

Supporting Statement A
Survey of Retail Prices
CMS-10241, OMB 0938-1041

Background

CMS has been performing a “Survey of Retail Prices” since 2011. This contract leverages a voluntary, monthly survey to collect drug ingredient costs from retail community pharmacies. Specifically, respondents’ data are used to develop average acquisition cost (AAC) based pricing for covered outpatient drugs purchased by retail community pharmacies, which is updated on a weekly basis and posted on [Medicaid.gov](https://www.medicaid.gov).

Since the inception of the monthly survey of retail community pharmacies, CMS has been using verified survey data to generate a publicly-available pricing database entitled the National Average Drug Acquisition Cost (NADAC) file. CMS has consistently received a sufficient number of monthly responses to develop statistically significant measurements of average cost for the purposes of publishing the NADAC benchmark according to its initial methodology. NADAC files are updated both weekly and monthly at <https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html>. Approximately 93%-97% of all covered outpatient drugs have pricing available on this file and most states are now using this file as a component of their Medicaid pharmacy reimbursement methodologies.

The methodology for the NADAC file, which outlines data quality requirements and provides a full description of the file, is publicly available at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf>.

Section 1902(a)(30)(A) of the Social Security Act (Act) requires, in part, that states have methods and procedures to assure that payment for Medicaid care and services is consistent with efficiency, economy, and quality of care. In accordance with these provisions, and in light of the OIG reports concerning published prices (OIG Audit reports – A-06-00-00023, A-06-01-00053, A-06-02-00041)[1], we believe it is necessary for states to have a reference price to base reimbursement for prescription drugs that is more accurate than the published prices that were the subject of the OIG reports.

The data will provide information which CMS expects to use to assure compliance with Federal requirements. Section 1927(f) provides, in part, that CMS may contract with a vendor to conduct monthly surveys of retail prices for covered outpatient drugs. The statute provides that such prices represent a nationwide average of consumer purchase prices, net of discounts and rebates. The statute further contemplates that the contractor provide notification when a drug product becomes generally available and that the contract include such terms and conditions as the Secretary shall specify, including a requirement that the vendor monitor the marketplace. We have included terms in our vendor contract to obtain additional information regarding marketplace prices (including pharmacy prices), which would be provided on a voluntary basis.

CMS is publicly providing the NADAC files for states to consider when developing an AAC reimbursement methodology. The NADAC is a pricing benchmark that is based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. This pricing

benchmark is based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey is conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date. Currently 46 states rely on the NADAC pricing files for their reimbursement rates to pharmacy providers for covered outpatient drugs. By facilitating a national survey of pharmacy acquisition costs, and making the resulting pricing benchmark available for states to use, CMS is significantly reducing the burden on states and retail community pharmacies that would occur if states were each obligated to produce their own pricing benchmarks.

The following documents are available on Medicaid.gov that review the NADAC procedures for calculations and Frequently Asked Questions:

- Webinar, Center for Medicaid and CHIP Services, CMS Retail Price Survey
<https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/december-5-2012webinarpresentation.pdf>
- National Average Drug Acquisition Cost (NADAC) Questions and Responses
<https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacqa.pdf>

Currently, up to 6,000 retail community pharmacies are randomly selected each month and have the option of voluntarily completing the survey. The initial sample size for the NADAC survey was determined during a time period when the NADAC was in development, but prior to the implementation of CMS-2345-FC and the adoption of the NADAC as the primary reimbursement benchmark for most state Medicaid programs. There are currently in excess of \$20 billion dollars of Medicaid pharmacy claims paid each year based on the NADAC file. The increased reliance on the NADAC file for claims payment significantly impacts the need for a robust and reliable source of survey data.

This 2023 iteration propose to remove the “Cover Sheet” and the “Dear Pharmacy Letter” since the upcoming mailings will consist only of a revised “Survey Tool.” We are also adding a Spanish version of the survey tool which is intended for retail community pharmacies in Puerto Rico. We are not proposing to change any of our currently approved burden estimates other than updating costs based on recent BLS wage data. Overall, the change increases our cost estimate by \$131,760. See section 15 of this Supporting Statement for details.

A. Justification

1. Need and Legal Basis

Section 1902(a)(30)(A) of the Act requires, in part, that States have methods and procedures to assure that payment for Medicaid care and services is consistent with efficiency, economy, and quality of care.

Section 1927(f) provides, in part, that CMS may contract with a vendor to conduct monthly surveys of retail prices for covered outpatient drugs.

CMS published a Covered Outpatient Drug final rule with comment (CMS-2345-FC) that went into effect April 1, 2017, and modified 42 CFR part 447, subpart I. This rule requires states to reimburse covered outpatient drugs at their actual acquisition cost (AAC). Many states have adopted the NADAC files to meet the new AAC reimbursement requirements.

