

period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC Web site at: <http://www.cdc.gov/vaccines/hcp/vis/index.html>.

#### Revised Vaccine Information Materials

The revised inactivated and live attenuated influenza vaccine information materials referenced in this notice were developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and healthcare provider organizations. Following consultation and review of comments submitted, the vaccine information materials covering inactivated and live attenuated influenza vaccine have been finalized and are available to download from <http://www.cdc.gov/vaccines/hcp/vis/index.html> or <http://www.regulations.gov> (see Docket Number CDC-2015-0016). The Vaccine Information Statements (VIS), are: “Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know” (publication date August 7, 2015) and

“Influenza (Flu) Vaccine (Live, Intranasal): What you need to know” (publication date August 7, 2015).

With publication of this notice, as of March 1, 2016, all health care providers will be required to provide copies of these updated inactivated and live attenuated influenza vaccine information materials prior to immunization in conformance with HHS/CDC’s August 7, 2015 Instructions for the Use of Vaccine Information Statements. Prior to that date, the previous edition of these two VISs can be used.

Dated: September 29, 2015.

**Sandra Cashman,**

*Acting Director, Division of the Executive Secretariat, Office of the Chief of Staff, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10565]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the 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.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by *November 4, 2015*.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Off-cycle Submission of Summaries of Model of Care Changes; *Use:* All Medicare Advantage (MA) Special Needs Plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA). The SNPs must submit Models of Care (MOC) as a component of the Medicare Advantage application process. Approval is based

on NCQA's evaluation of SNPs using MOC scoring guidelines. Based on their scores, SNPs receive an approval for a period of 1-, 2-, or 3-years. We are developing an MOC off-cycle revision process so that SNPs can revise the MOC to modify its processes and strategies for providing care during their MOC approval period. We will require that SNPs submit summaries of their MOC revisions to CMS for NCQA evaluation when a SNP makes significant changes to its MOC as described in the annual Announcement of Medicare Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call letter for CY 2015 and CY2016. The NCQA will review the summary of changes to verify that the revisions are consistent with the acceptable, high quality standards as included in the original approved MOC. The package has been revised subsequent to the publication of the 60-day **Federal Register** notice (June 17, 2015; 80 FR 34647). *Form Number:* CMS-10565 (OMB control number 0938-New); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 313; *Total Annual Responses:* 421; *Total Annual Hours:* 2,400. (For policy questions regarding this collection contact Susan Radke at 410-786-4450).

Dated: September 30, 2015.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0045]

#### International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ketamine and Nine Other Substances; Request for Comments

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 10 drug substances. These comments will be

considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs. This notice requesting comments is required by the Controlled Substances Act (the CSA).

**DATES:** Submit either electronic or written comments by October 15, 2015.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2015-N-0045 for International Drug Scheduling; Convention on Psychotropic Substances; Single

Convention on Narcotic Drugs; Ketamine; Phenazepam; Etizolam; 1-cyclohexyl-4-(1,2-diphenylethyl)-piperazine (MT-45); N-(1-Phenethylpiperidin-4-yl)-N-phenylacetamide (Acetylfentanyl);  $\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP); 4-Fluoroamphetamine (4-FA); para-Methyl-4-methylaminorex (4,4'-DMAR); para-Methoxymethylamphetamine (PMMA); 2-(ethylamino)-2-(3-methoxyphenyl)-cyclohexanone (Methoxetamine or MXE); Request for Comments. Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.