

provisions as well as our proposal for additional ESRD payments.

4. Inhalation and Home Infusion Drugs

For inhalation drugs furnished in connection with an item of DME, Medicare currently pays for: (i) The DME itself, (ii) servicing of the DME, and (iii) the inhalation or infusion drug. For inhalation drugs, Medicare also pays a dispensing fee.

Inhalation equipment, such as nebulizers and home infusion pumps, are paid under the DME benefit under the capped rental category. The supplier furnishes the equipment to a beneficiary and the supplier is paid 10 percent of the purchase price for the first three months and 7.5 percent of the purchase price for months 4 through 15 (that is, up to 120 percent) of the purchase price of the equipment. The supplier furnishes the equipment for as many months as the beneficiary needs it. The statute also provides for a purchase option for the beneficiary. If a beneficiary does not purchase the equipment, the supplier retains title to the equipment and could furnish it to another beneficiary. In this case, the payment occurs in a similar fashion and the supplier could be paid up to another 120 percent of the purchase price of the equipment. Medicare's payment includes delivery of the equipment to the patient and any necessary setup and training of the beneficiary in its use.

The statute specifies that Medicare also make payments for maintenance and servicing the equipment. Such maintenance and servicing payments cover 6-month periods beginning 7 months after initial use of the equipment. By statute, Medicare's payment for maintenance and servicing is equal to the lesser of a reasonable and necessary maintenance and servicing fee, or 10 percent of the total purchase price of the equipment.

In their September 2001 report described earlier (GAO-01-1118), the GAO noted that although there have been no recent analyses of the adequacy of Medicare DME payments, there are indications that the payments may be above market rates. We are unaware of any studies indicating that absent excessive Medicare payments for DME drugs, payment for the DME itself is inadequate. Nevertheless, we are interested in receiving convincing and comprehensive data from the public about any underpayment for inhalation and infusion durable medical equipment believed to exist and the applicability of that data under each of our four options revising the current payment methodology.

We note that it has been suggested that the current excessive Medicare payments for DME drugs are used to pay for inhalation and infusion services provided by DME suppliers that are not covered by the Medicare program. We believe it is inappropriate for excessive drug payments to subsidize these non-covered services.

5. Oral Drugs Provided by Pharmacies

Medicare makes no separate payment to pharmacies for dispensing covered Medicare drugs such as oral immunosuppressive and oral anti-emetic drugs. The GAO report did not make a recommendation with respect to dispensing fees for pharmacies. We are seeking public comment and data related to the appropriateness of dispensing fees under each of our four options for revising the current payment methodology.

C. Beneficiary Access to Drugs

Given our intent to pay appropriately for drugs and our proposed increases in payments for the costs related to furnishing and administering drugs, we do not believe that any beneficiaries will experience drug access issues as a result of our four proposed options. For the drugs (for example, the inhalation drugs) where we are not currently proposing changes in payments related to the administrative costs of furnishing the drugs, we are seeking comments and data supporting the appropriateness of any payment changes.

Although we do not believe any drug access issues will result from this proposed rule, we intend to monitor beneficiary access closely and may propose additional changes to our payment system in the future if necessary. The data sources we might examine in our access monitoring effort include claims data, surveys and focus groups, beneficiary inquiries to the 1-800-Medicare number, and environmental scanning activities.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Requirement:

Under proposed option 2 and option 3 for this regulation, a manufacturer of a new drug or a drug coming off patent would have to submit detailed information and a rationale to us for a new price, in order to receive a HCPCS code or continue the use of a HCPCS code, respectively. During the first year, the manufacturer would also have to provide updated information on the actual prices that Medicare physicians and supplier pay to purchase the drug.

The burden associated with these requirements is the time involved in providing us the information the first time and in providing us the updates. The burden of submitting the data should be minimal, as most of it will undoubtedly be electronically stored and transmitted. Submitting information should take no longer than 1 hour; updates would take no more than 30 minutes per year. Assuming a maximum of 50 Medicare Part B covered drugs per year either new, coming off patent, or subject to a manufacturer update in the first year based on actual sales, we expect the maximum aggregate burden per year would not exceed 150 hours. In addition, under option 3 a manufacturer could request an exception to price reduction in the first year. We believe that it would take an average of one hour to submit the request and the necessary data and certification. 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.

For proposed option 3 for this regulation we would collect, through various means, market-based price information. This information would be collected from any of the following: manufacturers, distributors, physicians and suppliers, and private insurers and health plans.

The burden associated with these requirements is the time involved in providing us the information. We expect it would take an average of one hour to provide us with this information. We expect the burden will not vary significantly regardless of the number of codes requested since this information