process. In addition, the Federal Travel Regulation (FTR) allows for actual expense reimbursement as provided in §§ 301–11.300 through 301–11.306.

For FY 2020, one new non-standard area (NSA) location was added for Boise, Idaho (Ada County). In addition, Park County, Montana was added to the Big Sky, Montana NSA area. In Montana, Missoula and Flathead Counties were separated into their own NSAs instead of a combined NSA. The standard CONUS lodging rate will increase from $94 to $96. The M&IE reimbursement rate tiers were unchanged for FY 2020. The standard CONUS M&IE rate remains at $55, and the M&IE NSA tiers remain at $56–$76.

GSA issues and publishes the CONUS per diem rates, formerly published in Appendix A to 41 CFR Chapter 301, solely on the internet at *www.gsa.gov/perdiem.* GSA also has removed and now solely publishes the M&IE deduction table from Appendix B to 41 CFR Chapter 301, which is used when employees are required to deduct meals from their M&IE reimbursement pursuant to FTR § 301–11.18, at *www.gsa.gov/mie.* This process, implemented in 2003, for per diem reimbursement rates and in 2015 (internet publication) and 2018 (removal from the FTR) for the M&IE deduction table, ensures more timely changes in per diem reimbursement rates established by GSA for Federal employees on official travel within CONUS.

Notices published periodically in the **Federal Register** now constitute the only notification of revisions in CONUS per diem reimbursement rates to agencies other than the changes posted on the GSA website.

Jessica Salmoiraghi,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2019–17416 Filed 8–13–19; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''*Safety Program in Perinatal Care (SPPC)—II Demonstration Project.*''

This proposed information collection was previously published in the **Federal Register** on May 1, 2019, and allowed 60 days for public comment. AHRQ received no substantive comments. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by date 30 days after date of publication.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Safety Program in Perinatal Care (SPPC)—II Demonstration Project

Maternal mortality and severe maternal morbidity (SMM) increased significantly and continuously in the United States (US) over the past 30 years. A considerable proportion of these adverse events are attributable to preventable harm and unintended consequences arising from clinical practice and the system of delivering perinatal care. To address these alarming trends, AHRQ has developed the Safety Program in Perinatal Care (SPPC). During its initial phase (SPPC–I), the program was comprised of three pillars: Teamwork and communication, patient safety bundles, and in situ simulations. Despite several promising results, the evaluation of SPPC–I revealed considerable hospital attrition due to heavy data burden and competing safety initiatives. Also, differences in the local adaptation of the SPPC–I patient safety bundles selected by implementation sites thwarted a meaningful cross-site comparison of programmatic impact.

The current, second phase of the program (SPPC–II), focuses on integrating the teamwork and communication pillar into patient safety bundles developed by key professional organizations and implemented in 20+ US states with technical assistance by the Alliance for Innovation on Maternal Health (AIM) program and funding from the Health Resources and Services Administration (HRSA). Of note, the model used by AIM to implement these bundles is through statewide perinatal quality collaboratives (PQC) aiming to enroll all birthing hospitals in the state in the PQC.

During the *Planning Phase* of SPPC–II, the contractor, Johns Hopkins University (JHU), developed SPPC–II Training Toolkits for two AIM patient safety bundles: Obstetric hemorrhage and severe hypertension in pregnancy. The aim of the SPPC–II *Demonstration Project* is to implement and evaluate an integrated AIM–SPPC II program that overlays the SPPC–II Training Toolkits and the AIM patient safety bundles and program infrastructure in two states—Oklahoma (OK), currently implementing the severe hypertension bundle; and Texas (TX), currently implementing the hemorrhage bundle.

Over the next five years, the AIM program is expected to cover about two thirds of US states. Therefore, there is need to determine the feasibility and impact of the proposed integrated AIM–SPPC II program, and inform future government funding decisions regarding these two programs.

To this end, the SPPC–II *Demonstration Project* has the following goals:

(1) To implement the integrated AIM–SPPC II program in birthing hospitals in OK and TX in coordination with AIM and the respective state PQC;

(2) To assess the implementation of the integrated AIM–SPPC II program in these hospitals; and

(3) To ascertain the short- and medium-term impact of the integrated AIM–SPPC II program on hospital (*i.e.,* perinatal unit) teamwork and communication, patient safety, and key maternal health outcomes.

This study is being conducted by AHRQ through its contractor, Johns Hopkins University (JHU) and the AIM program, JHU's subcontractor, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a (a)(1) and (2).

