0341. The approval expires on June 30, 2000. An agency may not conduct or sponsor, and a
person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: July 8, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–18594 Filed 7–15–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[BPD–845–PN]**

**RIN 0938–AH28**

## Medicare Program; Special Payment Limits for Home Oxygen

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

**ACTION:** Proposed notice.

**SUMMARY:** This notice would establish special payment limits for home oxygen. Currently, payment under the Medicare program for home oxygen and other items of durable medical equipment is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. Based on our experience and after consulting with representatives of home oxygen suppliers, we have determined that the Medicare fee schedule amounts for home oxygen are grossly excessive and are not inherently reasonable because they are excessively high relative to the payment amount for similar services by the Department of Veterans Affairs which uses a true competitive payment methodology. This notice would replace the use of the fee schedule amount and proposes that payment for home oxygen be equal to 80 percent of the lesser of the actual charge or a special payment limit set by HCFA, which would vary by locality. It is intended to prevent continuation of excessive payment. The special limit would be based on the average payment amount for home oxygen services by the Department of Veterans Affairs.

**DATES:** Comments will be considered if we receive them at the appropriate address, as provided below, by 5 p.m. on September 15, 1997.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–845–PN, P.O. Box 26676, Baltimore, MD 21207–0476.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–845–PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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**FOR FURTHER INFORMATION CONTACT:** William J. Long (410) 786–5655.

**SUPPLEMENTARY INFORMATION:**

### I. Background

*A. Payment Under Reasonable Charges*

Payment for durable medical equipment (DME) furnished under Part B of the Medicare program (Supplementary Medical Insurance) is made through contractors known as Medicare carriers. Before January 1, 1989, payment for DME was made on a reasonable charge basis by these carriers. 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 42 CFR part 405, subpart E of our regulations. 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 physician services) that is in effect on December 31st of the previous fee screen year, updated by the inflation adjustment factor.)

*B. Exception to the Reasonable Charge Payment Methodology—Special Reasonable Charge Limits*

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

The applicable regulations are located at § 405.502(g) and require us to 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

deficient charge. The limit is either a specific dollar amount or is based on a special method to be used in determining the reasonable charge.

Section 405.502(g)(1) provides the following examples of circumstances that may result in grossly deficient or excessive charges—

- The marketplace is not competitive.
- Medicare and Medicaid are the sole or primary source of payment for a service.
- The charges involve the use of new technology for which an extensive charge history does not exist.
- The charges do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.
- The prevailing charges for a service in a particular locality are substantially higher or lower than prevailing charges in other comparable localities, taking into account the relative costs of furnishing the services in the different localities.
- Charges are grossly lower than or exceed acquisition or production costs.
- There have been increases in charges for a service that cannot be explained by inflation or technology.
- The prevailing charges for a service are substantially higher or lower than the payments made for the service by other purchasers in the same locality.

Section 405.502(g)(3) requires that we publish proposed payment limits in the **Federal Register**. We then allow 60 days for receipt of public comments on the proposal. After we have considered all timely comments, we publish in the **Federal Register** a final notice announcing the special payment limits and our analyses and responses to the comments. Section 405.502(g)(3) also provides that the proposed and final notices must set forth the criteria and circumstances, if any, under which a carrier may grant an exception to the limit(s).

### *C. Durable Medical Equipment Fee Schedules*

On December 22, 1987, the Congress passed section 4062 of the Omnibus Budget Reconciliation Act of 1987, Public Law 100–203, which added section 1834(a) to the Act. Section 1834(a) provides for a fee schedule payment methodology for DME furnished on or after January 1, 1989. Section 4152(h) of the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, delayed the effective date of the oxygen fee schedule payment methodology until June 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.
- 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 and 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) of the Act 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 services and physician and reasonable charges under section 1842(b).

### *D. Current Payment for Home Oxygen*

Home oxygen is covered by the Medicare program as DME and is paid for in accordance with the methodology specified in the oxygen and oxygen equipment payment category. This methodology is contained in sections 1834(a)(5) and (9) of the Act. Section 1834(a)(5) requires that payment for oxygen and oxygen equipment be on a monthly basis. An add-on for portable oxygen equipment is provided under this section as well as a 50 percent increase in payments when the prescribed liter flow is greater than 4 liters of oxygen per minute or a 50 percent decrease in payments when the prescribed liter flow is less than 1 liter of oxygen per minute.

