

national associations and request that they notify their members about these changes. Finally, we will require our Medicare contractors to contact SLPs via bulletins or listserv announcements about these changes.

J. Section 144(b): Repeal of Transfer of Title for Oxygen Equipment

1. Payment Rules for Oxygen and Oxygen Equipment

a. Overview

The general Medicare payment rules for durable medical equipment (DME) are set forth in section 1834(a) of the Act and 42 CFR part 414, subpart D of our regulations. Section 1834(a)(1) of the Act and §414.210(a) of our regulations establish the Medicare payment for a DME item as equal to 80 percent of either the lower of the actual charge or the fee schedule amount for the item. The beneficiary coinsurance is equal to 20 percent of either the lower of the actual charge or the fee schedule amount for the item once the deductible is met.

Specific rules regarding payment for oxygen and oxygen equipment are set forth in section 1834(a)(5) of the Act and §414.226 of our regulations. Suppliers are paid a monthly payment amount for furnishing medically necessary oxygen contents (stationary and portable) and stationary oxygen equipment falling under the class described in

§414.226(c)(1)(i). Equipment in this class includes stationary oxygen concentrators, which concentrate oxygen from room air; stationary liquid oxygen systems, which use oxygen stored as a very cold liquid in cylinders and tanks; and gaseous oxygen systems, which administer compressed oxygen directly from cylinders.

We also pay a monthly add-on payment to suppliers furnishing medically necessary portable oxygen equipment falling under one of two classes described in §414.226(c)(1)(ii) and (iii). Equipment in these classes includes portable liquid oxygen systems, portable gaseous oxygen systems, portable oxygen concentrators, and oxygen transfilling equipment used to fill portable tanks or cylinders in the home. Both liquid and gaseous oxygen systems (stationary and portable) require on-going delivery of oxygen contents.

b. Provisions of the Deficit Reduction Act of 2005 (DRA)

Section 5101(b) of the DRA amended section 1834(a)(5) of the Act, limiting monthly payments to suppliers for oxygen equipment to 36 months of continuous use. At the end of this 36-month period, suppliers must transfer title to oxygen equipment rented on or after January 1, 2006 to the beneficiary. Payments for oxygen contents continue after title to the equipment has been transferred.

On November 9, 2006, we issued a final rule (71 FR 65884) to implement these changes. We amended §414.226 to clarify that the monthly payments for items falling under the classes now described in §414.226(c)(1)(i) thru (iii) are made for periods of continuous use not to exceed 36 months. We revised the rules regarding a period of continuous use for the rental of DME in §414.230 of our regulations to clarify the continuous use determination.

We also added a new paragraph (f) to §414.226 of our regulations, requiring a supplier to transfer title to the oxygen equipment to the beneficiary on the first day after the 36th continuous month in which payment is made for the equipment.

In addition, we revised §414.226 of our regulations to allow monthly payments to suppliers for furnishing gaseous or liquid oxygen contents for use with either beneficiary-owned stationary equipment or beneficiary-owned portable equipment.

Section 5101(b) of the DRA also authorized payments for maintenance and servicing of beneficiary-owned oxygen equipment if the Secretary determined such payments to be reasonable and necessary. In keeping with the longstanding Medicare policy to pay for maintenance and servicing of DME

that is owned by the beneficiary, we determined that paying for necessary repairs and periodic maintenance and servicing of beneficiary-owned oxygen equipment was reasonable and necessary to ensure that oxygen equipment owned by beneficiaries continued to function properly. Without these payments, we were concerned that there was little incentive for suppliers to maintain this equipment, because the equipment was no longer owned by the supplier. Our regulations setting forth this payment amount are discussed in more detail in section III.J.2.c. below in this section.

In the November 2006 final rule, we established other safeguards for beneficiaries receiving oxygen and oxygen equipment, which are set forth at §414.210(e)(5) and §414.226(g). Section 414.210(e)(5) requires suppliers - after transferring title to oxygen equipment - to furnish replacement equipment at no cost to the beneficiary or the Medicare program if the item furnished by the supplier does not last for the entire reasonable useful lifetime established for the equipment in accordance with §414.210(f)(1). Per §414.210(f), if oxygen equipment has been in continuous use by the beneficiary for the equipment's reasonable useful lifetime, the beneficiary may elect to obtain new equipment. Section 414.210(f)(1) of

our regulations states the reasonable useful lifetime for equipment is determined through program instructions. In the absence of program instructions, the carrier may determine the reasonable useful lifetime for equipment, but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment. If the beneficiary elects to obtain replacement oxygen equipment, payment is made in accordance with §414.226(a). Section 414.226(g)(2) prohibits suppliers from replacing oxygen equipment prior to the expiration of the 36-month rental period unless a specific exception applies. This was intended to protect the beneficiary from the supplier changing the beneficiary's equipment in order to maximize Medicare payments. For example, the supplier may want to move a beneficiary from a portable oxygen concentrator to portable gaseous equipment for which Medicare makes additional payments after the 36-month rental period ends.

