Supporting Statement – Part B

Collections of Information Employing Statistical Methods

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 universe is 100% of hospitals paid under the Outpatient Prospective Payment System (OPPS). There will be no sampling of this universe. There are approximately 4,500 hospitals that are currently paid under the OPPS. All hospitals paid under the OPPS are required to respond to this survey.

- 2. Describe the procedures for the collection of information including:
 - Statistical methodology for stratification and sample selection,
 - Estimation procedure,
 - Degree of accuracy needed for the purpose described in the justification,
 - Unusual problems requiring specialized sampling procedures, and
 - Any use of periodic (less frequent than annual) data collection cycles to reduce burden.

CMS is surveying the complete universe of hospitals paid under the OPPS for the survey period. Stratification and sampling will not be used. We expect to survey these hospitals every four (4) years. We believe that this frequency will appropriately balance the burden imposed on hospitals of completing the survey with ensuring that we capture the required data to inform payment rates as required under section 1833(t)(14)(D)(I)(ii) of the Act. However, this frequency is subject to revision based on the initial survey's results and other factors as appropriate. As described above, this is a required survey.

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 noted above, we are not proposing to use sampling for this survey. To increase the response rate, CMS announced its plan to collect data in notice and rulemaking for calendar year (CY) 2026 in the CY 2026 OPPS and Ambulatory Surgical Center (ASC) payment system proposed¹ and final rules.² Additionally, CMS will communicate the plan to collect data through the Medicare

¹ https://www.federalregister.gov/documents/2025/07/17/2025-13360/medicare-and-medicaid-programs-hospital-outpatient-prospective-payment-and-ambulatory-surgical

² Add web link when available.

Learning Network® (MLN). CMS will provide onboarding and training to hospitals for the Fee for Service Data Collection System (FFSDCS). As an additional means of increasing the response rate, CMS will provide hospitals with 3 months to respond to the survey to ensure that they have ample time to provide responses. If a hospital does not respond to the survey, CMS will mark the hospital down as a "non-respondent."

CMS is considering how to account for a non-responding hospital's drug acquisition costs and how those costs might be reflected in future payment rates. For example, a failure on the part of a hospital to respond to the survey could suggest that the hospital has minimal acquisition costs, or has lower acquisition costs than an otherwise similar hospital that responds to the survey, and the hospital is strategically withholding its response. In this case, if the data suggests, we may determine that groups of hospitals who do not respond to the survey have lower, or categorically different, acquisition costs for SCODs, and non-SCODs, than their otherwise similar counterparts under section 1833(t)(14)(A)(iii)(I) of the Act. In such instances, we would consider various appropriate ways, taking into account the hospital acquisition cost survey data, to determine the average acquisition cost. One method we might consider, depending on the cost survey data, could be to use the lowest acquisition cost reported among otherwise similar responding hospitals as a proxy for the acquisition costs for hospitals that do not respond to the survey. We might also consider supplemental data sources to inform our determination of average acquisition costs for hospitals for whom we lack cost acquisition survey data. For example, we might consider using, as available, pricing from the Federal Supply Schedule (FSS); 340B ceiling price; Average Sales Price plus 6 percent, 0 percent or another percentage; or other recognized drug pricing for payment for hospitals that do not respond to the survey. We could also consider a hospital's non-response to the survey when determining how to package drug costs for particular hospital groups.

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.

CMS will not perform a test. There is no sampling or stratification to test for this survey. Therefore, this is 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.

There is no sampling or stratification to test for this survey. There was no consultation of statistical aspects of design. Accordingly, special survey design is not applicable. We believe we will have a sufficient response rate and we will continue to consult with the CMS Office of the Actuary on how the response rate will affect how we use the results. Under section 1833(t)(14)(D)(iii) of the Act, a survey must have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. Consequently, we seek an adequate response rate to the survey and surveyed hospitals have an obligation to respond to the survey. Hospitals had ample notice in the CY 2026 OPPS/ASC proposed and final rules regarding the intent and the details of the OPPS Drug Acquisition Cost

Survey so we expect all hospitals would submit their acquisition costs in a timely manner to CMS. We understand that hospitals have significant drug acquisition costs, and so, consistent with the Comptroller's General experience conducting earlier drug acquisition cost surveys in which 83 percent of the hospitals surveyed provided usable data,³ we anticipate hospitals would want to respond to the survey to demonstrate these costs to CMS.

³ https://www.gao.gov/assets/gao-06-372.pdf. Page 7.