Section 1834(a)(9)(A) specifies how the monthly payment amount is computed. Section 1834(a)(9)(A) requires that each Medicare carrier compute a base local average monthly payment rate per beneficiary as an amount equal to the total reasonable charges for all items of oxygen and oxygen equipment (other than portable oxygen equipment) divided by the total number of months for all beneficiaries receiving oxygen during 1986. For 1989 and 1990, the base local average monthly payment rate was equal to 95 percent of the base local average monthly payment rate increased by the percentage increase in the CPI–U for the six-month period ending with December 1987. For subsequent years, the payment rate is increased by the covered item update, generally the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.

In addition, section 1834(a)(9)(B) requires the computation of a national limited monthly payment rate beginning in 1991. The national limited monthly payment rate is defined as an amount not to exceed 100 percent of the median of all local monthly payment rates computed for the item or less than 85 percent of the median.

Regulations implementing the statutory provisions of sections 1834(a)(9)(A) and (a)(9)(B) are contained in 42 CFR 414.226.

Currently, there are three types of oxygen delivery systems: gas, liquid, and concentrators. As a result of the fee schedule methodology, Medicare pays for home oxygen without regard to the type of system. The fee schedule amounts are based on an average of the amounts paid for all three types of oxygen delivery systems during the 1986 base period. A major expectation under this modality neutral payment methodology was that suppliers would be able to furnish the most cost effective and medically appropriate system to their patients.

The current fee schedule amounts for home oxygen are a result of the fee schedule methodology as specified in sections 1834(a)(5) and (9) of the Act and § 414.226 as discussed above.

Since the enactment of section 1834(a)(5), we have not utilized the special reasonable charge limits located at § 405.502(g) to determine whether the standard fee schedule payment rules for oxygen result in grossly deficient or excessive charges. However, as explained below, we are proposing to reduce Medicare's payment amounts for home oxygen because Medicare's payment amounts for oxygen are substantially higher than the payments made by another purchaser in the same locality.

### *E. Comparison With the Department of Veterans Affairs*

The Department of Veterans Affairs (VA) also administers a national program for the furnishing of oxygen to patients at home. The VA is different from Medicare and most other payers in that it uses a competitive bidding methodology for making payment, whereas Medicare carriers use historical charge data to establish a base local average monthly payment per

beneficiary that is used to determine a national limited monthly payment rate.

The primary objective of a competitive bidding methodology is to utilize competitive market forces in order to establish a payment amount that is closer to suppliers' marginal costs of doing business including a fair profit amount. Under competitive bidding, suppliers are required to specify in advance the minimum price they will accept for each product of service, and low bidders are awarded contracts on either an exclusive or non-exclusive basis to provide these items to program clients. In that bidders are in competition with one another, each bidder's bid is likely to reflect its true costs plus a reasonable rate of profit, because unrealistically high bid prices would ensure a bidder's exclusion from a particular segment of the market and unrealistically lower bids would result in reimbursement rates that are below costs. Therefore, we conclude that a competitive bidding methodology results in a bid that reflects a supplier's true costs plus a reasonable profit. In contrast, suppliers do not reveal their true costs to Medicare because Medicare reimbursement rates for oxygen reflect a ''reasonable charge'' methodology driven by supplier charges and then a modality neutral fee schedule derived from charges in a base year. These payment rates are likely, over time, to have little, if any, relationship to suppliers' costs.

No other payment methodology that we reviewed takes full advantage of competitive market forces to the extent of the competitive bidding methodology. Only in a competitive environment can buyers take full advantage of the sellers' marginal costs of doing business in that the potential for lost business is brought to bear on those suppliers whose prices exceed their competitors' prices. The lowest bid is the best indicator of the actual costs of supplying the product by an efficient supplier, plus a reasonable profit. Thus, we believe that the VA's competitive bidding payment methodology produces a payment amount that takes advantage of true competitive forces and, therefore, is a better measure upon which to compare current Medicare payment amounts.

Economic analyses of Medicare reimbursement arrangements have been undertaken for a variety of health care providers and suppliers over the past two decades. A principal motivation in these analyses is to understand how reimbursement arrangements affect the price taxpayers pay for the purchased good or service. In its 1990 ''Review of Reimbursement Methods of Other Payers for Durable Medical Equipment,'' Abt Associates Inc., found ample evidence that competitive bidding encourages suppliers to bid prices closer to their true costs while Medicare's reimbursement methods offer no such incentives to suppliers. Abt found that competitive bidding programs for oxygen concentrators at VA Medical Centers obtained reimbursement levels as much as 70 percent lower than Medicare. A similar procurement program for concentrators in the Utah Medicaid program obtained a monthly rental price that was 42 percent below the average Medicare prices in the State for the 1986 to 1988 period. The Minnesota Medicaid program obtained a monthly rental price for concentrators that was 60 percent below the Medicare prices in the State for this same three-year period.

