Supporting Statement – Part B

Hospital Survey for Specified Covered Outpatient Drugs (SCODs)
(CMS-10709; OMB 0938-New)

1. Describe (including a numerical estimate) the potential respondent universe and any sampling or other respondent selection method to be used. Data on the number of entities (e.g., establishments, State and local government units, households, or persons) in the universe covered by the collection and in the corresponding sample are to be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate expected response rates for the collection as a whole. If the collection had been conducted previously, include the actual response rate achieved during the last collection.

The sample will be 100% of the potential respondent universe. CMS contractors will make the survey available to all hospitals that purchased drugs through the 340B Program in the last quarter of 2018 or first quarter or 2019. Accordingly, we expect to receive up to approximately 1,400 responses. Each hospital that acquired drugs under the 340B program in the fourth quarter of 2018 and/or the first quarter of 2019 is requested to complete one survey that includes acquisition costs for each of the two quarters. sections 1833(t)(14)(A)(iii)(I) and (D)(ii) and (iii) of the Social Security Act (the Act) grant the Secretary authority to conduct a survey and use survey data in part to determine hospital acquisition cost for each specified covered outpatient drug.

2. Describe the procedures for the collection of information including:

Statistical methodology for stratification and sample selection

CMS is surveying the complete universe of 340B-covered hospitals for the survey period. Stratification and sampling will not be used.

3. Describe methods to maximize response rates and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield 'reliable' data that can be generalized to the universe studied.

As provided above, CMS contractors will announce the availability of the survey and receive the survey responses. Where the acquisition cost for any individual drug is unknown or left blank, CMS will use the 340B ceiling price as a proxy for the acquisition cost for that drug. CMS will also use 340B ceiling prices as proxies for the acquisition costs of drugs where a hospital fails to respond to the survey. Hospitals also have the option to utilize a Quick Survey checkbox feature, which will allow stakeholders to elect to use HRSA ceiling prices because they adequately reflect their 340B drug acquisition costs.

Data received in response to this collection may be used in a manner that would have a

significant impact on 340B hospitals' payment, and we believe the response rate will be high given the potential impact. CMS will seek comment through a notice of proposed rulemaking (NPRM) before making changes to payment rates based on the survey data we receive.

This collection is not based on sampling.

4. Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections of information to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions from 10 or more respondents. A proposed test or set of tests may be submitted for approval separately or in combination with the main collection of information.

Not applicable since CMS is not using a sampling methodology.

5. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

This survey is authorized by law and is being asked of 100 percent of the respondent universe, accordingly, special survey design is not applicable.