Section 414.226(g)(4) provides that, by no later than 2 months before the date on which the supplier must transfer title to oxygen equipment to the beneficiary, the supplier must disclose to the beneficiary: (1) whether, in the case of oxygen transfilling equipment and stationary or portable oxygen concentrators, it can maintain and service

the equipment after the beneficiary acquires title to it; and (2) whether, in the case of stationary or portable gaseous or liquid oxygen systems, it can continue to deliver oxygen contents to the beneficiary after the beneficiary acquires title to the equipment.

c. Medicare Improvements for Patients and Providers Act (MIPPA) Section 144(b) - Repeal of Transfer of Ownership of Oxygen Equipment

Section 144(b) of the MIPPA repeals the requirement that the supplier transfer title to oxygen equipment to the beneficiary after the 36-month rental period. In its place, section 144(b) establishes a 36-month rental cap and amends section 1834(a)(5)(F) of the Act by adding three new payment rules and supplier requirements for furnishing oxygen and oxygen equipment after the 36-month rental period. Each of these provisions is discussed below.

2. Provisions of the Final Rule with Comment Period

a. Furnishing Oxygen Equipment after the Rental Cap

As discussed above, section 144(b)(1) of the MIPPA amends section 1834(a)(5)(F)(ii)(I) of the Act, replacing the transfer of title provision with a 36-month rental cap. Under this new provision, the supplier that furnishes oxygen equipment during the 36-month rental period must continue to furnish the oxygen equipment after the 36-month

rental period. The supplier is required to continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment. Section 144(b) does not provide any exceptions to the requirement that the supplier continue furnishing the equipment during any period of medical need. For example, if the beneficiary relocates at some time after the 36-month rental period but before the end of the reasonable useful lifetime of the equipment, we interpret this provision to require that the supplier must make arrangements for the beneficiary to continue receiving the equipment at his or her new place of residence. This responsibility is not transferred to another supplier. It is important to note that our current regulation at §414.226(g)(1)(ii) does not apply this same requirement to situations in which the beneficiary relocates during the 36-month rental period. We welcome comments from interested parties on whether this requirement should be changed in light of the repeal of transfer of ownership of oxygen equipment and other recently enacted provisions of the MIPPA.

We are revising §414.226(f) to conform our regulations to this new requirement. We are deleting the transfer of ownership requirement and adding the new requirement that

the supplier must continue furnishing the oxygen equipment after the 36-month rental period during any period of medical need for the remainder of the reasonable useful lifetime of the equipment.

The language of the statute mandates that the supplier shall continue to furnish oxygen equipment after the 36-month rental period "during any period of medical need" rather than "during the period of medical need" for the remainder of the reasonable useful lifetime of the equipment. We interpret this to mean that the supplier is responsible for continuing to furnish the equipment at any time following the 36-month rental period and before the end of the equipment's reasonable useful lifetime, for any period of medical need, including multiple periods of medical need that are separated by periods when interruptions in the use of the equipment occur.

For example, if, following the 36-month rental period and before the end of the equipment's reasonable useful lifetime, the beneficiary is admitted to a hospital as an inpatient and then discharged from the hospital 3 weeks later, our interpretation requires the supplier to furnish the oxygen equipment for the period leading up to the hospital admission and for the period immediately following the hospital discharge through the end of the equipment's

reasonable useful lifetime. The supplier's responsibility to continue furnishing the equipment is not affected by the length of a break in medical need or by the number of any such breaks in medical need that occur after the 36-month rental period and before the end of the equipment's reasonable useful lifetime. Therefore, we are revising §414.230 to specify that a new period of continuous use will not begin following the 36-month rental period until the end of the equipment's reasonable useful lifetime. The supplier is responsible for furnishing the equipment after the 36-month rental period for any period of medical need for the remainder of the reasonable useful lifetime of the equipment. If a break in medical need occurs following the 36-month rental period, the supplier must resume furnishing the oxygen equipment after the break ends and the beneficiary once again has a medical need for the oxygen equipment. In such a case, the supplier is responsible for furnishing the item for no additional rental payments until the end of the equipment's reasonable useful lifetime. If the equipment's reasonable useful lifetime (which is determined based on the date the equipment is first delivered rather than the age of the equipment) ends during a break in medical need, the supplier is under no obligation to continue furnishing the equipment once the