An examination of the payment outcomes produced by the Medicare payment methodology and the reimbursement mechanisms for oxygen concentrators in Utah and Minnesota indicates that while starting at a lower level than Medicare, the competitive Medicaid payment levels decreased from the mid- to late-1980's, while the corresponding Medicare prices increased over the same period. We believe that the differences in both the absolute amounts of these prices and the opposing direction of price changes over time, demonstrate the inherent inability of Medicare's formulaic, historical, charge-based reimbursement methodology (whether fee schedule or reasonable charge) to accurately reflect the true costs of suppliers in the home oxygen market.

In its yearly home oxygen program report ''National Home Oxygen Program, FY94 Cost Review'', the VA indicated that the weighted average payment amount for oxygen concentrators is $125.96 per month. The VA reports that this amount includes the costs of the portable/back-up system and refills. In contrast, Medicare pays an average monthly payment amount of approximately $280 for a stationary oxygen system (including contents), regardless of the type of oxygen system, plus an average of $45 per month for a portable system, for a total of $325 per month. Thus Medicare is paying 2.6 times as much as the VA for an oxygen concentrator plus portable system and portable refills.

## II. Provisions of This Proposed Notice

Based on our experience and after consulting with representatives of home oxygen suppliers, we have determined that the Medicare fee schedule payment amounts for home oxygen are not inherently reasonable because they are grossly excessive relative to the payment amount for similar services by the VA which uses a true competitive payment methodology. In accordance with section 1842(b)(8) of the Act, we are proposing to replace the use of the current fee schedule payment with special payment limits for home oxygen.

### *A. Special Payment Limits for Home Oxygen*

For home oxygen services furnished to Medicare beneficiaries, we propose a special payment limit.

The national limited monthly payment rate for stationary home oxygen services for 1994 would be reduced by 40.11 percent, then updated by the covered item update for years subsequent to 1994. Similarly, the 1994 local stationary fee schedule amount for Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands, would be reduced by 40.11 percent, then updated by the covered item update for years subsequent to 1994.

We arrived at the 40.11 percent adjustment by comparing what Medicare would have paid for oxygen services in 1994 had it paid the 1994 VA weighted average payment amount for concentrators plus a 30 percent differential ($37.79). Using the VA weighted average of $125.96 for oxygen concentrators plus portable system, plus a 30 percent differential (i.e., $125.96 + $37.79 = $163.75) instead of Medicare's average payment amounts for a concentrator, i.e., approximately $325, would yield a reduction of 40.11 percent in annual costs of stationary oxygen.

The following chart illustrates this computation. Column B contains Medicare expenditures for home oxygen by type of oxygen system. We assumed the ratio of expenditures for portable equipment would be the same as the ratio of patients using portable equipment, that is, 82.4 percent for concentrators, 16 percent for liquid, and 1.6 percent for gas. We applied these ratios to total expenditures for portable equipment, that is, $143 million. Similarly, column C contains the number of Medicare beneficiary months by type of oxygen system. Medicare's oxygen concentrator expenditures for 1994 would have been $617,274,286, as reflected in column E, rather than the actual $1,210,578,776 had the payment rate calculations been based on VA's weighted average payment amount for concentrator plus portable systems (i.e., $125.96) plus a 30 percent differential (i.e., $163.75).

Medicare's total expenditures for home oxygen for 1994 would have been

$885,858,597 rather than the $1,479,163,088 had payment been based on the VA's payment amount for home oxygen plus a 30 percent differential. Thus, Medicare would have saved $593,304,490 (i.e., $1,479,163,088 less $885,858,597) or 40.11 percent.

We would point out that this proposed adjustment does not apply to Medicare's portable add-on even though such adjustment would be justified in that the VA payment amounts for concentrators include payment for portable oxygen equipment. We estimate that application of this proposed adjustment to portable equipment would generate an additional savings of 4 percent. We specifically solicit comments on applying the adjustment to portable equipment.

We would also point out that the 40.11 percent reduction could be further reduced since it does not take into account that the VA also pays less for gas and liquid equipment and contents than Medicare.

