

did not do so, making the company liable under the rule.⁷

The Health Breach Notification Rule was first issued more than a decade ago, but the explosion in connected health apps make its requirements more important than ever. While we would prefer to see substantive limits on firms' ability to collect and monetize our personal information, the rule at least ensures that services like Flo need to come clean when they experience privacy or security breaches. Over time, this may induce firms to take greater care in collecting and monetizing our most sensitive information.

Conclusion

We are pleased to see a notice provision in today's proposed order, but there is much more the FTC can do to protect consumers' data, and hold accountable those who abuse it. Where Congress has given us rulemaking authority, we should use it.⁸ And where we have rules already on the books, we should enforce them. Here, the Health Breach Notification Rule will have its intended effect only if the FTC is willing to enforce it.

We believe enforcing the rule was warranted here, and we respectfully dissent from the Commission's failure to do so. Particularly as we seek more authority from Congress in the privacy space, it is critical we demonstrate we are prepared to use the authorities we already have.

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⁷ See 16 CFR 318.7 (stating that a violation of the rule constitutes a violation of a trade regulation rule). Notably, California's recent action against a similar fertility-tracking app charged with similar privacy violations included a \$250,000 civil penalty. Press Release, Cal. Att'y Gen., Attorney General Becerra Announces Landmark Settlement Against Glow, Inc.—Fertility App Risked Exposing Millions of Women's Personal and Medical Information (Sep. 17, 2020), <https://oag.ca.gov/news/press-releases/attorney-general-becerra-announces-landmark-settlement-against-glow-inc-%E2%80%93>

⁸ We have previously articulated opportunities to make use of our existing authorities when it comes to data protection. See Statement of Commissioner Rohit Chopra Regarding the Report to Congress on the FTC's Use of Its Authorities to Protect Consumer Privacy and Security, Comm'n File P065404 (June 18, 2020), <https://www.ftc.gov/public-statements/2020/06/statement-commissioner-rohit-chopra-regarding-report-congress-ftcs-use-its>; Remarks of Commissioner Rebecca Kelly Slaughter at Silicon Flatirons, The Near Future of U.S. Privacy Law, University of Colorado Law School (Sep. 6, 2019), https://www.ftc.gov/system/files/documents/public_statements/1543396/slaughter_silicon_flatirons_remarks_9-6-19.pdf.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-0909]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled CDC Diabetes Prevention Recognition Program (DPRP) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on June 15, 2020, to obtain comments from the public and affected agencies. CDC received 30 unique sets of public comments. Within the 30 sets of comments, there were 126 questions/comments answered by CDC. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC 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

CDC Diabetes Prevention Recognition Program (DPRP) (OMB Control No. 0920-0909, Exp. 02/28/2021)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's Division of Diabetes Translation (DDT) established and administers the National Diabetes Prevention Program's (National DPP) Diabetes Prevention Recognition Program (DPRP), which recognizes organizations that deliver diabetes prevention programs according to evidence-based requirements set forth in the 'Centers for Disease Control and Prevention Diabetes Prevention Recognition Program Standards and Operating Procedures' (DPRP Standards). Additionally, the Centers for Medicare and Medicaid Services (CMS) Medicare Diabetes Prevention Program (MDPP) expansion of CDC's National DPP was announced in early 2016, when the Secretary of Health and Human Services determined that the Diabetes Prevention Program met the statutory criteria for inclusion in Medicare's expanded list of healthcare services for beneficiaries (<https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/>). This is the first time a preventive service model from the CMS Innovation (CMMI) Center has been expanded. After extensive testing of the DPP model in 17 sites across the U.S. in 2014–2016, CMS proposed the MDPP in Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh § 424.59), authorizing CDC-recognized organizations to prepare for enrollment as MDPP suppliers beginning in January 2018 in order to bill CMS for these services. Only organizations in good standing with the CDC DPRP are eligible as MDPP suppliers. CDC continues to work with CMS to support the MDPP.

CDC requests an additional three years of OMB approval to continue collecting the information needed to administer the DPRP and information

needed by CMS to support the MDPP benefit. Based on experience with the DPRP from 2011–2020, including data analysis, and feedback from applicant organizations and internal and external partners, CDC plans to revise the DPRP Standards and the associated information collection.

