

dangerous crossings, ropes, or boats to ferry goods and people across waterways.

Parties:

Principal Supplier: Acrow Corporation of America.

Obligor: Ministry of Finance of the Republic of Angola.

Guarantor(s): None.

Description of Items Being Exported: 186 modular steel panel bridges and ancillary bridging equipment, as well as technical training and advisory services.

Information on Decision: Information on the final decision for this transaction will be available in the "Summary Minutes of Meetings of Board of Directors" on <http://exim.gov/newsandevents/boardmeetings/board/>.

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

Authority: Section 3(c)(10) of the Export-Import Bank Act of 1945, as amended (12 U.S.C. 635a(c)(10)).

Joyce B. Stone,

Assistant Corporate Secretary.

[FR Doc. 2023-18249 Filed 8-23-23; 8:45 am]

BILLING CODE 6690-01-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's

Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than September 25, 2023.

A. *Federal Reserve Bank of New York* (Ivan J. Hurwitz, Head of Bank Applications) 33 Liberty Street, New York, New York 10045-0001. Comments can also be electronically sent to comments.applications@ny.frb.org:

1. *Helios Bancorp Inc.*; to become a bank holding company by acquiring Alpine Capital Bank, both of New York, New York.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023-18223 Filed 8-23-23; 8:45 am]

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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: "Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan Survey Database." In accordance with the Paperwork Reduction Act of 1995, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by October 23, 2023.

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

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

Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan Survey Database

AHRQ requests that OMB reapprove AHRQ's collection of information for the AHRQ Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan Survey Database: OMB Control number 0935-0165, expiration November 30, 2023 (the CAHPS Health Plan Database). The CAHPS Health Plan Database consists of data from the AHRQ CAHPS Health Plan Survey. Health plans in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The CAHPS Health Plan Database was developed by AHRQ in 1998 in response to requests from health plans, purchasers, and the Centers for Medicare & Medicaid Services (CMS) to provide comparative data to support public reporting of health plan ratings, health plan accreditation and quality improvement.

This research has the following goals:

(1) To maintain the CAHPS Health Plan Database using data from AHRQ's standardized CAHPS Health Plan Survey to provide results to health care purchasers, consumers, regulators and policy makers across the country.

(2) To offer several products and services, including aggregated results presented through an Online Reporting System, summary chartbooks, custom analyses, and data for research purposes.

(3) To provide data for AHRQ's annual National Healthcare Quality and Disparities Report.

(4) To provide state-level data to CMS for public reporting on *Medicaid.gov* and *Data.Medicaid.gov* that does not display the name of the health plans.

Survey data from the CAHPS Health Plan Database is used to produce four types of products: (1) An annual chartbook available to the public on the CAHPS Database website (<https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/cahps-database/2022-hp-chartbook.pdf>); (2) individual participant reports that are confidential and customized for each participating organization (e.g., health plan, Medicaid agency) that submits their data; (3) a research database available to researchers wanting to conduct additional analyses; and (4) data tables provided to AHRQ for inclusion in the National Healthcare Quality and Disparities Reports.

This study is being conducted by AHRQ through its contractor, Westat,

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; quality measurement and development, and database development. 42 U.S.C. 299a(a)(1), (2) and (8).

Method of Collection

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

- **Registration Form**—The point-of-contact (POC), often the sponsor from Medicaid agencies and health plans, completes a number of data submission steps and forms, beginning with the completion of the online registration form. The purpose of this form is to collect basic contact information about the organization and initiate the registration process.
- **Health Plan Information Form**—The purpose of this form, completed by the participating sponsor organization, is to collect background characteristics of the health plan.
- **Data Use Agreement**—The purpose of the data use agreement, completed by the participating sponsor organization, is to state how data submitted by health

plans will be used and provide confidentiality assurances.

- **Data Files Submission**—POCs upload their data file using the Health Plan data file specifications to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden hours for the respondent to participate in the database. The burden hours pertain only to the collection of Medicaid data from State Medicaid agencies and individual Medicaid health plans because those are the only entities that submit data through the data submission process. The 125 POCs in Exhibit 1 are a combination of an estimated 115 State Medicaid agencies and individual health plans (Sponsors), and 10 vendor organizations.