RECOMPUTATION OF MEDICARE OXYGEN EXPENDITURES

| Type of Stationary Oxygen System | 1994 Expenditures for Oxygen (Stationary and Contents and Portable) Source 1 | 1994 Number of Beneficiary Months Source 1 | Revised Average Monthly Payment Amount Source 2 | 1994 Expenditures Based on Revised 1994 VA Concent. Pricing (C X D) for Concentrators B for Liquid and Gas |
|---|---|---|---|---|
| A | B | C | D | E |
| Total | 1,479,163,088 | 4,559,200 | ..... | 885,858,597 |
| Concentrators | 1,210,578,776 | 3,769,660 | 163.75 | 617,274,286 |
| Liquid | 249,994,932 | 728,900 | ..... | 249,994,932 |
| Gas | 18,589,379 | 60,640 | ..... | 18,589,379 |

*Inherent Reasonableness Adjustment*

| | |
|---|---|
| 1994 Total Expenditures = (B) | 1,479,163,088 |
| Minus Total 1994 Expenditures Based on VA Concentrator Prices = (E) | 885,858,597 |
| Amount That Would Have Reduced Total Expenditures had Expenditures Been Based on VA Prices = (B—E) | 593,304,490 |
| Result: Reduce 1994 Oxygen Fees By (40.11%) | 593,304,490/B |

Source 1: from 1994 HCFA data files

Source 2: based on weighted average VA monthly rental payment for concentrators + 30 percent.

This formula recognizes that suppliers' costs of doing business with Medicare are somewhat higher than the VA. The VA, by its very nature is a provider as well as a payer of services. The VA's dual role has resulted in a series of administrative features which reduces the supplier's costs. In addition, the VA preauthorizes all services before they are provided to patients thus effectively removing the need for suppliers to add a cost factor for uncollectible services or bad debts.

Given that Medicare is a payer and not a provider of services, and given the size and geographic distribution of Medicare's beneficiary population, it would be difficult to duplicate these administrative features for the Medicare program. Therefore, in the absence of such features, some of the cost differences between Medicare and the VA payments for oxygen can be explained by the higher costs of doing business with Medicare. Another factor, less easy to quantify, is the industry's assertion that an exact comparison of the VA's payment allowances with Medicare's allowances is inappropriate because of the dynamics of the oxygen marketplace. An economist described in some detail the potential for a situation in which an industry may sell the yield of excess capacity in a smaller market for less than the price at which it could afford to sell the product to a larger market if the demand were great enough to require additional manufacturing capacity. This argument rests on the contention that the VA's consumption of oxygen is so small in comparison to Medicare's that the industry's pricing reflects the marginal value of excess productivity, not the full cost of basic production. We also tentatively accept this argument and have also made allowance for it since sections 1842(b)(8) and (b)(9) require that a special payment limit be realistic and equitable.

The 30 percent differential is designed to be a proxy for these costs and other factors identified and unidentified, that may affect the differences between the prices the VA pays for oxygen and the prices HCFA pays.

We arrived at the differential by taking account of factors explicitly known to us and then by doubling the resultant estimate to assure that we have more than offset the effect of estimating errors and omissions.

We would note that the industry itself has previously indicated, in writing, that there is a 15 percent cost disadvantage attributable to furnishing oxygen services to Medicare beneficiaries as compared with the VA. We are tentatively accepting the industry's finding and have included this amount as part of the 30 percent cost differential.

We would expect this differential to be sustained only if the comments we receive on this notice provide the necessary documentation and support for the contentions that underlie it. In this connection, we believe there is a real burden on the industry to provide documentation to support these contentions. We would note that the industry's only written contention—that the differential is 15 percent—would have led us to recommend a 45 percent reduction in the price of stationary oxygen. Thus, we are particularly interested in receiving comments and further data relating to the factors that underlie the cost differential and the values assigned to them. Commentors are encouraged to submit verifiable data.

We are also interested in receiving comments regarding the implementation of this payment reduction. We realize that a 40.11 percent reduction in payment allowances for oxygen is significant. For this reason, we would consider alternative implementation methodologies, such as phasing in the 40.11 percent reduction over a period of time.

*B. Applicability*

The initial special payment limits we propose would apply to home oxygen furnished on or after the effective date of the published final notice and before January 1, 1998. For home oxygen furnished in calendar year 1997, the

special payment limits would be equal to the initial special payment limits increased by the 1995, 1996, and 1997 covered item update factors (the factor used to update other items of DME). The covered item update for 1995, 1996, 1997, and each subsequent year, is defined in section 1834(a)(14)(B) of the Act as the percentage increase in the consumer price index-urban for the 12-month period ending with June of the previous year. The covered item update factor for 1995, 1996, and 1997 is 2.5, 3.0, and 2.8 percent respectively. For each calendar year after 1997, 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.

*C. Proposed Payment for Home Oxygen*

We propose that payment for a stationary home oxygen system, which includes the oxygen delivery device and all supplies and accessories as well as the contents for the portable system, equal 80 percent of the lesser of the actual charge for the system or the appropriate special payment limit, as described in section A. above.

