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

Notes: This December 2025 iteration is being submitted to OMB for approval with non-substantive changes. With the exception of this and the following added paragraphs, please note that we are not proposing any changes to Supporting Statements A and B. Instead, the nonsubstantive changes are limited to the English and Spanish versions of the NADAC Survey Tool. For details, see the attached Justification for Non substantive Change.

The contents of this Supporting Statement and the associated attachments have been reviewed to ensure that they are consistent with the Trump administration's policies, goals, and objectives.

Respondent Universe and Sampling Methods:

As of July 1, 2023, there are 62,499 retail community pharmacies in the United States, including the District of Columbia and Puerto Rico. The sampling methodology is a simple random sampling and will include all retail community pharmacies nationwide. Pharmacies that have been selected for a survey will be withheld from future survey selection for a three-month period. Surveys will be performed monthly to collect acquisition cost data from pharmacies regarding their purchase cost of prescription drugs.

Procedures for the Collection of Information:

Pharmacies selected to participate in each monthly survey will be contacted by mail and requested to provide copies of their drug purchase records (i.e., invoices) covering the most recent 30-day period. Alternatively, pharmacies may contact their drug suppliers/wholesalers and request that they send the information on their behalf. The information may be supplied in hard copy or electronically, and may be returned via mail, fax or email. Based on the contractor's experience performing surveys to collect pharmacy acquisition costs, the time required by individual pharmacies to comply with the survey request is 30 minutes or less.

Information received from the pharmacies is entered or imported into an electronic database. Depending on how the information is provided by the pharmacy, the data may be data-entered, scanned or electronically imported into the database. After the database is populated, the information undergoes a rigorous scrubbing process to ensure the integrity of the data. For example, the scrubbing process includes validating the data entry, confirming that the National Drug Code (NDC) exists, is active, and is included in the Medicaid covered outpatient drug file, comparisons of the unit prices to other published reported prices, validating drug package sizes, etc.

All NDCs are then grouped based on similar chemical composition, strength, and drug form. Reports for each drug group are prepared and analysis of the data can begin.

Methods to Maximize Response Rates and Deal with Non-response:

Communicating the goals, objectives and processes for complying with the survey is essential in maximizing survey response rates. This is accomplished through outreach to pharmacies, their industry representatives and all other stakeholders. Through this outreach process, the purpose of the study is made clear and the advantages of participating are highlighted. Addressing known concerns is also essential to improving response rates. For example, pharmacies may be reluctant to provide their invoice records for fear they could be made available to their competitors or used for other purposes. By including in the outreach the privacy and confidentially procedures, pharmacies can become comfortable with the limitations on how their data are used as well as how their privacy and confidentiality will be maintained. The amount of effort and resources needed to comply with the survey request is also a frequent concern of survey respondents. Since the amount of time required to comply with a survey is correlated to the response rate, we have minimized the burden of completing the survey. The survey respondents do not need to answer questions as would typically be the case with a survey. They are simply asked to photocopy existing records, or they may send an electronic file of their purchase records.

Following outreach to pharmacies, when a pharmacy is selected to participate in a survey they receive a clearly worded survey request letter (aka survey tool). The survey tool communicates all the steps necessary to be completed by the respondent and offers a toll free telephone number and website if the respondent has questions.

As with any reliable survey, non-responses are examined to determine bias. CMS is particularly interested in evaluating non-response bias tied to costs. We are able to address this type of bias since we know the population size and characteristics. Therefore, if appropriate, the sample can be weighted. We will closely monitor non-response rates.

Tests of Procedures or Methods to be Undertaken:

To date, the sampling methodology used is simple random sampling of all of the pharmacies in the "universe" (i.e., 62,499). Once collected, the data have been averaged at the drug group level to produce an aggregate average cost for each group. If additional details are desired in the future, data may be further divided by various pharmacy characteristics in addition to the drug group level. For example, it may be of interest to produce separate averages for chain versus independent pharmacies for each drug group. In addition, we will measure the precision of the averages by estimating confidence intervals for each of the average costs. Ideally, the survey would aim to achieve sufficient precision that the margin of error for a 95% confidence interval of average drug cost is no more than 5% of the sample mean for a given drug group. Precision is enhanced by larger sample sizes and diluted by greater variation in costs across pharmacies. Unfortunately, this variability cannot be known prior to the sampling and thus precision cannot be predicted with confidence.

An important caveat is that the sample size ultimately depends upon the number of pharmacies chosen for the sample that agree to participate. If a large number of pharmacies decline to participate, then precision will be adversely affected. The ability to modify the sample size based on trends in participation rates will allow for

responsiveness in adjusting the sample size to ensure continued statistical validity of averages by drug group calculated from survey data. Larger sample sizes would have the greatest impact on drug groups for which the number of cost observations received has been low. Furthermore, if greater detail is needed to further segment averages by pharmacy characteristic, a larger number of cases will be needed to satisfy the specified criterion.

The current sample sizes, with some flexibility to make future adjustments, are based upon our best estimate of the likely outcomes. The precision of the results will be examined to determine the number of drug groups that satisfy the specified criterion. In subsequent months, the margins of error will be examined and the sample size recommendations may be revised to reflect the actual variability in the data and the participation rate.

Individuals Consulted on Statistical Aspects and Individuals Analyzing Data:

Myers & Stauffer, LC was awarded a contract on July 8, 2021 to perform a "Survey of Retail Prices."

Myers & Stauffer will be utilizing David Bivin, Ph.D. to serve as the lead statistician for this project. Dr. Bivin is a Professor Emeritus of Economics at Indiana University. Dr. Bivin consults with peer colleagues on economic and statistical issues as needed.

Allan Hansen, Principal/Partner, and Linda Wiant, R.Ph, will serve as lead data analysts.