beneficiary again has medical need for the oxygen. However, in accordance with §414.210(f), the beneficiary may elect to obtain new equipment in these situations where the reasonable useful lifetime of the equipment ends during a break in need. If the beneficiary elects to obtain new equipment, a new 36-month rental period and a new reasonable useful lifetime (currently 5 years for oxygen equipment) begin.

We note that, in accordance with section 5101(b)(2)(B) of the DRA, the rental period for beneficiaries receiving oxygen equipment on December 31, 2005, began on January 1, 2006. However, in accordance with §414.210(f)(1), the reasonable useful lifetime of durable medical equipment, including oxygen equipment, begins on the date that the equipment is first delivered to the beneficiary. The reasonable useful lifetime of oxygen equipment furnished to beneficiaries on December 31, 2005, was not adjusted to begin anew on January 1, 2006, to correspond with the start of the 36-month rental period. Therefore, in these situations, the equipment's reasonable useful lifetime may end at any point during or after the 36-month rental period.

For example, if oxygen equipment was delivered to a beneficiary on May 1, 2003, and the beneficiary continued

to use the equipment beyond January 1, 2006, the 36-month rental period for the equipment would begin on January 1, 2006, and end on December 31, 2008. However, because the reasonable useful lifetime of the equipment ended on April 30, 2008, the beneficiary could have elected to obtain new oxygen equipment on May 1, 2008, prior to the end of the 36-month rental period for the equipment. In another example, if oxygen equipment was delivered to a beneficiary on July 1, 2004, and the beneficiary continued to use the equipment beyond January 1, 2006, the 36-month rental period for the equipment began on January 1, 2006, and will end on December 31, 2008. In this case, the reasonable useful lifetime of the equipment would end on June 30, 2009, and the beneficiary could elect to obtain new oxygen equipment on July 1, 2009, only 6 months after the end of the 36-month rental period for the equipment. In these situations, a new 36-month rental period and a new reasonable useful lifetime (for the new equipment) would begin after the end of the existing equipment's reasonable useful lifetime if the beneficiary elects to obtain new equipment.

We are also revising §414.210(e) (1), (2), (e)(4) and (e)(5) to delete regulatory text which relates to beneficiary ownership of oxygen equipment. In addition, we

are deleting §414.210(e)(3) because beneficiaries will no longer own oxygen tanks and cylinders. Because §414.210(e)(3) is being deleted, we are redesignating §414.210(e)(4) and §414.210(e)(5) as §414.210(e)(3) and §414.210(e)(4), respectively.

We are also modifying §414.226 to state that the protection against supplier replacement of oxygen equipment, unless an exception applies, continues to be in effect after the 36-month rental period ends. Specifically, we are revising §414.226(g)(2) to indicate that this prohibition applies until the expiration of the reasonable useful lifetime established for the equipment. As discussed in the November 9, 2006 final rule (71 FR 65894), we believe this is a necessary safeguard for the beneficiary against changes in equipment made by the supplier in order to maximize payments resulting from moving from one payment class or modality to another. Finally, we are deleting §414.226(g)(4) because the transfer of ownership of oxygen equipment provision has been repealed, rendering this provision inapplicable.

b. Payment for Oxygen Contents after the Rental Cap

Section 144(b)(1) of the MIPPA amends section 1834(a)(5)(F)(ii)(II) of the Act and requires us to continue to make payments to suppliers for furnishing

oxygen contents after the 36-month rental cap for oxygen equipment ends. Under this provision, an oxygen supplier that furnished liquid or gaseous oxygen equipment during the 36-month rental period, and is required by section 1834(a)(5)(F)(ii)(I) of the Act to continue furnishing the equipment after the 36-month rental period ends, will receive payment for furnishing oxygen contents necessary for use with liquid or gaseous oxygen equipment after the 36-month rental period. Section 1834(a)(5)(F)(ii)(II) of the Act establishes the payment amount for the oxygen contents as that set forth in section 1834(a)(9) of the Act.

