

programs to send the amount of the rebate to the supplier rather than to the beneficiary. We would still have no way of knowing in all instances if the charge submitted by the supplier included the manufacturer's rebate unless the supplier clearly marked and deducted an amount for the manufacturer's rebate. We believe the special payment limits for HCPCS code E0607 accurately reflect the maximum net costs incurred by non-Medicare patients who purchase or rent home blood glucose monitors (the supplier's charge less the manufacturer's rebate).

Comment: One commenter stated that the prices listed in the Bruce catalog do not reflect the time spent by suppliers on teaching patients how to use the monitors.

Response: As we noted earlier, the special payment limit of \$58.71 exceeds most net prices that we have reviewed. The prices charged by suppliers generally include the cost of all services necessary to ensure the proper use of the home blood glucose monitor. This service includes teaching a beneficiary how to use the monitor. Therefore, the special payment limit amount of \$58.71 should also include the cost for any time spent by a supplier in assisting a beneficiary. The pricing information that we reviewed included prices obtained from pharmacies and other retail store outlets. In addition, 5 of the 6 monitors listed in the Bruce catalog include either an instruction manual or instructional audio or video cassettes that explain how to use the monitors.

Comment: Several commenters stated that the special payment amounts are too low and would result in a negative impact on beneficiary access to standard home blood glucose monitors.

Response: This issue was discussed in section III.B. of the proposed notice (59 FR 759) and in section VI.B. below.

V. Provisions of the Final Notice

The following special payment limits represent a 3-percent increase over the limits published in the proposed notice and apply to standard home blood glucose monitors furnished to Medicare beneficiaries on or after the effective date of this final notice and before January 1, 1995:

- For a new monitor furnished in the continental U.S., the upper payment limit will be \$58.71. In Alaska, Hawaii, Puerto Rico, and the Virgin Islands, the upper payment limit will be \$66.95.

- For a used monitor, the upper payment limit will be 75 percent of the special payment limit for a purchased new monitor. For CY 1994, the special payment limit for a purchased new home blood glucose monitor furnished

in the continental U.S. will be \$58.71; the special payment limit for a used monitor will be \$44.03.

- For a rented monitor, the special payment limit will be equal to 10 percent of the special payment limit for a purchased new monitor. For CY 1994, the special payment limit for a purchased new home blood glucose monitor will be \$58.71; the monthly special payment limit for a rented monitor will be \$5.87. The total payment for a rented monitor may not exceed the lower of the actual charge or the special payment limit for the purchase of the monitor.

- For each calendar year after 1994, the special payment limits will be equal to the special payment limits for the preceding calendar year increased by the covered item update factor for the calendar year during which the limits will apply. The covered item update factor is generally equal to the change in the CPI-U for the 12-month period ending June 30 of the preceding year.

VI. Regulatory Impact Statement

A. Introduction

This final notice will reduce unnecessary Medicare program expenditures for standard home blood glucose monitors. Currently, payment under the Medicare program for home glucose monitors is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. Under this final notice, payment for the remainder of CY 1994 will be equal to 80 percent of the lesser of the actual charge or the appropriate special payment limit listed in this notice.

We are establishing special payment limits for the remainder of CY 1994 for a purchased new home blood glucose monitor for Medicare beneficiaries of \$58.71 if the monitor is furnished within the continental U.S. and \$66.95 if furnished in Alaska, Hawaii, Puerto Rico, or the Virgin Islands.

During CY 1993, the Medicare program made payments to suppliers of approximately \$17 million for approximately 130,000 home blood glucose monitor services of which 89,585 were purchased new home blood glucose monitors. We estimate that imposing special payment limits for purchased new home blood glucose monitors will produce savings of approximately \$5 million annually, or \$25 million from FY 1995 through FY 1999. Since purchased new home blood glucose monitors account for approximately 92 percent of Medicare expenditures for home blood glucose monitors, we anticipate negligible savings due to our reduction of payment

for used or rented home blood glucose monitors.

B. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a notice will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all suppliers and manufacturers of home blood glucose monitors are considered to be small entities.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a notice 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 604 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 of a Metropolitan Statistical Area and has fewer than 50 beds.

In determining whether to adjust payment rates for standard home blood glucose monitors, we considered the potential impacts on quality, access, and beneficiary liability of the adjustment, including the likely effects on assignment rates and participation rates of suppliers (as required by section 1842(b)(8)(C) of the Act).

This notice will affect suppliers of standard home blood glucose monitors. Their total Medicare payments could be reduced by the amount of the estimated savings. Suppliers can choose the option of accepting assignment, which means they agree to accept Medicare's approved amount as payment in full. As a consequence of our reducing payments for code E0607, the number of suppliers accepting assignment of beneficiary claims for Medicare payment for this code may decrease. These suppliers may choose instead to charge beneficiaries the full difference between the amount charged and the lower Medicare payment. Also, the number of suppliers who elect to become "participating suppliers" may decrease as a result of reduced payments for code E0607. Under the Medicare participation program, a supplier that decides to become a "participating supplier" must agree to accept assignment for all covered services furnished to Medicare beneficiaries. Participating suppliers benefit by being listed in the Medicare Participating Physician/Supplier Directories, known as Medpads, which are compiled by the Medicare carriers and furnished to various senior citizen