Each sponsor, which is made up of State Medicaid agencies and individual health plans, and vendor will register online for submission. The online Registration form will require about 5 minutes to complete. Each sponsor will also complete a Health Plan information form of information about each Health Plan such as the name of the plan, the product type (e.g., HMO, PPO), the population surveyed (e.g., adult Medicaid or child Medicaid). Each year,

the prior year’s plan data are preloaded in the plan table to lessen burden on the Sponsor. The Sponsor is responsible for updating the plan table to reflect the current year’s plan information. The online Health Plan Information form takes on average 30 minutes to complete per health plan with each POC completing the form for four plans on average. The Data Use Agreement (DUA) will be completed by the 115 participating State Medicaid agencies or individual health plans. Vendors do not sign or submit DUAs. The DUA requires about 5 minutes to sign and upload. Each submitter will provide a copy of their questionnaire and the survey data file in the required file format. Survey data files must conform to the data file layout specifications provided by the CAHPS Database. Submitters will upload one data file per health plan. Once a data file is uploaded the file will be checked automatically to ensure it conforms to the specifications and a data file status report will be produced and made available to the submitter. Submitters will review each report and will be expected to fix any errors in their data file and resubmit if necessary. It will take about 1 hour to submit the data for each plan, and each POC will submit data for four plans on average. The total burden is estimated to be 710 hours annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Registration Form	125	1	5/60	10
Health Plan Information Form	115	4	30/60	230
Data Use Agreement	115	1	5/60	10
Data Files Submission	115	4	1	460
Total	470	NA	NA	710

Exhibit 2 shows the estimated annualized cost burden based on the respondents’ time to complete one

submission process. The cost burden is estimated to be \$36,222 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Registration Form	125	10	^a 57.61	\$576
Health Plan Information Form	115	230	^a 57.61	13,250
Data Use Agreement	115	10	^b 102.41	1,024
Data Files Submission	115	460	^c 46.46	21,372
Total	470	710	NA	36,222

* National Compensation Survey: Occupational wages in the United States May 2021, “U.S. Department of Labor, Bureau of Labor Statistics.”

^a Based on the mean hourly wage for Medical and Health Services Managers (11–9111).

^b Based on the mean hourly wage for Chief Executives (11–1011).

^c Based on the mean hourly wages for Computer Programmers (15–1251).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, 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 21, 2023.

Marquita Cullom,
Associate Director.

[FR Doc. 2023–18221 Filed 8–23–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0588]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice for Blood and Blood Components and Reducing the Risk of Transfusion-Transmitted Infections

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 25, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0116. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice for Blood and Blood Components and Reducing the Risk of Transfusion-Transmitted Infections

OMB Control Number 0910–0116—Revision

This information collection helps support FDA implementation of statutory and regulatory requirements that govern current good manufacturing practice (CGMP) for blood and blood components. We have issued regulations in parts 606, 610, 630, and 640 (21 CFR parts 606, 610, 630, and 640) setting forth applicable standards and procedures that include associated reporting, recordkeeping, and disclosure requirements. Respondents to the collection of information are licensed and registered-only establishments that collect blood and blood components intended for transfusion or further manufacturing use. We provide information on our website at <https://www.fda.gov/vaccines-blood-biologics/blood-blood-products> regarding CGMP for blood and blood products, including available Agency resources.

We are revising the information collection to support implementation of annual reporting to FDA of the release of unsuitable blood donations from establishments that intend for their activities to fall under the compliance policy set forth in the draft guidance for industry entitled “Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements” (May 2022). The draft

guidance describes FDA’s compliance policy for certain regulations. Blood establishments that collect blood and blood components, including Source Plasma, must comply with requirements in § 630.30 regarding donation suitability. However, the draft guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment’s failure to comply with this requirement and describes proposed procedures for such an establishment’s filing of annual reports on the release of unsuitable donations to FDA. Specifically, under this policy, when finalized, when the donation is otherwise suitable under § 630.30(a), FDA does not intend to take regulatory action if blood establishments release donations for transfusion or further manufacture when the review of records, required after donation under § 630.30(a)(2), identifies the donation as unsuitable because of inadvertent failure to follow procedures to ensure that the donation would not adversely affect the health of the donor, namely for:

- blood pressure (§ 630.10(f)(2));
- pulse (§ 630.10(f)(4));
- weight (§ 630.10(f)(5));
- donation frequency for Whole Blood and Red Blood Cells collected by apheresis (§ 630.15(a)(1));
- pregnancy (§ 630.10(e)(2)(v)); and
- red blood cell loss for plasma collected by plasmapheresis (§ 630.15(b)(6)).

The draft guidance sets forth that FDA intends to apply the compliance policy provided blood establishments that elect to release unsuitable units as described in the guidance report the release of unsuitable donations to FDA annually. The draft guidance document is available for download at <https://www.fda.gov/media/158608/download>. We issued the guidance document consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We intend on finalizing the guidance document upon OMB approval of the attendant information collection. When finalized, the guidance will supersede the guidance entitled, “Alternative Procedures for Blood and Blood Components During the COVID–19 Public Health Emergency; Guidance for Industry,” dated April 2020.

As explained in section III.A of the guidance, licensed and registered-only blood establishments must maintain records as required under § 606.160; investigate the error that resulted in the collection of an unsuitable donation under § 630.30(a)(2); and submit a report to FDA annually if they intend for their activities to fall under this