

Supporting Statement for Paperwork Reduction Act
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.

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>

The title of this information collection request has been revised to reflect that the annual report had been suspended in our currently approved iteration. The burden was also removed at that time. The survey letter has been updated by providing the current CMS group director's name. The costs have been adjusted by considering the most recent BLS wage estimates. Otherwise, this iteration does not propose any burden changes.

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 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 18,269 small business pharmacies out of the total 62,650 participating pharmacies (29.2%).

This monthly survey randomly draws from 2,500 pharmacies a month. This would result in an estimated average of 730 small business pharmacies that would be included in this voluntary monthly survey.

6. Less Frequent Collection

Data must be collected annually to meet the requirements of the law.

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 March 15, 2018 (83 FR 11538). No comments were received.

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.

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 Estimate (Total Hours and Costs)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 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 Benefit (at 100%) | Adjusted Hourly Wage |
|----------------------|-----------------|------------------|--------------------------|----------------------|
| Pharmacy Technicians | 29-2052 | \$15.90/hr | \$15.90/hr | \$31.80/hr |

Burden Estimates

The survey will be sent out monthly to 2,500 random pharmacies. 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 \$31.80/hr for a pharmacy technician to complete the NADAC Survey Request for Information. Annually, we estimate a total of 30,000 (2,500 surveys/month x 12 months) pharmacies and 15,000 hr (30,000 pharmacies x 30 min) at a cost of \$477,000 (15,000 hr x \$31.80/hr) or \$15.90 per survey.

Information Collection/Reporting Instruments and Instruction/Guidance Documents

National Average Drug Acquisition Cost (NADAC) Survey Request for Information

Dear Pharmacy (Letter)

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

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The costs have been adjusted by considering the most recent BLS wage estimates. Otherwise, this iteration does not propose any burden changes.

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.

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.