*D. Carrier-Granted Exceptions*

We are not proposing any circumstances under which a carrier may grant an exception to the application of the proposed special payment limit. We solicit comments on any circumstances where such an exception should be granted.

**III. Other Provisions Considered Under This Proposed Notice**

In developing this proposed notice, we also considered a number of other factors and met with industry representatives. These other factors as well as the industry representatives' major comments are discussed below.

*A. Technological Changes*

Although we did not directly rely on technological changes to determine either that our payments are grossly excessive or that our proposed special payment limit is realistic and equitable, we did rely on information regarding technological changes to conclude that reliance on the VA's competitive bidding methodology was appropriate as a basis of comparison with Medicare payments.

Under the modality neutral oxygen payment methodology that went into effect in 1989, suppliers have greatly reduced their operating costs by taking advantage of less costly means of oxygen delivery. Suppliers have increased their use of less costly oxygen concentrators and reduced their use of the more costly gas and liquid systems. The Office of Inspector General's report ''Trends in Home Oxygen Use'' (OEI–03–91–00710), dated August 1991, found that oxygen concentrator usage has increased since 1986, both in absolute terms and as a percentage of total services for all types of systems. According to the report, from 1986 to 1988 oxygen concentrator usage increased, while gaseous system usage decreased and liquid system usage remained constant. In 1986, the number of Medicare patients using oxygen concentrators was 66 percent. By 1989, 78 percent of all Medicare patients were using oxygen concentrators.

HCFA data for the period 1987 to 1994 indicates that Medicare patients using concentrators increased from 68 percent to 82.7 percent.

The VA indicates that 80 percent of their patients used concentrators in 1994.

Oxygen concentrators produce oxygen for patients by removing impurities from room air, for example, nitrogen. Patients receive oxygen from tubing attached to these concentrator machines. Unlike compressed gas and liquid oxygen, which must be replaced or filled on a regular basis, concentrators require no contents. Suppliers favor these devices for home use of oxygen due to the decreased costs associated with not having to make costly oxygen deliveries to the patient's home.

A 1993 study by ECRI, a nonprofit, healthcare research institute located in Pennsylvania that evaluates the safety, performance, and cost effectiveness of healthcare technology, found that suppliers chose to maximize their profits and minimize the need for ongoing support by providing oxygen concentrators to patients. ECRI pointed out in testimony before the Senate Appropriations Subcommittee on Labor, Health and Human Services on November 2, 1994, that it found that suppliers are excessively reimbursed for oxygen services. ECRI testified: ''The acquisition cost of oxygen concentrators, as reported by the manufacturers to us in 1993, ranged from $965 to $1,175 for units with a 5-liter per minute capacity.''

With regard to maintenance requirements of oxygen concentrators, ECRI testified: ''They have, for all practical purposes, an unlimited service life as all components may be replaced. We have estimated the service frequency of the components through review of the service manuals and interviews with service centers and DME providers.'' ECRI goes on to estimate that the total annual cost for the maintenance of a concentrator is $405.

Assuming an oxygen concentrator has a useful life of 5 years, an oxygen supplier's equipment cost per month would be about $17 (i.e., $1,000 / 60 months) and another $34 in cost for maintenance (i.e., $405 / 12 months) for a total cost of $51 per month to the supplier.

Another technological improvement in the provision of oxygen services is the use of oxygen conserving devices. These devices, which conserve oxygen when the patient is not inhaling, can reduce the amount of oxygen normally consumed by up to 50 percent. We are unsure of the extent to which these devices are used with oxygen equipment and specifically request comments concerning the frequency with which these devices are used.

By taking into account the increased use of less costly oxygen concentrators by suppliers since the base year (i.e., 1986), we estimate that suppliers are incurring 6.8 percent less in costs than they would have if this increase had not taken place. We determined this percentage decrease by computing the increased use of less costly oxygen concentrators and applied the applicable charge for the less costly concentrators to the increase in utilization of these systems. We presented our analysis of the increased use of concentrators to the industry representatives. Their comments and our responses are discussed in C. below.

*B. Payments Made by Other Purchasers*

Similarly, we did not directly rely on payments made by other purchasers to determine either that our payments are grossly excessive or that our proposed special payment limit is realistic and equitable. However, we did rely on such information to conclude that reliance on the VA's competitive bidding methodology was appropriate as a basis of comparison with Medicare payments.

