

confidential”—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Heather Hipsley,

Deputy General Counsel.

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BILLING CODE 6750-01-P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (“PRA”), the Federal Trade Commission (“FTC” or “Commission”) is seeking public comment on its proposal to extend for an additional three years the Office of Management and Budget clearance for information collection requirements of its Affiliate Marketing Rule, which applies to certain motor vehicle dealers, and its shared enforcement with the Consumer Financial Protection Bureau (“CFPB”) of the provisions (subpart C) of the CFPB’s Regulation V regarding other entities (“CFPB Rule”). The current clearance expires on January 31, 2020.

DATES: Comments must be filed by November 26, 2019.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “Affiliate Marketing Disclosure Rule, PRA Comment: FTC File No. P0105411” on your comment, and file your comment online at <https://www.regulations.gov>, by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT:

Katherine McCarron, Attorney, Division of Privacy and Identity Protection,

Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Room CC-8232, Washington, DC 20580, (202) 326-2333.

SUPPLEMENTARY INFORMATION: The Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”) was enacted on July 21, 2010.¹ The Dodd-Frank Act transferred to the CFPB most of the FTC’s rulemaking authority for the Affiliate Marketing provisions of the Fair Credit Reporting Act (“FCRA”).² The FTC retained rulemaking authority for its Affiliate Marketing Rule (16 CFR 680) solely for motor vehicle dealers described in section 1029(a) of the Dodd-Frank Act as predominantly engaged in the sale and servicing of motor vehicles, the leasing and servicing of motor vehicles, or both.³ Additionally, the FTC shares enforcement authority with the CFPB for provisions of Regulation V subpart C (12 CFR 1022.21) that apply to entities other than those specified above.

As mandated by section 214 of the Fair and Accurate Credit Transactions Act (“FACT Act”), Public Law 108-159 (Dec. 6, 2003), the Affiliate Marketing Rule (“Rule”) requires covered entities to provide consumers with notice and an opportunity to opt out of the use of certain information before sending marketing solicitations. The Rule generally provides that, if a company communicates certain information about a consumer (eligibility information) to an affiliate, the affiliate may not use it to make or send solicitations to the consumer unless the consumer is given notice and a reasonable opportunity to opt out of such use of the information and does not opt out.

To minimize compliance costs and burdens for entities, particularly any small businesses that may be affected, the Rule contains model disclosures and opt-out notices that may be used to satisfy the statutory requirements. The Rule also gives covered entities flexibility to satisfy the notice and opt-out requirement. Covered entities may send the consumer a free-standing opt-out notice to satisfy the Rule’s requirements or add the opt-out notice to privacy notices already provided to consumers, such as those provided in accordance with the provisions of Title V, subtitle A of the Gramm Leach Bliley Act (“GLBA”).⁴ As a result, the time necessary to prepare or incorporate an opt-out notice is likely to be minimal because covered entities may either use the model disclosure verbatim or base

their own disclosures upon it. Moreover, verbatim adoption of the model notice does not constitute a PRA “collection of information.”⁵ The Rule also provides that affiliated companies may send a joint disclosure to consumers, thereby eliminating the need for each affiliate to send a separate disclosure. Staff anticipates that affiliated entities will choose to send a joint notice, which will reduce the number of notices required under the Rule.

Burden Statement

Under the PRA, 44 U.S.C. 3501-3521, the FTC is requesting that OMB renew the clearance (OMB Control Number 3084-0131) for the information collection burden associated with the Rule.⁶ Staff estimates that there are approximately 54,753 franchise/new car and independent/used car dealers in the U.S.⁷ Applying an estimated rate of affiliation of 16.75%, staff estimates that there are approximately 9,171 motor vehicle dealerships in affiliated families that may be subject to the Rule’s affiliate sharing obligations. Staff further estimates an average of five businesses per family or affiliated relationship, and anticipates that affiliated entities will choose to send a joint notice as permitted by the Rule. Therefore, staff estimates that approximately 1,834 business families would be subject to the Rule.

Staff assumes that all or nearly all motor vehicles subject to the Rule’s provisions are also subject to the Commission’s Privacy of Consumer Financial Information Rule under the Gramm-Leach-Bliley Act (16 CFR 313) (“Privacy Rule”). Entities that are subject to the Commission’s GLBA

⁵ “The public disclosure of information originally supplied by the Federal government to the recipient for purpose of disclosure to the public is not included within [the definition of collection of information].” 5 CFR 1320.3(c)(2).

