DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day–21–0062]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled ''Supplemental Measurements for Exploratory Research Regarding Exposure During Activities Conducted on Synthetic Turf Fields with Tire Crumb Rubber Infill'' to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on February 12, 2021 to obtain comments from the public and affected agencies. ATSDR received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Supplemental Measurements for Exploratory Research Regarding Exposure During Activities Conducted on Synthetic Turf Fields with Tire Crumb Rubber Infill (OMB Control No. 0923–0062, Exp. Date 10/31/2021)—Extension—Office of Community Health and Hazard Assessment, Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

ATSDR is requesting a two-year extension for the research study, titled ''Supplemental Measurements for Exploratory Research Regarding Exposure During Activities Conducted on Synthetic Turf Fields with Tire Crumb Rubber Infill.'' (OMB Control No. 0923–0062, expiration date 10/31/2021). ATSDR is seeking Paperwork Reduction Act (PRA) clearance to extend the data collection period due to delays encountered with the COVID–19 pandemic.

Currently in the United States, there are more than 12,000 synthetic turf fields in use. While the Synthetic Turf Council has set guidelines for the content of crumb rubber used as infill in synthetic turf fields, manufacturing processes result in differences among types of crumb rubber. Additionally, the chemical composition may vary highly between different processes and source materials and may vary even within granules from the same origin.

The research protocol, Collections Related to Synthetic Turf Fields with Crumb Rubber Infill, has been conducted previously under two information collection requests (ICRs): Activity 1 under OMB Control No. 0923–0054 (expiration date 01/31/2017) and Activities 2 and 3 under OMB Control No. 0923–0058 (expiration date 08/13/2018), which were limited to collections from August to October, 2017. Activities 2 and 3 aimed to evaluate and characterize the human exposure potential to constituents in crumb rubber infill among a convenience sample of 60 field users (Activity 2) and to collect biological specimens (blood and urine) from 45 participants (Activity 3). Due to the limited enrollment and collection period, the target Activity 2 and Activity 3 sample sizes were not met in 2017.

The current request seeks to conduct supplemental measurements to expand the exploratory analysis conducted under OMB 0923–0058. The current request allows for further investigation of patterns observed in the preliminary data from the 2017 pilot-scale exposure measurements of individuals playing on synthetic turf fields with crumb rubber infill and includes collecting data from a small number of individuals who play on grass fields.

In December 2020, ATSDR submitted a change request to OMB to incorporate COVID–19 prevention and protection measures. The change request was approved on 2/22/2021. The COVID–19 prevention and protection measures will be implemented before data collection begins.

The current study is a larger-scale supplemental assessment of exposure potential for individuals who use/play on synthetic turf fields with tire crumb rubber infill. The study includes persons who use synthetic turf with crumb rubber infill (*e.g.,* facility users) and who routinely perform activities that would result in a high level of contact to crumb rubber. The study also includes persons who use natural grass fields. This allows for evaluation of potential high-end exposures to constituents in synthetic turf among this group of users and for comparison to individuals who do not play on synthetic turf fields with tire crumb rubber infill. The respondents are administered a detailed questionnaire on activity patterns on synthetic turf with crumb rubber infill. This instrument allows ATSDR to characterize exposure scenarios, including the nature and duration of potential exposures. Additionally, we are collecting urine samples pre- and post-activity. The urine samples will be analyzed for polyaromatic hydrocarbons and then archived for future analysis.

For the extension request, there are no changes to the instruments, the total burden hours, and to the total number of respondents. The research study aims to screen a total of 220 participants for eligibility. The sample size for synthetic turf field users is 150 and 50 for the

natural grass field users. The total burden hours for the research study is 184 hours among all of the 220 respondents. There is no cost to the respondents other than their time in the study.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)
Adult/Adolescent Facility Users	Eligibility Screening Script	110	1	5/60
	Adult and Adolescent Questionnaire	100	1	30/60
	Exposure Measurement Form	100	1	20/60
Parents/Guardians of Youth/Child Facility Users	Eligibility Screening Script	110	1	5/60
	Youth and Child Questionnaire	100	1	30/60
Youth/Child Facility Users	Exposure Measurement Form	100	1	20/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10185]

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

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

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 the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and 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 July 26, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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' website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

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:* Revision of a previously approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements; *Use:* Section 1860D–12(b)(3)(D) of the Act provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate. Pursuant to our statutory authority, we codified these information collection requirements for Part D sponsors in regulation at 42 CFR 423.514(a).

Data collected via the Medicare Part D reporting requirements will be an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. For all reporting sections (Enrollment and Disenrollment, Medication Therapy Management (MTM) Programs, Grievances, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, and Employer/Union Sponsored Sponsors), data are reported electronically to CMS. The data collected via the MTM and Grievances reporting sections are used in the Medicare Part C and D Star Ratings and Display Measures. The other reporting sections' data are analyzed for program oversight to ensure the availability, accessibility, and acceptability of sponsors' services, such as coverage determinations and appeals processes, and opioid safety edits at the time of dispensing. *Form Number:* CMS–10185 (OMB control number: 0938–0992); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 814; *Total Annual Responses:* 12,575; *Total Annual Hours:* 16,463. (For policy questions regarding this collection contact Chanelle Jones at 410–786–8008).