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

(a) *Training of AIM Team Leads* from 48 birthing hospitals in OK and 210 birthing hospitals in TX (*i.e.,* all birthing hospitals enrolled in the respective state

PQC) on using teamwork and communication tools and strategies in clinical obstetric practice. The training will be conducted in-person, through a full-day workshop organized in collaboration and coordination with the AIM program and state PQCs, and led by JHU. Only one such training workshop will be conducted in OK using the SPPC–II Toolkit for severe hypertension in pregnancy. Given the size of the state, potential long distances to be traveled by trainees, and the cost-efficiency of coordinating with back-to-back regional PQC meetings planned in TX this fall, five training workshops will be conducted in this state using the SPPC–II Toolkit for obstetric hemorrhage. We expect about half of the birthing hospitals in both states to send 2 hospital champions, of which one to be designated as AIM Team Lead, for training. JHU will keep and bi-annually update a roster of AIM Team Leads in each hospital to assess the need for training of new AIM Team Leads if turnover occurs. Training workshop evaluation forms will be distributed for completion by trainees on a voluntary basis to assess the perceived utility of training workshops.

(b) *Training of all frontline clinical staff* in 48 birthing hospitals in OK and 210 birthing hospitals in TX on teamwork and communication tools and strategies will be coordinated by AIM Team Leads in each hospital by: (a) Providing unique trainee IDs and information for them to access 8 training e-modules online (with option to leave voluntary comments/suggestions), and (b) using the JHU-developed facilitator guide included in the SPPC–II Toolkits to facilitate brief, in-person demonstration sessions on how to use the information from the training e-modules in clinical practice. Each of the eight training e-modules will take about 15 minutes to complete online, for a total of about 120 minutes. Because these training e-modules will be accessed and completed online, tracking of e-module completion and re-take, needed to assess overall staff exposure to training, is possible through the online training platform.

(c) *Coaching calls* will be organized monthly and led by JHU to address program implementation questions and assist with potential challenges. AIM Team Leads in all *Demonstration Project* hospitals will be invited to join these calls and ask questions. A list of coaching call participants and topics addressed will be maintained by JHU.

(d) *AIM Team Lead self-administered baseline surveys* will be made available 2–3 weeks before the AIM Team Leads training workshop, together with a corresponding consent form. The purpose of this survey is to assess key characteristics of project hospitals, including human resources, processes in place for AIM bundle implementation, and use of teamwork and communication tools in clinical practice. Respondents will have the option to complete the survey online or on paper, in line with the current administration of the Hospital Survey on Patient Safety Culture. The expected response rate for this survey is 95% in both states.

(e) *Clinical staff self-administered baseline surveys* will be made available before the first training workshop with AIM Team Leads, together with a corresponding consent form. The purpose of this survey is to assess baseline levels of previous teamwork and communication training, overall use of teamwork and communication tools and strategies, teamwork and communication perceptions, experience with AIM bundle implementation. Three respondents will be randomly selected in each hospital using comprehensive lists of clinical staff developed by the AIM Team Leads. These lists will be updated by AIM Team Leads on a quarterly basis to capture new hires and staff turnover. Respondents will be given the option to complete the survey online or on paper, in line with the administration of the national Hospital Survey on Patient Safety Culture. The expected response rate for this survey is 85% in both states.

(f) *Qualitative, semi-structured interviews with AIM Team Leads* will be conducted by phone about 3–4 months after their training workshop to assess the perceived utility of the training and assistance needed with the rollout of training to all frontline clinical staff using the e-modules and facilitation sessions to consolidate the information. An interview guide developed based on the Consolidated Framework for Implementation Research framework will be used to conduct the interviews, together with a corresponding consent form.

(g) *Clinical staff self-administered implementation surveys* will be made available at about 6, 18, and 30 months after the first AIM Team Leads training, together with a corresponding consent forms, to assess training knowledge, transfer, and results such as use of teamwork and communication tools and strategies, teamwork and communication perceptions, experience with AIM bundle implementation overlaid with the teamwork and communication tools. The time points were chosen to assess: *Early* adoption and results of the training (6-month survey); adoption and results of the training at the *time when unit culture changes are expected* per available implementation research (18-month survey); and medium-term program sustainability (30-month survey). For each survey, three respondents will be randomly selected in each hospital using the most up to date comprehensive lists of clinical staff developed by the AIM Team Leads. Respondents will have the option to complete these surveys online or on paper, in line with the administration of the national Hospital Survey on Patient Safety Culture. The expected response rates are 80%, 77.5% and 75% for surveys completed at 6, 18 and 30 months after AIM Team Leads training workshops, respectively.

(h) AIM program data will be obtained from the AIM program, a subcontractor of JHU's, under data use agreements with coordinating bodies of state PQCs in the fall of 2019. These data are needed for the evaluation of the SPPC–II *Demonstration Project* to assess changes in key AIM program processes and maternal health outcomes, such as severe maternal morbidity, throughout the project.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden ours for the respondents' time to participate in the SPPC–II Demonstration Project.

