

## 2. Purchased Used Home Blood Glucose Monitors

Historically, the Medicare-allowed payment amounts for the purchase of used DME have been set at approximately 75 percent of the corresponding allowed payment amounts for the purchase of new DME. Based on this ongoing policy, for purchased used home blood glucose monitors, we stated in the proposed notice that the special payment limits would be equal to 75 percent of the special payment limits for purchased new monitors. If the special payment limit for a purchased new home blood glucose monitor would be \$57, the special payment limit for the purchased used monitor would be \$42.75.

## 3. Rented Home Blood Glucose Monitors

Historically, the Medicare-allowed payment amounts for the rental of DME have been set at approximately 10 percent of the corresponding allowed payment amounts for the purchase of new DME. Based on this ongoing policy, for rented home blood glucose monitors, the special payment limits under the proposed notice would be equal to 10 percent of the special payment limits for purchased new monitors. If the special payment limit for a purchased new home blood glucose monitor would be \$57, the special payment limit for a rented monitor would be \$5.70 each month. The total payment for a rented monitor would not be allowed to exceed the lower of the actual charge or the special payment limit for the purchase of the monitor.

### B. Applicability

The initial special payment limits in the proposed notice would have applied to standard home blood glucose monitors furnished before January 1, 1994. (However, as noted above, the proposed notice was not published until after that date.) We proposed that, for standard home blood glucose monitors furnished in CY 1994, the special payment limits would be equal to the initial special payment limits increased by the 1994 covered item update factor (the factor used to update other items of DME). (The covered item update for 1994, and each subsequent year, is defined in section 1834(a)(14)(B) of the Act as the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.) For each calendar year after 1994, we proposed that the special payment limits would be equal to the special payment limits for the preceding calendar year increased by the covered item update

for the calendar year to which the limits would apply.

These special payment limits would not apply to home blood glucose monitors with special features (HCPCS code E0609).

### III. Supplier Consultation

Sections 1834(a)(10)(B) and 1842(b)(9)(A)(i) of the Act require that we consult with representatives of the suppliers likely to be affected by any change in payment before making a determination that a fee schedule amount(s) is not inherently reasonable by reason of its grossly excessive or deficient amount. In the proposed notice (59 FR 757), we discussed the meeting held on June 15, 1993, with representatives of suppliers of home blood glucose monitors (hereinafter referred to as supplier representatives). The purpose of the meeting was to discuss issues relating to Medicare payment for these devices. The supplier representatives were primarily concerned about the use of manufacturer rebate information in determining appropriate Medicare payment amounts for home blood glucose monitors. They maintained that the rebate programs were purely a marketing tool used by the manufacturers to promote the sale of their monitors, that the rebates do not relate in any way to the "market price" of the monitors, and that the rebate programs were not permanent and, therefore, should not be used as a basis for establishing payment amounts. The supplier representatives also maintained that some rebate programs are not available in some areas of the United States.

The OIG report, previously cited, stated that manufacturer rebates for home blood glucose monitors generally range from about \$30 to \$75 and that the duration of the rebate offer is continually extended, often lasting for more than 1 year or until a new model is introduced. Given the facts underlying the pricing of these monitors, we believed the retail prices of home blood glucose monitors less the available rebate amounts are reasonable measures of the market value of these devices. We are not aware of any manufacturer rebate that is not offered on a nationwide basis.

### IV. Discussion of Public Comments on the Proposed Notice

In response to the January 1994 proposed notice, we received 8 timely items of correspondence. Comments were received from a variety of correspondents, including manufacturers of home blood glucose

monitors, the Health Industry Manufacturers Association, the National Association of Retail Druggists, Blue Cross and Blue Shield of Illinois, pharmacies, and medical equipment suppliers. These comments and our responses are discussed below.

*Comment:* One commenter was confused by section II.B. of the proposed notice which deals with the applicability of the initial special payment limits (59 FR 758). In section II.B. of the proposed notice, we state that the initial limits "would apply to standard home blood glucose monitors furnished on or after the effective date of the published final notice and before January 1, 1994." The commenter asked if the initial special payment limits would apply to new claims for standard home blood glucose monitors furnished in calendar year 1993 that are received after the date of the final notice.

*Response:* We proposed to apply the initial special payment limits in the proposed notice to standard home blood glucose monitors furnished before January 1, 1994. However, since we did not publish a final notice by January 1, 1994, no payments will be made based on these proposed special payment limits for any claims for standard home blood glucose monitors. Rather, the revised special payment limits presented in section V of this final notice will 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. The special payment limits for CY 1995 will be equal to the 1994 special payment limits increased by the 1994 covered item update factor.

*Comment:* One commenter requested that we further define home blood glucose monitors with special features (HCPCS code E0609).

*Response:* The descriptor for HCPCS code E0609 is "blood glucose monitor with special features (e.g., voice synthesizers, automatic timer, etc.)." Section 60-11 of the Medicare Coverage Issues Manual (HCFA-Pub. 6) provides that there are "blood glucose monitoring systems designed especially for use by those with visual impairments. The monitors used in such systems are identical in terms of reliability and sensitivity to the standard blood glucose monitors (also described in section 60-11). They differ by having such features as voice synthesizers, automatic timers, and specially designed arrangements of supplies and materials to enable the visually-impaired to use the equipment without assistance." The special payment limits do not apply to monitors that are medically necessary and that