

confidentiality, and integrity of such personal information.

Part III of the proposed order requires any business that Mr. Grago controls, directly or indirectly, that collects personal information online to obtain initial and biennial data security assessments for twenty years.

Part IV of the agreement prohibits Respondent from misrepresenting any fact material to the assessments required by Provision III.

Part V requires any business that Mr. Grago controls directly or indirectly, including ClixSense, to submit an annual certification from a senior corporate manager (or senior officer responsible for its information security program) that Respondent has implemented the requirements of the Order and is not aware of any material noncompliance that has not been corrected or disclosed to the Commission.

Parts VI through IX of the proposed order are reporting and compliance provisions, which include recordkeeping requirements and provisions requiring Respondent to provide information or documents necessary for the Commission to monitor compliance. Part X states that the proposed order will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

By direction of the Commission.

Julie A. Mack,
Acting Secretary.

Statement of the Federal Trade Commission

April 24, 2019

Today, the Commission announces cases against ClixSense and i-Dressup,¹ which include allegations that the companies failed to employ reasonable security to protect consumers' sensitive data. The orders obtained in these matters contain strong injunctive provisions, including new requirements that go beyond requirements from previous data security orders. For example, the orders include requirements that a senior officer provide annual certifications of compliance to the Commission, and explicit provisions prohibiting the defendants from making

misrepresentations to the third parties conducting assessments of their data security programs. These new requirements will provide greater assurances that consumers' data will be protected going forward.

Since joining the Commission, we have instructed staff to closely review our orders to determine whether they could be strengthened and improved—particularly in the areas of privacy and data security. Through ongoing discussions both internally and with external stakeholders, including through our public *Hearings on Competition and Consumer Protection in the 21st Century* and the comment process,² we continue to consider changes to our orders. We will adjust our data security orders, as needed, to reflect our ongoing discussions regarding the FTC's remedial authority and needs, as well as the specific facts and circumstances of each case.

We are particularly committed to strengthening the order provisions regarding data security assessments of companies by third parties. The Commission expects that these third parties will faithfully assess data security practices to identify potential noncompliance with appropriate order provisions. Future orders will better ensure that third-party assessors know they are accountable for providing meaningful, independent analysis of the data practices under examination. The announcements today reflect the beginning of our thinking, but we anticipate further refinements, and these orders may not reflect the approach that we intend to use in every data security enforcement action going forward.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality Notice of Meetings

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Five AHRQ Subcommittee Meetings.

SUMMARY: The subcommittees listed below are part of AHRQ's Health Services Research Initial Review Group Committee. Grant applications are to be reviewed and discussed at these

meetings. Each subcommittee meeting will commence in open session before closing to the public for the duration of the meeting.

DATES: See below for dates of meetings:

1. *Health System and Value Research (HSVR)*
Date: May 22, 2019 (Open from 8:00 a.m. to 8:30 a.m. on May 22nd and closed for remainder of the meeting)
2. *Health Care Research and Training (HCRT)*
Date: May 23–24, 2019 (Open from 8:00 a.m. to 8:30 a.m. on May 23rd and closed for remainder of the meeting)
3. *Healthcare Effectiveness and Outcomes Research (HEOR)*
Date: June 5–6, 2019 (Open from 8:30 a.m. to 9:00 a.m. on June 5th and closed for remainder of the meeting)
4. *Healthcare Information Technology Research (HITR)*
Date: June 6–7, 2019 (Open from 8:00 a.m. to 8:30 a.m. on June 6th and closed for remainder of the meeting)
5. *Healthcare Safety and Quality Improvement Research (HSQR)*
Date: June 12–13, 2019 (Open from 7:30 a.m. to 8:00 a.m. on June 12th and closed for remainder of the meeting)

ADDRESSES: Hilton Rockville & Executive Meeting Center, 1750 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: (To obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.)

Heather Phelps, Acting Committee Management Officer, Office of Extramural Research Education and Priority Populations, Agency for Healthcare Research and Quality (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 427-1128.

SUPPLEMENTARY INFORMATION: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), AHRQ announces meetings of the above-listed scientific peer review groups, which are subcommittees of AHRQ's Health Services Research Initial Review Group Committees. Each subcommittee meeting will commence in open session before closing to the public for the duration of the meeting. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). The grant applications and the discussions could disclose confidential trade secrets or commercial

¹ Although the Commission's settlement with i-Dressup addresses broader COPPA violations, this statement focuses specifically on the data security requirements set forth in the proposed stipulated order.

² See, e.g., *FTC Hearings on Competition and Consumer Protection in the 21st Century* (Session 9—Data Security), Dec. 11–12, 2018, <https://www.ftc.gov/news-events/events-calendar/ftc-hearing-competition-consumer-protection-21st-century-december-2018>.

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Agenda items for these meetings are subject to change as priorities dictate.

Gopal Khanna,

Director.

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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.”

DATES: Comments on this notice must be received by July 1, 2019.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

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

SUPPLEMENTARY INFORMATION:

Proposed Project

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

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection. Maternal mortality and severe maternal morbidity (SMM) increased significantly and continuously in the United States (U.S.) 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+ U.S. 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 U.S. 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 health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care 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, and (b) using the JHU-developed facilitator guide