Key changes are a direct result of DPRP data analyses and discussion with National DPP stakeholders, including those serving vulnerable populations. Key changes allow for the optional collection of Hemoglobin A1C levels, and for weight/physical activity minutes to be combined (a new method), to determine Full recognition; the required collection of Application Delivery Mode questions; revised organizational type information; program enrollment motivation/enrollment source information; adding Gender; and the removal of Session ID. Three data elements have been minimally revised and no other data elements have been added to the one-time application form;

and, three have been revised, one has been deleted, and four have been added to the evaluation data elements, as per below:

Application Form

- (1) Delivery Mode- follow-up questions (revised)
- (2) Class Type (revised)
- (3) Organization Type (revised)

Evaluation Data Elements

- (4) Enrollment Motivation (new)
- (5) Enrollment Source (revised)
- (6) Session ID (deleted)
- (7) HBA1C Value (new)
- (8) Participant’s Gender (new)

During the period of this Revision, CDC estimates receipt of approximately 300 DPRP application forms per year. The estimated burden per one-time, up-front application response is one hour. CDC further estimates receipt of semi-annual evaluation data (two hours at each submission) from the new 300 organizations per year plus existing organizations who also submit semi-

annual evaluation data. The total estimated average annualized evaluation burden to respondents is 8,700 hours. This includes an estimate of the time needed to extract and compile the required data records and fields from an existing electronic database, review the data, create or enter a data file in the required format (*i.e.*, CSV file), and submit the data file via the National DPP website for upload into the DPRP Data Portal. The estimated burden per response is modest since the information requested for DPRP recognition is routinely collected by most organizations that deliver lifestyle change programs for their own internal evaluation and possible insurance reimbursement purposes, including Medicare under the MDPP benefit. Participation in the DPRP is voluntary, data are de-identified, no Personally Identifiable Information (PII) is collected by CDC, and there are no costs to respondents other than their time. CDC is requesting a three-year approval.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Public sector organizations that deliver type 2 diabetes prevention programs.	DPRP Application Form	90	1	1
	DPRP Evaluation Data	630	2	2
Private sector organizations that deliver type 2 diabetes prevention programs.	DPRP Application Form	210	1	1
	DPRP Evaluation Data	1470	2	2

Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Requirement for Negative Pre-Departure COVID-19 Test Result or Documentation of Recovery From COVID-19 for all Airline or Other Aircraft Passengers Arriving Into the United States From Any Foreign Country

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Agency Order.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and

Human Services (HHS) announces an Agency Order requiring negative pre-departure COVID-19 test results or documentation of recovery from COVID-19 for all airline or other aircraft passengers arriving into the United States from any foreign country. This Order was signed by the CDC Director on January 25, 2021 and supersedes the previous Order signed by the CDC Director on January 12, 2021.

DATES: This Order was effective January 26, 2021.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16-4, Atlanta, GA 30329. Email: *dgmqpolicyoffice@cdc.gov*.

SUPPLEMENTARY INFORMATION: This Order prohibits the introduction into the United States of any aircraft passenger departing from any foreign country unless the passenger: (1) Has a negative pre-departure test result for SARS-CoV-2, the virus that causes COVID-19 (Qualifying Test); or (2)

written or electronic documentation of recovery from COVID-19 after previous SARS-CoV-2 infection in the form of a positive viral test result and a letter from a licensed health care provider or public health official stating that the passenger has been cleared for travel (Documentation of Recovery).

This Order supersedes the previous Order signed by the CDC Director on January 12, 2021. This Order further clarifies the exemption categories for federal law enforcement and U.S. Department of Defense (DOD) personnel observing DOD precautions to prevent the transmission of COVID-19 during travel. This Order also replaces the previous language concerning the ability of airlines and aircraft operators to request specific waivers and replaces it with a limited humanitarian exemption category allowing individuals and organizations to request an exemption. To be eligible for this limited humanitarian exemption, the individual or organization must demonstrate both: (1) Exigent circumstances where emergency travel is required to preserve health and safety (*e.g.*, emergency