

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

Background

CMS is performing a “Survey of Retail Prices”. This contract focuses on the retail community pharmacy ingredient costs. This provides for a voluntary survey of the average acquisition costs of all covered outpatient drugs purchased by retail community pharmacies. The prices are updated on a weekly basis and posted on Medicaid.gov.

Since the inception of monthly surveying of retail community pharmacies for covered outpatient drug acquisition pricing, CMS has consistently been receiving a statistically significant number of responses monthly. The verified survey data has generated a publically-available pricing database entitled the National Average Drug Acquisition Cost (NADAC) file. The 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 for their pharmacy reimbursement methodologies.

The methodology for the NADAC file, which reviews the data quality requirements, as well as the full description of the file, is also publically 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 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 more accurate reference price to base reimbursement for prescription drugs.

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 publically providing the National Average Drug Acquisition Cost (NADAC) files for states to consider when developing an Actual Acquisition Cost (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.

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

<https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/december-5-2012webinarpresentation.pdf>

<https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacqa.pdf>

We propose to expand the number of retail community pharmacies that are sent the survey request each month. Currently, 2,500 pharmacies are randomly drawn each month and have the option of voluntarily completing the survey request. To further expand the survey population to derive more responses each month and ensure statistical validity to the NADAC pricing file, we propose to expand the survey population to up to 6,000 retail community pharmacies surveyed each month. This would remain a voluntary survey for completion. Overall, the change would add 21,000 hr (total) per year.

We also propose to add a Survey Cover Sheet that explains protections for drug acquisition cost data submitted by pharmacies. The document has no burden.

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. 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 the voluntary surveys to retail community pharmacies each month.
- Pharmacies will have the option of completing the survey.
- If completed, it should take a pharmacy technician no longer than 30 minutes to complete the survey and return it to the contracted vendor.
- The contracted vendor will perform the necessary calculations to determine the NADAC reimbursement rates.

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 by electronic submission (scanning and e-mailing).

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 participating pharmacies will be included in the voluntary pharmacy survey, to include small business pharmacies. There are approximately 17,938 small business pharmacies out of the total 61,585 participating pharmacies (29.2%).

This monthly survey randomly draws from up to 6,000 pharmacies a month. This would result in an estimated average of 1,752 small business pharmacies that would be included in this voluntary monthly survey. ($6,000 \times 29.2\% = 1,752$)

6. Less Frequent Collection

Data must be collected monthly to ensure accurate and current pricing files.

7. Special Circumstances

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 secret, 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 May 21, 2021 (86 FR 27623). While comments were due July 20, 2021, none were received.

The 30-day notice published in the Federal Register on September 2, 2021 (86 FR 49332). Comments must be received by October 4, 2021.

9. Payment/Gift To Respondent

There are no payments of gifts associated with this collection.

10. Confidentiality

There is no personal identifying information collected in the documents.

In this September 2021 iteration we propose to add a Survey Cover Sheet that explains protections for drug acquisition cost data submitted by pharmacies. The document has no burden.

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 2020 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage	Fringe Benefits and Overhead	Adjusted Hourly Wage
Pharmacy Technicians	29-2052	\$17.52/hr	\$17.52/hr	\$35.04/hr

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 overhead 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 6,000 random pharmacies per month. The same pharmacy is not expected to receive the survey more than once every two years.

We estimate it would take no more than 30 minutes at \$35.04/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 \$1,261,440 (36,000 hr x \$35.04/hr) or \$17.52 per survey.

Information Collection/Reporting Instruments and Instruction/Guidance Documents

Survey Cover Sheet (explains protections for drug acquisition cost data submitted by pharmacies)
(New)

National Average Drug Acquisition Cost (NADAC) Survey Request for Information (No changes)

Dear Pharmacy (Letter) (No changes)

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

14. Cost to the Federal Government

There are no costs to the federal government.

15. Program or Burden Changes

In this September 2021 iteration, we propose to expand the number of retail community pharmacies that are sent the survey request each month. Currently, 2,500 pharmacies are randomly drawn each month and have the option of voluntarily completing the survey request. To further expand the survey population to derive more responses each month and ensure statistical validity to the NADAC pricing file, we propose to expand the survey population to up to 6,000 retail community pharmacies surveyed each month. This would remain a voluntary survey for completion. Overall, the change would add 21,000 hr (total) per year.

The costs have been adjusted by considering the most recent BLS wage estimate which increased by \$1.62/hr (from \$15.90/hr to \$17.52/hr). Otherwise, this iteration does not propose any other burden changes than the voluntary survey population database being increased to 6,000 pharmacies each month. Overall, the change would add \$784,440 hr per year (from \$477,000/yr to \$1,261,440/yr).

We also propose to add a Survey Cover Sheet that explains protections for drug acquisition cost data submitted by pharmacies. The document has no burden.

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 is 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.