

is predominately stored electronically by these entities. Assuming a maximum of 1000 of the above entities are requested to provide information in a given year, the maximum aggregate burden associated with this information is 1000 hours per year.

Under option 4, bidders would have to submit a bid. They would have to demonstrate that they have sufficient capacity, that the source of the drugs is the wholesaler or distributor for the wholesaler, and that they have arrangements for shipment within a specified time frame. They would be required to have a procedure for resolving disputes.

The burden associated with the competitive acquisition program would be the time it would take a bidder to submit the bid and to document that it has met the requirements. We expect it would take an average of approximately 40 hours to collect the information for competitive bidding under option 4. Given that we are seeking comment on the number of geographic areas to conduct the competitive bidding, it is not possible to estimate the aggregate burden.

Also under option 4 we are requesting information from manufacturers on the Average Sales Price of a drug. We believe that it would take an average of one hour to collect this information. Given the universe of approximately 450 Medicare drug codes and assuming an average of 10 manufacturers per drug code, the maximum aggregate burden associated with this activity would be 4500 hours per quarter.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, DRDI, DRD-B, Attn: Julie Brown, Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

Comments submitted to OMB may also be emailed to the following address: email: [baguilar@omb.eop.gov](mailto:baguilar@omb.eop.gov); or faxed to OMB at (202) 395-6974.

#### IV. Response to Public Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able

to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

#### V. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132. Executive Order 12866 (as amended by Executive Order 13258, which reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for final rules with economically significant effects (that is, a final rule that would have an annual effect on the economy of \$100 million or more in any 1 year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities). As described below, we have simulated the effect of changes in payment resulting from the implementation of each of the four options for revising the current drug payment methodology. We have also simulated the impact of our proposed increase in payments for the administrative costs related to furnishing drugs.

Since this rule is considered to be a major rule because it is economically significant, we have prepared a regulatory impact analysis. The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a Regulatory Flexibility Analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

For purposes of the RFA, physicians and non-physician practitioners are considered small businesses if they generate revenues of \$8.5 million or less. Approximately 96 percent of physicians are considered to be small entities. There are in excess of 20,000 physicians and other practitioners that receive Medicare payment for drugs. These physicians are more concentrated in the specialties of oncology, urology, and rheumatology. Of the physicians in these specialties, approximately 40 percent are in oncology and 45 percent in urology.

For purposes of the RFA, approximately 98 percent of suppliers of DME and prosthetic devices are considered small businesses according to the Small Business Administration's (SBA) size standards. We estimate that 106,000 entities bill Medicare for DME, prosthetics, orthotics, surgical dressings, and other equipment and supplies each year. Total Medicare expenditures for DME are approximately \$7 billion per year, of which approximately \$1 billion are for DME drugs.

The impact of this proposed rule on an individual physician or DME supplier is dependent on the mix of drugs they provide to Medicare beneficiaries. For example, under the market monitoring option a physician could: (1) Determine the quantities of drugs that the physician provides to Medicare beneficiaries; (2) determine the proposed impact on that physician for drugs which have been studied by GAO and OIG based on the quantities the physician provides, the information in Table 3, and our proposed transition as described in section II.A.3.f; and, (3) determine the proposed impact on that physician for drugs which have not been studied by GAO and OIG based on the quantities the physician provides and our proposal to pay 80 percent to 90 percent of AWP as discussed earlier in section II.A.3.c. Different impacts will result from this calculation depending on the mix of drugs provided.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. To the extent changes in drug payments would have any impact on small rural hospitals, it would be limited to the few drugs they might furnish with pass-through status