2. Information Users

- CMS will have their contracted vendor send out voluntary surveys to retail community pharmacies each month.
- Pharmacies will have the option of completing the voluntary survey.
- It should take a pharmacy technician no longer than 30 minutes to complete the survey and return it to the contracted vendor. Pharmacies can also respond to the survey by electronically submitting a monthly purchase report, which is readily available from the pharmacy's wholesaler. The average time to respond to the survey would likely be less than 30 minutes for large chain organizations, as they typically have the capacity to submit responses for multiple individual pharmacies simultaneously.

The contracted vendor will perform the necessary calculations to determine the NADAC reimbursement rates. Once the file has been finalized, the data will be posted on Medicaid.gov weekly. The states use this file to assure compliance with Federal requirements to meet reimbursement requirements for covered outpatient drugs.

3. Use of Information Technology

The NADAC survey response is available in both hard copy and electronic format. Pharmacies can submit one month's of invoices by fax, mail, or e-mail.

4. Duplication of Similar Information

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

All retail community pharmacies will be included in the voluntary survey, to include small business pharmacies. There are approximately 17,938 small business pharmacies out of the total 61,585 retail community pharmacies (29.1%). The survey population of up to 6,000 pharmacies would result in an estimated average of 1,746 small business pharmacies being surveyed each month (i.e., $6,000 \times 29.1\% = 1,746$).

6. Less Frequent Collection

Based on the pace of changes in the pharmaceutical marketplace, data must be collected monthly to ensure accurate and current pricing files.

7. Special Circumstances

As indicated above in section 6, data must be collected monthly to ensure accurate and current pricing files. Otherwise, there are no special circumstances as this information collection request does not do any of the following:

- Require respondents to report information to the agency more often than quarterly;
- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Make use of a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Require the use of a statistical data classification that has not been reviewed and approved by OMB;
- Includes a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Require respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

The 60-day notice published in the Federal Register on August 1, 2023 (88 FR 50157). No comments were received.

The 30-day notice published in the Federal Register on October 16, 2023 (88 FR 71367). Comments must be received by November 15, 2023.

9. Payment/Gift To Respondent

There are no payments or gifts associated with this collection.

10. Confidentiality

There is no personal identifiable information collected in the documents.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/2022/may/oes_nat.htm). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Pharmacy Technicians	29-2052	19.35	19.35	38.70

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

The survey will be sent out monthly to no more than 6,000 random pharmacies per month. Pharmacies that have been selected for a survey will be withheld from future survey selection for a three-month period.

We estimate it would take no more than 30 minutes at \$38.70/hr for a pharmacy technician to complete the NADAC Survey Request for Information. Annually, we estimate a total of 72,000 (6,000 surveys/month x 12 months) pharmacies and 36,000 hr (72,000 pharmacies x 0.5 hr) at a cost of \$1,393,200 (36,000 hr x \$38.70/hr) or \$19.35 per survey. Since this is a voluntary survey, to the extent that pharmacies choose not to respond, the total burden could be less.

Information Collection/Reporting Instruments and Instruction/Guidance Documents

NADAC Survey Tool (Revised)

This is the English version of the NADAC (National Average Drug Acquisition Cost) survey tool.

NADAC Notificacion de Encuesta e Instrucciones (New)

This is the Spanish version of the NADAC (National Average Drug Acquisition Cost) survey tool.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

14. Cost to the Federal Government

Vendor Cost: Current option period from July 1, 2023 through June 30, 2024 is \$3,518,671

15. Program or Burden Changes

This 2023 iteration does not propose any burden changes other than updating costs based on recent BLS wage data. Our currently approved collection uses BLS' 2020 wage of \$35.04/hr (adjusted) while this collection of information request uses BLS' 2022 wage of \$38.70/hr (also adjusted). The increase of \$3.66/hr results in an overall increase of \$131,760 (from \$1,261,440 to \$1,393,200).

We also propose to remove the "Cover Sheet" and "Dear Pharmacy Letter" since the upcoming mailings will consist only of the revised "Survey Tool."

A Crosswalk and Track Change version of the revised Survey Tool are attached along with the new Spanish version of the survey. Since this is the first iteration of the Spanish Survey Tool, there is no Crosswalk or Track Change version of that tool.

The Spanish version of the survey tool is intended for retail community pharmacies in Puerto Rico.

16. Publication and Tabulation Dates

The Retail Price Survey will be performed for 12 months after the contractual start date and will continually renew annually thereafter. Drug prices from the collected information will be averaged and posted weekly on Medicaid.gov, but the respondents' individual information will never be disclosed and will be considered confidential.

17. Expiration Date

The expiration date will be displayed.

18. Certification Statement

There are no exceptions to the certification statements.

B. Collection of Information Employing Statistical Methods

The use of statistical methods for collection does not apply.