delegated to her (21 CFR 5.82), finds that new evidence of clinical experience not contained in the application and not available until after the supplement to the application for the indication was approved, evaluated together with the evidence available when the supplement to the application for the indication was approved, shows that bromocriptine is not shown to be safe for the prevention of physiological lactation upon the basis of which the indication was approved (21 U.S.C. 355(e)(2)).

Therefore, pursuant to the foregoing finding, approval of the indication is hereby withdrawn, effective February 16. 1995.

Dated: December 27, 1994.

#### Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 95–1074 Filed 1–13–95; 8:45 am] BILLING CODE 4160–01–F

# Health Care Financing Administration [BPD-778-FN]

RIN 0938-AG28

#### Medicare Program; Special Payment Limits for Home Blood Glucose Monitors

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Final notice.

**SUMMARY:** This notice establishes special payment limits for standard home blood glucose monitors, identified as code E0607 of the HCFA Common Procedure Coding System (HCPCS). This final notice is intended to prevent excessive payment for these items. Currently, payment under the Medicare program for home blood glucose monitors and other items of durable medical equipment (DME) is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. This notice requires that payment for standard home blood glucose monitors be equal to 80 percent of the lesser of the actual charge or a special payment limit.

**DATES:** This notice is effective February 16, 1995.

FOR FURTHER INFORMATION CONTACT: Joel Kaiser, (410) 966–4499.

### SUPPLEMENTARY INFORMATION:

### I. Background

A. Special Reasonable Charge Limits

Payment for DME furnished under Part B of the Medicare program (Supplementary Medical Insurance) is made through contractors known as carriers. Before January 1, 1989, payment for DME was made on a reasonable charge basis. The methodology used by the carriers to establish reasonable charges is set forth in sections 1833 and 1842(b) of the Social Security Act (the Act) and in 42 CFR part 405, subpart E. Reasonable charge determinations are generally based on customary and prevailing charges derived from historic charge data. The reasonable charge for an item of DME was generally set at the lowest of the following factors:

- The supplier's actual charge for the item.
  - The supplier's customary charge.
- The prevailing charge in the locality for the item.

(The prevailing charge may not exceed the 75th percentile of the customary charges of suppliers in the locality.)

• The inflation indexed charge (IIC). The IIC is defined in § 405.509(a) as the lowest of the fee screens used to determine reasonable charges for services, supplies, and equipment paid on a reasonable charge basis (excluding physicians' services) that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor.

Section 1842(b)(3) of the Act requires that all payments made under Part B of the Medicare program must be reasonable. Paragraphs (8) and (9) of section 1842(b) of the Act provide that we may establish a special reasonable charge limit for a category of service if, after consultation with representatives of affected parties, we determine that the standard rules for calculating reasonable charges result in grossly deficient or excessive charges.

Applicable regulations are located at § 405.502(g). Section 405.502(g) requires that we consider the available information that is relevant to the category of service and establish reasonable charge limits that are realistic and equitable. The limit on the reasonable charge is an upper limit to correct a grossly excessive charge or a lower limit to correct a grossly excessive charge. The limit is either a specific dollar amount or is based on a special method to be used in determining the reasonable charge.

#### B. DME Fee Schedules

Section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100–203), which added section 1834(a) to the Act, provides for a fee schedule payment methodology for DME furnished on or after January 1, 1989. (This fee schedule payment methodology is set forth in 42 CFR part 414, subpart D.) Sections 1834(a)(1)(A) and (B) of the Act provide that Medicare payment for DME is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. Section 1834(a) of the Act classifies DME into the following payment categories:

• Inexpensive or other routinely purchased DME.

• Items requiring frequent and substantial servicing.

• Certain customized items.

Oxygen and oxygen equipment.

• Other items of DME (capped rental items).

There is a separate methodology for determining the fee schedule payment amount for each category of DME. The fee schedules are adjusted annually by a covered item update factor. The covered item update factor is generally equal to the change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending June 30 of the preceding year.

Section 1834(a)(10)(B) provides that we may apply the special payment limits authority of paragraphs (8) and (9) of section 1842(b) to covered items of DME and suppliers of these items and payments under section 1834(a) in the same manner as these provisions apply to physician's services and physicians and reasonable charges under section 1842(b).

## C. Payment for Home Blood Glucose Monitors (Code E0607)

Standard home blood glucose monitors allow individuals to measure their blood glucose and, then, alter their diets or insulin dosages to ensure that they are maintaining an adequate blood glucose level. Home blood glucose monitors are covered by the Medicare program as DME and are classified under the inexpensive and other routinely purchased DME payment category defined in section 1834(a)(2) of the Act. Section 1834(a)(2) specifies that inexpensive and other routinely purchased DME are those items of DME that have a purchase price that does not exceed \$150 or are acquired at least 75 percent of the time by purchase. We determined that home blood glucose monitors belong in this category based on a review of data that show that these monitors are acquired at least 75 percent of the time by purchase.

Section 1834(a)(2) requires that payment for items falling within this category be made on a purchase or rental basis and that local purchase and rental fee schedule amounts be calculated for each item. Section 414.220(c)(1) provides for the calculation of purchase fee schedules