Early this year, we requested payment data from other insurers to compare Medicare's payment amounts. In most instances, the payment amounts of other insurers are the same as or more than Medicare's payment amounts. The reason for the payment similarities is that many insurers use Medicare's current fee schedule payment methodology or its previous reasonable charge methodology. In either case, the resulting payment allowances are very near Medicare's current fees. This finding does not necessarily indicate that Medicare's allowances are not grossly excessive. The other insurers' payment allowances may also be grossly

excessive. In other words, if Medicare's allowances are excessive using a fee schedule or reasonable charge methodology, and other insurers use the same or a similar methodology, then the other insurers' allowances will also be excessive. It appears from the data of the other insurers that Medicare is a model for other insurers when it comes to making payment for home oxygen and that most other insurers duplicate Medicare's payment methodology resulting in very similar payment amounts.

Also, a number of Medicaid insurers, such as New York, Ohio, and Minnesota pay significantly less for home oxygen than Medicare. All of these States pay less than $200 per month for a stationary oxygen system while the 1995 Medicare payment in each of these States is $308, $308, and $262 per month respectively. This indicates to us that there are a number of payers, typically those that use a different payment methodology or base period other than Medicare's, that are paying significantly less than Medicare yet attract a sufficient number of suppliers to furnish home oxygen to their insured beneficiaries. This further indicates to us that in at least these three States, the Medicare payment amounts for home oxygen are grossly excessive in comparison with these States' payment amounts.

However, because of the mixed reporting by insurers other than the VA, we are unable to reach any definitive conclusions regarding the reasonableness of Medicare's payments on a national basis with respect to other payers other than the VA. We specifically solicit comments with regard to payments by other insurers. We would point out that a comparison to many insurers may be inappropriate due to the other insurers' heavy reliance on Medicare's payment methodology. As such, a comparison would merely mirror Medicare's payment amounts. We would also point out, however, that some States pay significantly less than what Medicare pays for the same service yet are able to attract a sufficient number of suppliers to provide oxygen services. In particular, the VA pays significantly less for home oxygen than does Medicare and manages to attract a sufficient number of suppliers to provide its patients with home oxygen.

Of the States responding to our request for payment data, 22 use a fee schedule similar to Medicare's fee schedule. Two others use a reasonable charge methodology and another State reports using a cost methodology. Of the remaining States, three use a negotiated rate methodology, two use a competitive bidding methodology, and a single State pays based on a percent of the submitted charge.

*C. Supplier Consultation*

Section 1842(b)(9)(A) of the Act requires 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 is not inherently reasonable by reason of its grossly excessive or deficient amount.

Over the past two and one half years, we had numerous discussions with supplier representatives concerning Medicare payment amounts for home oxygen services. We met with industry representatives to discuss the use of VA data for purposes of comparing the VA payment amounts with Medicare's payment amounts. On August 30, 1995, we held a public meeting with supplier representatives to formally discuss issues relating to Medicare payment for home oxygen. Since the August 30th meeting, we had several rounds of discussions with industry representatives. After publication of this proposed notice, we expect to receive additional comments that will be considered in making a determination regarding whether our payment amounts for home oxygen are inherently reasonable. The following is a synopsis of the comments and concerns of the supplier representatives as expressed at and since the August 30th meeting.

The supplier representatives wanted to know if, after studying our findings, they could submit additional comments. We indicated that we would consider any comments they chose to submit from and including the August 30th meeting until the end of the 60-day comment period. The major comments we received are included in the discussion below. All comments received during the 60-day comment period will be discussed in a final notice. Moreover, we may elect to engage in further consultation with industry representatives if the comments we receive make such further consultation necessary or appropriate.

Some supplier representatives expressed concern with the data we used in estimating that suppliers are incurring 6.8 percent less in costs than they would have incurred had they not taken advantage of less costly oxygen delivery systems. We indicated that we would share these data with them and did meet with selected supplier representatives on September 8, 1995 to review these data.

Some supplier representatives asserted that suppliers of oxygen equipment are using more costly liquid oxygen systems as a percentage of all oxygen systems than they were using during the base period and that more patients are using portable systems than were used during the base period. We agree with the supplier representatives that suppliers of oxygen equipment are using more costly liquid oxygen systems than used during the base period, however, since it is impossible to ascertain from our data the amount of oxygen being used in portable oxygen systems or to ascertain the extent of patients utilizing oxygen conserving devices, we are unable to either validate or challenge the supplier representatives' assertions at this time. Therefore, until we are able to obtain sufficient data to address these assertions, we will not use data that indicates that suppliers are using less costly oxygen delivery systems in the inherent reasonableness process.

