementing it for approved prescription drug products that exceed the new maximum tablet or capsule strength. FDA is also requiring safety labeling changes, including a new boxed warning, for acetaminophen-containing prescription drug products to address new safety information about the risk of liver damage.

DATES: Sponsors of approved prescription drug products containing more than 325 milligrams (mg) of acetaminophen have until January 14, 2014 to request that FDA withdraw approval of the product's application, after which they may be subject to action by FDA.

FOR FURTHER INFORMATION CONTACT: Faith Dugan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6182, Silver Spring, MD 20993–0002, 301–796–3446.

SUPPLEMENTARY INFORMATION:

I. Acetaminophen Drug Products and Liver Injury

Acetaminophen is the generic name of a drug used in many over-the-counter (OTC) oral pain-relievers such as Tylenol, and in prescription combination drug products such as Vicodin and Percocet. Acetaminophen is one of the most widely used drugs in the United States in both prescription and OTC products. This notice applies only to acetaminophen-containing drug products that are labeled for prescription use and marketed under approved new drug applications (NDAs) or abbreviated new drug applications (ANDAs). OTC acetaminophen drug products are not affected by this notice.[1]

All acetaminophen-containing prescription products are combinations with other drug ingredients, primarily opioids in various strengths. These other drug ingredients include the opioids hydrocodone bitartrate (*e.g.,* Vicodin), oxycodone hydrochloride (*e.g.,* Percocet), codeine phosphate (*e.g.,* Tylenol with Codeine), dihydrocodeine, tramadol hydrocholoride, and pentazocine hydrochloride, as well as butalbital (a barbiturate) and caffeine (a stimulant).[2] General references to "acetaminophen combinations" or "acetaminophen combination products" in this notice refer to all such products. There are no prescription drug products that contain only acetaminophen.

Prescription combination drugs account for approximately 20 percent of the total acetaminophen drug market, and include some of the most widely prescribed and sold prescription drug products in the United States. (The remaining 80 percent of the acetaminophen drug market consists of OTC products.) Acetaminophen-hydrocodone combinations account for more than half of all prescriptions for acetaminophen combination drug products in the United States, and for many years, have also been the most-prescribed products in the U.S. retail market (Ref. 1). Unlike other drugs commonly used to reduce pain and fever (*e.g.,* nonsteroidal anti-inflammatory drugs (NSAIDS) such as aspirin, ibuprofen, and naproxen), at recommended doses acetaminophen

[1] FDA continues to monitor the occurrence of adverse events associated with both prescription and OTC acetaminophen products. Any action relating to additional safety measures for OTC acetaminophen products will be taken separately from this notice, through rulemaking as part of the ongoing OTC monograph proceeding for internal analgesic drug products.

[2] The opioid ingredient propoxyphene has also been widely used in combination with acetaminophen under the brand name Darvocet as well as in many generic products. On November 19, 2010, FDA announced that Darvocet was being voluntarily withdrawn from the market at FDA's request due to significant safety concerns about propoxyphene. FDA also requested that makers of generic propoxyphene-acetaminophen combination products withdraw their products from the market. Additional information about the status of propoxyphene-containing drug products can be found on FDA's Web site at *http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm233800.htm.*