We are revising §414.226(d) and (f) to specify that payment shall be made for oxygen contents for use with supplier-owned liquid or gaseous oxygen equipment furnished after the 36-month rental period. An oxygen supplier that furnishes liquid or gaseous oxygen equipment during a 36-month rental period must continue to furnish both the oxygen equipment and contents for any period of medical need for the remainder of the reasonable useful lifetime of the liquid or gaseous oxygen equipment established in accordance with §414.210(f)(1).

This requirement is necessary because liquid and gaseous oxygen systems (stationary and portable) require

on-going delivery of oxygen contents in tanks or cylinders to furnish oxygen to the patient. When read in conjunction with section 1834(a)(5)(F)(ii)(II) of the Act, we interpret the mandate in section 1834(a)(5)(F)(ii)(I) of the Act to include oxygen contents, as well as oxygen equipment, given the nature of this benefit and the requirement that Medicare continue to pay for oxygen contents following the 36-month rental period.

As noted in section III.J.2.a. of this final rule with comment period, we are revising §414.226(f) to specify that the supplier must make arrangements for the beneficiary to continue receiving the equipment if the beneficiary relocates at some time after the 36-month rental period but before the end of the reasonable useful lifetime of the equipment. Likewise, for the reasons set forth in section III.J.2.a. above, we are revising §414.226(f) to specify that, in the case of liquid or gaseous equipment (stationary and portable) the supplier must make arrangements for the beneficiary to continue receiving oxygen contents if the beneficiary relocates at some time after the 36-month rental period but before the end of the reasonable useful lifetime of the liquid or gaseous equipment (stationary and portable). The supplier must make arrangements for the beneficiary to continue receiving

the oxygen contents and equipment at his or her new residence.

c. Maintenance and Servicing of Supplier-Owned Oxygen Equipment after the Rental Cap

Section 1834(a)(5)(F)(ii)(III) of the Act, as amended by section 144(b)(1) of the MIPPA, authorizes payments for maintenance and servicing of supplier-owned oxygen equipment after the 36-month rental period if the Secretary determines that such payments are reasonable and necessary. Section 5101(b)(1) of the DRA previously authorized payment for reasonable and necessary maintenance and servicing of beneficiary-owned oxygen equipment.

i. Current payment for maintenance and servicing of oxygen equipment

In the August 3, 2006 proposed rule for implementing section 5101(b) of the DRA (71 FR 44082), we discussed the fact that it is longstanding Medicare policy to pay for repair (fixing or mending) of beneficiary-owned DME if such services are necessary to keep the equipment functioning. It is also longstanding Medicare policy to pay for non-routine maintenance of beneficiary-owned DME (that is, extensive maintenance that must be performed by skilled technicians). These policies were discussed in the November 9, 2006 final rule (71 FR 65918) and are set forth

in §414.210(e)(1) and sections 40 and 50 of chapter 20 of the Medicare Claims Processing Manual (Pub. 100-04). In keeping with these longstanding Medicare policies, we proposed to pay for both services when performed on beneficiary-owned oxygen equipment following passage of the DRA (see the proposed rule published on August 3, 2006 (71 FR 44082)).

In response to the August 3, 2006 proposed rule, we received public comments concerning the safe use and maintenance and servicing of oxygen equipment once the supplier transferred title of the equipment to the beneficiary. Commenters raised concerns that beneficiaries would be unable to properly maintain their equipment and that unless Medicare paid for maintenance and servicing of beneficiary-owned equipment, suppliers would not have any incentive to provide these services.

In response to these concerns, we finalized our proposal to pay for necessary repairs and non-routine maintenance of beneficiary-owned oxygen equipment (See 71 FR 65917 through 65919) in accordance with the rules set forth at §414.210(e). In addition, we revised §414.210(e) to allow for payment for general maintenance and servicing of beneficiary-owned oxygen equipment other than liquid or gaseous equipment (stationary and portable).

Section 414.210(e)(2) authorized payment for 30 minutes of labor for general maintenance and servicing of beneficiary-owned oxygen transfilling equipment and stationary or portable oxygen concentrators every 6 months, beginning 6 months after transfer of title to the equipment to the beneficiary. Medicare also made payment for parts replaced during the general maintenance and servicing of the beneficiary-owned oxygen equipment. As indicated in the November 9, 2006 final rule (71 FR 65917), we consider this payment for general maintenance and servicing to be an important beneficiary safeguard. The maintenance and servicing payments encourage suppliers to keep beneficiary-owned oxygen equipment in good repair which ensures the safety of the beneficiary.