Some supplier representatives have challenged the VA data indicating that we should conduct an independent recalculation and verification of the VA data. We do not believe it would be appropriate for us to conduct a recalculation and verification of a VA report. We have discussed with the VA the information contained in its report on a number of occasions. The VA indicated confidence in its report and we have no evidence upon which to question either the VA's integrity or the accuracy of its fundamental calculations.

In its FY 1994 report, which is used for analysis and decision making in this notice, the developers of the report have included all commercial costs for all facilities. In response to suggestions from the oxygen industry and others, the VA's National Center for Cost Containment worked closely with these facilities in the development and reporting of data to assure the accuracy of these cost figures. Therefore, the FY 1994 Cost Review represents an exacting effort to gather accurate cost information from the 164 facilities that have home oxygen programs. An improvement over previous year's analysis is the development of ''weighted averages'' for each of the monthly average costs per patient modality. This has provided for a more meaningful comparison with Medicare data as well as an overview of the VA Home Oxygen Program nationally, because weighted averages account for the extreme variances in costs for a small number of facilities.

Some supplier representatives indicated that they believe that we have been indiscriminately and inappropriately selective in our choice of the VA program as the sole comparative payor to Medicare and that

we have ignored information solicited from other payers. We have addressed this issue above indicating that the mixed reporting by these other insurers did not furnish any conclusive information regarding the reasonableness of Medicare's payments on a national basis. We would point out that a comparison to many insurers may be inappropriate due to the other insurers' heavy reliance on Medicare's payment methodology. As such, a comparison would merely mirror Medicare's payment amounts. We would also point out, however, that some States pay significantly less than what Medicare pays for the same service yet are able to attract a sufficient number of suppliers to provide oxygen services. In particular, the VA pays significantly less for home oxygen than does Medicare and manages to attract a sufficient number of suppliers to provide its patients with home oxygen.

Some supplier representatives indicated that they believe that the VA payment amount is ''unbundled,'' that is, it represents only the cost of the oxygen concentrator and not the oxygen contents of a portable system, accessories used with the concentrator, set-up and delivery charges, etc. However, the VA report states: ''This year's figures include costs for *all* components of the modalities including refills to the portable/back-up or system itself, as appropriate.'' (See page vii of the FY 1994 VA report.) This assertion indicates to us that the VA's payment amounts include not only the same bundle of services as is included in Medicare's bundled rate for oxygen concentrators but also the portable equipment that is paid separately by Medicare.

Some supplier representatives indicated that our analysis failed to consider supplier costs. We do not believe that we are required to include an analysis of supplier costs. Although the regulations at § 405.502(g)(1)(iv) allow us to consider supplier costs as an example of factors in making an inherent reasonableness determination, they do not require such consideration. Moreover, we did not consider supplier costs, in part, because, in our experience, such costs are unattainable. A United States General Accounting Office Report to Congress entitled: ''Medicare, Effect of Durable Medical Equipment Fee Schedules on Six Suppliers' Profits'' (GAO/HRD–92–22), dated November, 1991, states: ''DME suppliers do not maintain records in a manner that permits direct computation of costs and profits by DME item. * * *'' Although we have not evaluated supplier costs directly, we have considered supplier costs indirectly by relying on the VA's competitive bidding methodology to draw our conclusions regarding the relationship of costs to Medicare payment.

As discussed previously, under the VA's competitive bidding methodology, bidders make bids that reflect their true costs (plus a reasonable rate of profit).

## IV. Regulatory Impact Statement

### *A. Executive Order 12866*

Executive Order 12866 (E.O. 12866) requires us to prepare an analysis for any notice that meets one of the E.O. 12866 criteria for a ''significant regulatory action''; that is, that may—

- Have an annual effect on the economy of $100 million or more or 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;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

This proposed notice would reduce unnecessary Medicare program expenditures for home oxygen services. Currently, payment under the Medicare program for home oxygen services 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 proposed notice, payment would be equal to 80 percent of the lesser of the actual charge or the appropriate special payment limit proposed by this notice.

We are proposing special payment limits for home oxygen services that would reduce the national limited monthly payment rate for home oxygen services for 1994 by 40.11 percent, then updated by the covered item update for years subsequent to 1994. Similarly, the 1994 local fee schedule amount for Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands, would be reduced by 40.11 percent, then updated by the covered item update for years subsequent to 1994.

We estimate that the proposed special payment limits would produce the following savings:

[By fiscal year, savings in millions of dollars]

| | |
|---|---|
| 1997 | $120 |
| 1998 | 200 |
| 1999 | 230 |
| 2000 | 240 |
| 2001 | 260 |

We have determined that the provisions of this proposed notice would meet the $100 million criterion. Therefore, it is a significant regulatory action and an impact analysis under E.O. 12866 is required.