⁶ While the FTC shares enforcement authority with the Federal Reserve System, Commodity Futures Trading Commission, National Credit Union Administration, Office of the Comptroller of the Currency, and the Federal Deposit Insurance Corporation, for the Consumer Financial Protection Bureau’s counterpart affiliate sharing rule, Regulation V (Subpart C), 12 CFR 1022.21, the CFPB has assumed 95% of the burden associated with its affiliate sharing rule. See Consumer Financial Protection Bureau, *Agency Information Collection Activities: Submission for OMB Review; Comment Request*, 82 FR 32,686 (2017); CFPB Supporting Statement, *Fair Credit Reporting Act (Regulation V)* 12 CFR 1022, OMB Control Number: 3170-0002 (2017). In addition, the CFPB has estimated that the burden associated with Regulation V’s affiliate sharing provisions is *de minimis*.

⁷ This figure is based on estimates by the National Automobile Dealers Association and the National Independent Automobile Dealers Association. See, e.g., *NADA Data 2018: Annual Report*; *NIADA.com*.

¹ Public Law 111-203, 124 Stat. 1376 (2010).

² 15 U.S.C. 1681 *et seq.*

³ See Dodd-Frank Act, at section 1029 (a), (c).

⁴ 15 U.S.C. 6801 *et seq.*

privacy notice regulation already provide privacy notices to their customers. Absent an exception, financial institutions must provide an initial privacy notice at the time the customer relationship is established and then annually so long as the relationship continues. 15 U.S.C. 6803. Staff's estimates assume that in all or nearly all cases covered institutions will choose to incorporate the affiliate marketing opt-out notice into the initial and annual GLBA privacy notices. In 2015, Congress, as part of the FAST Act, amended the GLBA to provide an exception under which financial institutions that meet certain conditions are not required to provide annual notices to customers.⁸ Staff seeks comment on how the use of this exception by institutions that are required to provide an affiliate

marketing notice will impact the burden estimates for these entities. Institutions that claim the FAST Act exemption and forego sending required annual privacy notices in some years will nonetheless be required to send a separate affiliate marketing notice to comply with their obligations under the Rule.

Staff estimates that the 1,834 covered motor vehicle business families will spend on average about 5 hours per year to comply with the Affiliate Sharing Rule beyond their separate obligations under the Privacy Rule, yielding a total annual hours burden of 9,170 hours. Staff's estimates take into account the time necessary to determine compliance obligations; create the notice and opt-out, in either paper or electronic form; and disseminate the notice and opt-out. Staff's estimates presume that the availability of model disclosures and

opt-out notices will simplify the compliance review and implementation processes, thereby significantly reducing the compliance burden.

Staff estimates the associated labor cost by adding the hourly mean private sector wages for managerial, technical, and clerical work and multiplying that sum by the estimated number of hours. The private sector hourly wages for these classifications are \$50.11, \$41.51, and \$17.19, respectively.⁹ Estimated hours spent for each category are 2, 2, and 1, respectively. Multiplying each occupation's hourly wage by the associated time estimate, yields the annual labor cost burden per respondent which is then multiplied by the estimated number of respondents to determine the cumulative annual labor cost burden: \$367,588 per year.

Hourly wage and labor category	Hours per respondent	Total hourly labor cost	Number of respondents	Approx. total annual labor costs
\$50.11 Management Employees	2	\$100.22	1,834	\$183,803
41.51 Technical Staff	2	83.02	152,259
17.19 Clerical Workers	1	17.19	31,526
.....	367,588

Because the FACT Act and the Rule contemplate that the affiliate marketing notice can be included in the GLBA notices, the capital and non-labor cost burden on regulated entities would be greatly reduced. Covered entities typically already provide notices to their customers so there are no new capital or non-labor costs, as the Affiliate Marketing notice may be consolidated into their annual privacy notice. Thus, Staff estimates that any capital or non-labor costs associated with compliance for these entities are *de minimis*.

Request for Comment

Pursuant to Section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (1) Whether the disclosure, recordkeeping, and reporting requirements are necessary, including whether the resulting information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are valid; (3) how to improve the quality, utility, and clarity of the disclosure requirements; and (4)

how to minimize the burden of providing the required information to consumers. In addition, staff seeks comment on how the FAST Act exception that exempts certain institutions that are required to provide an affiliate marketing notice from sending annual privacy notices will impact the burden estimates for these entities.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before November 26, 2019. Write "Affiliate Marketing Disclosure Rule, PRA Comment: FTC File No. P0105411" on your comment. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it through the <https://www.regulations.gov> website by following the instructions on the web-based form provided. Your comment, including your name and your state—will be placed on the public

record of this proceeding, including the <https://www.regulations.gov> website.