An estimated 387 AIM Team Leads from the 258 Demonstration Project sites will be trained during 8-hour workshops using the SPPC–II Toolkit. An evaluation form, which will take approximately 5 minutes to complete, will be distributed to them at the end of the workshop, and about 75% of them (290 AIM Team Leads) are expected to complete the evaluation. They will also be asked to extract from an available human resources computerized database and update bi-annually rosters of frontline clinical staff in their units—first extraction and each update is expected to take about 5 minutes.

An estimated 15,480 frontline clinical staff are expected to be trained using the training e-modules in the SPPC–II Toolkit. Completion of the 8 e-modules will take about 2 hours. These trainings will be complemented by four 15-min facilitation sessions led by AIM Team Leads in their respective units. The AIM Team Leads will track attendance of the facilitation session, work estimated to take about 15 minutes after each session.

Monthly 1-hour coaching calls will be organized during the first 18 months of the project and at least one

representative from about half of the sites is expected to participate at each coaching call.

Several surveys will be administered throughout the Demonstration Project, specifically: Baseline, 20-minute surveys with AIM Team Leads at each of 258 sites; baseline, 25-minute surveys with 3 randomly selected frontline clinical staff at each of 258 sites; 30-minute implementation surveys with 3 randomly selected frontline clinical staff at each of 258 sites will be conducted at 6, 18, and 30 months after the initial training workshops in both states. In addition, one-hour qualitative interviews will be conducted with 25 AIM Team Leads in the 2 states about 3–4 months after the initial training workshops in their respective state.

We will inform AIM Team Leads of the DUAs put in place to access AIM data—this will take about 5 minutes.

The total annual burden hours are estimated to be 54,654 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Training of AIM Team Leads	387	1	8	3,096
Frontline staff rosters developed by AIM Team Leads	258	6	0.08	124
Evaluation form for training of AIM Team Leads	290	1	0.08	23
Training of frontline clinical staff	15,480	1	2.00	30,960
Facilitation sessions	15,480	4	0.25	15,480
Tracking attendance of facilitation sessions	258	4	1.00	1,032
Coaching calls	129	18	1.00	2,322
Self-administered baseline surveys with AIM Team Leads	258	1	0.33	85
Self-administered baseline surveys with clinical staff	774	1	0.42	325
Qualitative semi-structured interviews with AIM Team Leads	25	1	1.00	25
Self-administered implementation surveys with clinical staff at 6 months	774	1	0.50	387
Self-administered implementation surveys with clinical staff at 18 months	774	1	0.50	387
Self-administered implementation surveys with clinical staff at 30 months	774	1	0.50	387
DUA for AIM data	258	1	0.08	21
Total	36,048	NA	NA	54,654

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $1,489,998.34 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Training of AIM Team Leads	387	3,096	$49.83	$154,273.68
Frontline staff rosters developed by AIM Team Leads	258	124	49.83	6,178.92
Evaluation form for training of AIM Team Leads	290	23	49.83	1,146.09
Training of frontline clinical staff	15,480	30,960	66.32	2,053,267.20
Facilitation sessions	15,480	15,480	66.32	1,026,633.60
Tracking attendance of facilitation sessions	258	1,032	49.83	51,424.56
Coaching calls	129	2,322	66.32	153,995.04
Self-administered baseline surveys with AIM Team Leads	258	85	49.83	4,235.55
Self-administered baseline surveys with clinical staff	774	325	66.32	21,554
Qualitative semi-structured interviews with AIM Team Leads	25	25	49.83	1,245.75
Self-administered implementation surveys with clinical staff at 6 months	774	387	66.32	25,665.84
Self-administered implementation surveys with clinical staff at 18 months	774	387	66.32	25,665.84
Self-administered implementation surveys with clinical staff at 30 months	774	387	66.32	25,665.84
DUA for AIM data	258	21	49.83	1,046.43
Total	36,048	54,716		1,489,998.34

* National Compensation Survey: Occupational wages in the United States May 2017 "U.S. Department of Labor, Bureau of Labor Statistics."

[a] Hourly wage for nurse-midwives ($48.36; occupation code 29–1161).

