Supporting Statement Part B

"SURVEY OF RETAIL PRICES: PAYMENT AND UTILIZATION RATES, AND PERFMANCE RANKINGS"

CMS-10241, OMB 0938-1041

"Survey of Retail Prices"

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Respondent Universe and Sampling Methods:

As of September 1, 2021, there are 63,183 retail community pharmacies in the United States, including the District of Columbia. The sampling methodology is a simple random sampling and will include all retail community pharmacies nationwide. At this time, there are no plans in place to re-sample pharmacies from month to month. 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 by 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 is 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. The letter 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.

With any 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:

The sampling methodology is simple random sampling of all of the pharmacies in the universe. Once collected, the data will be averaged at the drug group level to produce an aggregate average cost.

In addition, we will measure the precision of the averages by estimating confidence intervals for each of the average costs. 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.

There are several caveats to this conclusion. The first is that nationwide data are likely to be more variable than data from specific states. If that is the case, a smaller number of cases will satisfy the 5% criterion. The second 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, then precision will be adversely affected.

Our proposed sample sizes 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 prescribed criterion. In the first several months following the initial sample, the margins of error will be examined and the sample size recommendations revised to reflect the actual variability in the data and the participation rate.

We intend to look at a hybrid criterion in which the margin of error is measured in dollar values and as a percent of the mean with a drug group's margin of error deemed acceptable if it satisfies one or both criteria.

<u>Individuals Consulted on Statistical Aspects and Individual Analyzing Data:</u>

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 of Economics at Indiana University. Dr. Bivin consults with peer colleagues on economic and statistical issues as needed.

Michael Sharp, R.Ph, and Allan Hansen will serve as lead data analysts.