We expect suppliers of home oxygen services and beneficiaries to be affected by this special payment limit. We do not have sufficient data to predict exactly the nature of the impact of this proposed notice or the magnitude of such impact. Below, we discuss likely outcomes.

1. Suppliers

Suppliers of home oxygen would review the special payment limits to determine what strategy would maximize their profits. In response to a final notice that implemented the special payment limits as the proposed notice, we expect them to compare this limit to their costs of furnishing home oxygen to Medicare beneficiaries. We would expect that as a result of this comparison, many suppliers may seek to economize by reducing unnecessary expenditures. Many suppliers may consider whether or not to continue to accept assignment on Medicare claims. Suppliers that provide mostly home oxygen services would be more adversely affected by the special payment limits than those suppliers that also provide the full range of durable medical equipment in addition to oxygen because they will have other revenue sources from which to obtain income.

2. Beneficiaries

The effect of the proposed special payment limits on beneficiaries depends on whether there is a significant local change in the assignment rate. If the assignment rate were to remain the same, beneficiaries may expect lower coinsurance since the fee schedule amount for oxygen would be lower. However, if the assignment rate goes down, beneficiaries may have to make a greater effort to find a supplier that accepts assignment or have increased out-of-pocket expenses.

3. Conclusion

The primary benefit expected to result from this proposal is the anticipated reduction in the cost to the Medicare program of home oxygen services and reduced coinsurance payments by beneficiaries to the extent that suppliers continue to accept assignment. The disadvantages that could result from this proposed special payment limit

would be more initial out-of-pocket expenses for the beneficiary if the assignment rate is reduced.

*B. Regulatory Flexibility Act*

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless we certify that a notice would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us 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. Such an 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 of a Metropolitan Statistical Area and has fewer than 50 beds.

In determining whether to adjust payment rates under section 1842(b)(8)(A) and (9)(A) of the Act, we are required to consider the potential impacts on quality, access, and beneficiary liability of the adjustment, including the likely effects on assignment rates, reasonable charge reductions on unassigned claims, and participation rates of suppliers.

This proposed reduction in Medicare payment would affect suppliers of home oxygen. These suppliers would have their payment allowances for Medicare home oxygen patients reduced. Suppliers can choose to accept assignment, which means they agree to accept Medicare's approved amount as payment in full. It is possible that, as a consequence of our reducing payments for home oxygen, the number of suppliers accepting assignment of a beneficiary's claim for Medicare payment for these services may decrease if suppliers 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 or remain ''participating suppliers'' may decrease as a result of reduced payments for home oxygen. 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 Medpards, which are compiled by the Medicare carriers and furnished to various senior citizen groups. A Medicare beneficiary can obtain the Medpard for his or her State from the Medicare carrier.

Suppliers who do not accept assignment and charge more than the Medicare approved amount can collect the balance; that is, the actual charge minus Medicare payment, from the beneficiary. Therefore, beneficiaries who receive services from suppliers who do not accept assignment are exposed to greater financial liability than those who receive services from a supplier taking assignment. As a result, Medicare beneficiaries may choose to deal with suppliers who accept assignment in order to reduce their financial liability. We expect that this special payment limit would have minimal effects on the quality of home oxygen services furnished to beneficiaries since we do not expect suppliers to reduce the quality or the type of services provided. Also, we expect only minimal effects on beneficiary access to home oxygen, even in rural areas, since we do not expect many suppliers to discontinue supplying oxygen.

Although a payment reduction of 40.11 percent for home oxygen appears large, it is a result of Medicare's grossly excessive payment allowances that have resulted in windfall profits. We would expect suppliers to adjust to the elimination of this windfall accordingly.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

## IV. Paperwork Reduction Act

This notice does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 through 3511).

## V. Response to 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 comments in the preamble to that document. Moreover, we may elect to engage in further consultation with industry representatives if comments we receive make such further consultation necessary or appropriate.

**Authority:** Sections 1834(a) and 1842(b) of the Social Security Act (42 U.S.C. 1395m and 1395u).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 14, 1997.

**Bruce C. Vladeck,**

*Administrator, Health Care Financing Administration.*

Dated: May 6, 1997.

**Donna E. Shalala,**

*Secretary.*

[FR Doc. 97–18716 Filed 7–11–97; 1:30 pm]

BILLING CODE 4120–03–P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–4200–N–85]**

## Submission for OMB Review: Comment Request

**AGENCY:** Office of Administration, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comments due date: August 15, 1997.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

**SUPPLEMENTARY INFORMATION:** The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).