[b] Weighted mean hourly wage for obstetrician-gynecologists ($113.10; occupation code 29–1064; 30%); nurse-midwives ($49.83; occupation code 29–1161; 30%); registered nurses ($35.36; occupation code 29–1161; 20%); and nurse practitioners ($51.86; occupation code 29–1171; 20%).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the

collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 8, 2019.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2019–17398 Filed 8–13–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2374]

Drugs Intended for Human Use That Are Improperly Listed Due to Lack of Annual Certification or Identification of a Manufacturing Establishment Not Duly Registered With the Food and Drug Administration; Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its intention to begin inactivating drug listing records that are improperly listed in accordance with FDA requirements because these drug listings are not certified as being active and up to date or are associated with a manufacturing establishment that is not currently registered with FDA. FDA's regulations governing drug establishment registration and drug listing require registrants to notify FDA if commercial distribution of a listed drug is discontinued. They also require firms to submit drug listing updates if any material changes are made to information previously submitted, including a change in manufacturing establishment(s). FDA has found that listings for many drug products do not comply with these regulations because they have not been updated in over a year, they have not been certified as being up to date, or they identify within the listing information at least one manufacturing establishment that is not currently registered with FDA. Many of the drugs that are the subject of these listings appear to no longer be in commercial distribution. The purpose of this notice is to remind registrants of their legal obligations and announce that, if drug listings are not appropriately updated, certified, or associated with a registered establishment, they will be marked by FDA as ''inactive,'' and the date of inactivation will be added to the listing record. This process will result in the closure of drug records in all public drug listing databases maintained by FDA, including the National Drug Code (NDC) Directory and the NDC SPL Data Elements (NSDE) file, until corrections to the relevant listings are made.

DATES: This notice is applicable September 13, 2019.

FOR FURTHER INFORMATION CONTACT: Paul Loebach, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2262, Silver Spring, MD 20993–0002, 301–796–2173, *Paul.loebach@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) and part 207 (21 CFR part 207) of FDA's regulations have long required owners or operators of drug manufacturing establishments to register their establishments with FDA. In this notice, the term ''manufacture'' refers to all activities that trigger the drug establishment registration obligation under part 207, including repacking, relabeling, and salvaging as defined in part 207. Registrants are also required by section 510 and part 207 to ''list'' each drug manufactured at their establishments for commercial distribution and submit updated drug listing information to FDA twice yearly, in June and December, notifying FDA if this information has changed. Specifically, section 510(i)(2) and (j) of the FD&C Act require registered establishments to report and periodically update, among other information, listing information for each drug manufactured, prepared, propagated, compounded, or processed by them for commercial distribution in the United States. Under 21 CFR 207.49, 207.53, and 207.54, registrants must provide listing information that corresponds to the activity or activities they engage in for that drug.

As part of the drug listing information they submit to FDA, registrants must identify all establishments where a ''listed drug'' (as the term used in the context of section 510 of the FD&C Act and part 207) is manufactured or provide a source NDC that enables FDA to identify such establishments. Registered establishments must also report to FDA the discontinuation of commercial distribution of a listed drug (section 510(j)(2)(B) of the FD&C Act) and any material change in drug listing information previously submitted, which includes any changes in the establishment(s) where the drug is manufactured (section 510(j)(2)(D) of the FD&C Act and 21 CFR 207.1). On August 31, 2016, FDA amended part 207 to require drug manufacturers and other registrants, at the time of registration renewal, to certify that no changes have occurred to their listings that were not submitted or updated during the current calendar year (81 FR 60170 and § 207.57 (21 CFR 207.57)). The first certifications under this new requirement were due during the registration renewal period from October 1 to December 31, 2017 (81 FR 60170 at 60201 and § 207.57). Establishments and labeler code holders are also required to update contact information (name, telephone number, and email) submitted to FDA within 30 calendar days of any changes (21 CFR 207.25(g), 207.29(a)(3), and 207.33(c)(2)).

Complete, accurate, and up-to-date establishment registration and drug listing information is essential to FDA's mission. FDA relies on establishment registration and drug listing information in administering several key programs, including drug establishment inspections, postmarketing surveillance, counterterrorism, recalls, drug quality reports, adverse event reports, monitoring of drug shortages and availability, supply chain security, and identification of products that are marketed without an approved application. If registration and listing information is outdated or otherwise unreliable (such as inaccurate, superfluous, incomplete, or missing), the integrity of the drug establishment registration and listing database—and FDA's ability to rely on the reported information for these programs—is compromised. Drug registration and listing information is also widely used outside FDA for several purposes, including electronic drug prescribing, prescription drug reimbursement, and patient education. A review of our data shows that the types of errors discussed in this notice affect tens of thousands of records. Therefore, the inclusion of such incorrect or outdated information in FDA's NDC Directory, the NSDE file, or other public drug listing databases can negatively affect public health.

II. Circumstances Under Which Certain Drug Listing Information Becomes Inaccurate

Each registrant must list all drugs it manufactures for commercial distribution within 3 days of initial