If you file your comment on paper, write "Affiliate Marketing Disclosure Rule, PRA Comment: FTC File No. P0105411" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610, Washington, DC 20024. If possible, please submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the public record, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other

⁸ Fixing America's Surface Transportation Act ("FAST Act"), Public Law 114-94, 129 Stat. 1312, Section 75001 (Dec. 4, 2015) (amending 15 U.S.C. 6803 to exempt financial institutions from the annual notice requirement if they meet certain criteria, and if they have not changed their policies and practices with regard to disclosing nonpublic

personal information from the policies and practices that were disclosed in the most recent disclosure sent to consumers).

⁹ The classifications used are "Management Occupations" for managerial employees, "Computer and Mathematical Science Occupations" for technical staff, and "Office and

Administrative Support" for clerical workers. See OCCUPATIONAL EMPLOYMENT AND WAGES—MAY 2018, U.S. Department of Labor, released March 29, 2019, Table 1 ("National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2018"): <http://www.bls.gov/news.release/ocwage.htm>.

state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before November 26, 2019. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Heather Hipsley,

Deputy General Counsel.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.612]

Announcement of the Intent To Award an Emergency Single-Source Grant

AGENCY: Administration for Native Americans (ANA), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of intent to issue an emergency single-source award to 500 Sails, Inc. in Saipan, Commonwealth of the Northern Mariana Islands.

SUMMARY: The ACF, ANA, Division of Program Operations (DPO) intends to award a grant of \$106,638 to 500 Sails, Inc. in Saipan, Commonwealth of the Northern Mariana Islands. The purpose of the award is to support restoration of culturally significant sites and a digital storytelling project after the devastating effects of Typhoon Yutu in October, 2018.

DATES: The intended period of performance for this award is 09/30/2019 through 09/29/2020.

FOR FURTHER INFORMATION CONTACT: Carmelia Strickland, Director, Division of Program Operations, Administration for Native Americans, 330 C Street SW, Switzer Bldg. 4115, Washington, DC 20201. Telephone: 202–401–6741; Email: Carmelia.Strickland@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: An emergency declaration by President Donald Trump was issued for the Commonwealth of the Northern Mariana Islands (CNMI) on October 27, 2018. In the spring of 2019, ANA’s Pacific Basin Training and Technical Assistance Center performed an assessment of community needs that were not addressed by other federal agencies in response to the catastrophic storm. A report was prepared for ANA with a series of projects aiming to reduce the post-traumatic stress of 200 Chamorro and Carolinian community members through storytelling, and to repair and/or restore six culturally significant sites and two ANA project sites. Currently, the CNMI government is burdened with the reconstruction of homes and governmental infrastructure that were damaged by Typhoon Yutu. The award will be carried out by 500 Sails, Inc., a non-profit organization located in Saipan, CNMI, to serve as the grants administrator and project coordinator for the proposed projects. 500 Sails, Inc.

is a current ANA grantee with an ending 3-year project period and has successfully administered an ANA award. They have the organizational capacity, including accounting and data management, as well as qualified staff in place. In addition, the organization has the community connections, partnerships, and experience to successfully implement the award. The Board of Directors for 500 Sails, Inc has included a board resolution in support of the application and the 9 proposed projects. The activities within the project are designed to incorporate cultural ways of supporting the recovery after Typhoon Yutu. The proposed projects include the cultural component that no other federal agency could provide, and it allows for a holistic approach to the recovery. Most of the projects include volunteer opportunities for community members to help in the rebuilding of their community. The application will be awarded in compliance with HHS policy for emergency awards, including after an objective review has been conducted.

Statutory Authority: Section 803(a) of the Native American Programs Act of 1974 (NAPA), 42 U.S.C. 2991b.

Elizabeth Leo,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2019–20996 Filed 9–24–19; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6294]

Changes to Existing Medical Software Policies Resulting From Section 3060 of the 21st Century Cures Act; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Changes to Existing Medical Software Policies Resulting From Section 3060 of the 21st Century Cures Act.” This guidance provides clarity on FDA’s current thinking regarding changes made by the 21st Century Cures Act (Cures Act) to the definition of a medical device and the resulting effect on guidances related to medical device software.