similar information or report available. T–MSIS will remove current multiple reporting for similar data by the state to CMS.

Although T–MSIS will report more frequently, (monthly vs. quarterly) the amount of data collected through the expanded dataset will enable efficient processing to more efficiently satisfy data collection needs, thus eliminating additional similar duplicate current reporting processes.

Form Number: CMS–R–284 (OCN 0938–0345). *Frequency:* Quarterly (MSIS) and Monthly (T–MSIS). *Affected Public:* State, Local, or Tribal Governments. *Number of Respondents:* 51. *Total Annual Responses:* 816. *Total Annual Hours:* 8,160. (For policy questions regarding this collection contact Kay Spence. at 410–786–1617. 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 Email 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 *January 2, 2013:* OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: November 27, 2012.

Martique Jones,

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

[FR Doc. 2012–29052 Filed 11–30–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4169–NC]

Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient Experiences With Emergency Department Care

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

ACTION: Request for information.

SUMMARY: This document is a request for information regarding consumer and patient experiences with emergency department care.

DATES: The information solicited in this notice must be received at the address provided below by February 1, 2013.

ADDRESSES: In responding to this solicitation, please reply via email to CMS *ED_Survey@cms.hhs.gov* or by postal mail at Centers for Medicare and Medicaid Services, Attention: Sai Ma, Mailstop C1–14–18, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Sai Ma (410) 786–1479.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 3011 of the Affordable Care Act, the Department of Health and Human Services (HHS) developed the National Quality Strategy to create national aims and priorities to guide local, state, and national efforts to improve the quality of health care. This strategy established three aims supported by six priorities that focus on better care, healthy people/healthy communities, and affordable care.[1] The six priorities include: (1) Making care safer by reducing harm caused by the delivery of care; (2) ensuring that each person and family are engaged as partners in their care; (3) promoting effective communication and coordination of care; (4) promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease; (5) working with communities to promote wide use of best practices to enable healthy living; and (6) making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models Surveys focusing on the patient and caregiver experience, including those discussed later and the Emergency Department care survey under development, support the goals of the National Quality Strategy for providing better care.

The Centers for Medicare & Medicaid Services (CMS) has already implemented patient experience surveys for health and drug plans, inpatient hospitals, and home health agencies. While CMS and the Agency for Healthcare Research and Quality (AHRQ) have developed additional Consumer Assessment of Healthcare Providers and Systems (CAHPS®) surveys for in-center hemodialysis facilities, nursing homes, and clinician and group practices, none of these surveys address consumers' and patients' experiences with emergency department services. A patient's experience in an emergency department is an essential component of their overall healthcare experience in a hospital, and we believe that a patient survey evaluating such care will further support the HHS's goals and priorities.

The target population for the emergency department patient experience of care survey is consumers/patients and caregivers of patients who received emergency department care. The emergency department is a unique environment within the health care system, bridging the world of outpatient and inpatient care. This makes existing patient experience instruments designed for either outpatient care or inpatient care only partially relevant for capturing patient experiences (for example, none of the existing surveys addresses patients' experience regarding transitions from emergency room to inpatient care). Having a rigorous, well-designed emergency department survey will allow us to understand patients' perspectives on their experiences in emergency departments and how such experiences change over time. This information will ultimately be used to help improve the quality of care patients receive in emergency departments.

We are in the process of reviewing potential topic areas, as well as publicly available instruments and measures, for the purpose of developing a consumer and patient experience survey that will enable objective comparisons of emergency department experiences across the country. The principal focus is to develop a survey for consumers and patients 18 years of age and older. However, we are also interested in how a survey could also be developed for pediatric patients.

II. Solicitation of Information

We are soliciting the submission of suggested topic areas (such as ''communication with providers,'' ''pain control'' or ''waiting time'') as well as publicly available instruments for capturing patient experiences with emergency department care. We are interested in instruments and items that can measure quality of care from the patient's and caregiver's perspective, including pediatric patients, and track changes over time.

[1] Please see U.S. Department of Health and Human Services, *Report to Congress, National Strategy for Quality Improvement in Health Care,* (March 2011), available at *http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf.*

We are looking for suggested topic areas and publicly available instruments in which—(1) The source of information is from consumers and patients who directly received care at an emergency department or caregivers who were directly involved in the care (for example, parents of young children); and (2) patients or caregivers identified the information as important to them in evaluating emergency department care (for example, wait time, medical staff and physician communication). Existing instruments that have been tested, have a high degree of reliability and validity, and evidence of wide use is preferred.

The following information would be especially helpful in any comments responding to this request for information:

- A brief cover letter summarizing the information requested above for submitted instruments and topic areas, respectively, and how the submission will help fulfill the intent of the patient experiences survey;
- (Optional) Information about the person submitting the material for the purposes of follow up questions about the submission which includes the following:
  - ++ Name.
  - ++ Title.
  - ++ Organization.
  - ++ Mailing address.
  - ++ Telephone number.
  - ++ Email address.
  - ++ Indication that the topic area or instrument is publicly available.
- When submitting topic areas, we encourage including to the extent available the following information:
  - ++ Detailed descriptions of the suggested topic area(s) and specific purpose(s).
  - ++ Relevant peer-reviewed journal articles or full citations.
- When submitting publicly available instruments or survey questions, we encourage including to the extent available the following information:
  - ++ Name of the instrument.
  - ++ Copies of the full instrument in all available languages.
  - ++ Topic areas included in the instrument.
  - ++ Measures derived from the instrument. Instrument reliability (internal consistency, test-retest, etc) and validity (content, construct, criterion-related).
  - ++ Results of cognitive testing.
  - ++ Results of field testing.
  - ++ Current use of the instrument (who is using it, what it is being used for, what population it is being used with, how instrument findings are reported, and by whom the findings are used).
  - ++ Relevant peer-reviewed journal articles or full citations.
  - ++ CAHPS® trademark status.
  - ++ Survey administration instructions.
  - ++ Data analysis instructions.
  - ++ Guidelines for reporting survey data.

We are developing this survey and plan to submit it to AHRQ for recognition as a Consumer Assessment of Healthcare Providers and Systems (CAHPS®) survey. The survey will be developed in accordance with CAHPS® Survey Design Principles and implementation instructions will be based on those for CAHPS® instruments (*https://www.cahps.AHRQ.gov/About-CAHPS/Principles.aspx*).

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

Dated: October 2, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–29104 Filed 11–30–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0477]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational Device Exemptions Reports and Records

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 January 2, 2013.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0078. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Investigational Device Exemptions Reports and Records—(OMB Control Number 0910–0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices, and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) added section 520(g)(6) to the FD&C Act and permitted changes to be made to either the investigational device or to the clinical protocol without FDA approval of an investigational device exemption (IDE) supplement. An IDE allows a device, which would otherwise be subject to provisions of the FD&C Act, such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of part 812 (21 CFR part 812) is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. The IDE regulation is designed to encourage the development of useful medical devices and allow investigators the maximum freedom possible, without jeopardizing the health and safety of the public or violating ethical standards. To do this, the regulation provides for different levels of regulatory control, depending on the level of potential risk the investigational device presents to human subjects. Investigations of significant risk devices, ones that present a potential for serious harm to the rights, safety, or welfare of human subjects, are subject to the full requirements of the IDE regulation. Nonsignificant risk device investigations, i.e., devices that do not present a potential for serious harm, are