The payment authorized by §414.210(e)(2) did not apply to liquid or gaseous oxygen equipment (stationary or portable) because we believe the supplier should ensure that the tanks and cylinders are functioning properly at the time it is furnishing oxygen contents.

Also, in response to concerns regarding the safe use and disposal of beneficiary-owned oxygen tanks and cylinders, we revised §414.210(e)(3) to allow payment for pick up of beneficiary-owned oxygen tanks and cylinders that are no longer medically necessary.

ii. Revisions as a result of the MIPPA

(1) Findings related to non-routine maintenance and servicing (including repair)

Section 1834(a)(5)(F)(ii)(III), as amended by section 144(b)(1) of the MIPPA, authorizes similar payments for maintenance and servicing of supplier-owned oxygen equipment furnished after the 36-month rental period if we determine such payments are reasonable and necessary. Based on a careful review of this issue, as discussed below, we have determined that at this time it is not reasonable and necessary to pay for non-routine maintenance and servicing (including repair) of supplier-owned oxygen equipment. Given that the supplier owns the equipment, we believe that the supplier should be responsible for maintaining their equipment in working order as they did during the 36-month rental period.

In addition, oxygen equipment is largely reliable equipment which requires minimal maintenance and servicing during the first 5 years of use. Warranties covering 5 years are generally available for the top selling brands of oxygen equipment and as discussed in the November 9, 2006 final rule (71 FR 65917), we understand from manufacturers that such products are generally dependable. The Department of Veterans Affairs (VA) has

reported to us that, based on their experience, oxygen concentrators will usually operate for 5 years without the need for significant repair or replacement of costly parts. The VA purchases and maintains oxygen equipment, including oxygen concentrators, for veterans through its Veterans Integrated Service Network (VISN).

In a September 2006 report entitled "Medicare Home Oxygen Equipment: Cost and Servicing," (OEI-09-04-00420), the Office of Inspector General (OIG) of the Department of Health and Human Services similarly found that only minimal servicing and maintenance for oxygen concentrators and portable equipment is necessary. The OIG also found that suppliers train beneficiaries to perform routine maintenance of the equipment. As noted in that report, services performed by suppliers during visits to the homes of beneficiaries to perform maintenance and servicing of oxygen concentrators include checking the flow rate prescribed by the physician and checking the concentration of oxygen delivered by the unit.

Moreover, the OIG found that only 22 percent of Medicare beneficiaries use oxygen equipment for 36 months or more. Therefore, oxygen equipment is returned to suppliers before the end of the 36-month rental period in approximately 78 percent of cases, and suppliers are then

able to furnish the equipment to other beneficiaries, starting new 36-month periods of rental payments for the same equipment. Based on current Medicare fee schedule amounts, during a 5-year period in which a supplier rents an oxygen concentrator to multiple beneficiaries, each using the equipment for less than 36 months, the supplier is paid \$11,957 for furnishing the oxygen concentrator, the average cost of which was found by the OIG to be \$587. Even in the minority of cases in which beneficiaries use oxygen equipment for more than 36 months, the supplier is paid \$7,174 for furnishing the equipment. Given this level of reimbursement, it is reasonable to assume that each Medicare beneficiary should be receiving a fairly new piece of oxygen equipment. If the supplier chooses instead to provide older equipment to the beneficiary, we expect that the supplier, and not Medicare or the beneficiary, should be responsible for performing any non-routine maintenance and servicing (including repair) of the supplier-owned equipment to ensure that it continues to function properly during the 5-year reasonable useful lifetime of the equipment.

(2) Finding related to routine maintenance and servicing

We have determined at this time that it is not reasonable and necessary to make payments for repair or

non-routine maintenance and servicing (including repair) of supplier-owned oxygen equipment. We have made an initial determination that payments for periodic, in-home visits by suppliers to inspect certain oxygen equipment and provide general maintenance and servicing during these visits are reasonable and necessary for the safety of the beneficiary. Therefore, for CY 2009 only, we are revising §414.210(e)(2), which provides payment for general maintenance and servicing of certain beneficiary-owned oxygen equipment, to apply to routine maintenance and servicing of supplier-owned oxygen concentrators and transfilling equipment furnished after the 36-month rental period consistent with our authority in section 1834(a)(5)(F)(ii)(III) of the Act. Based on our preliminary analysis, we believe that payments in CY 2009 for periodic inspection and general maintenance and servicing of oxygen concentrators and transfilling equipment are reasonable and necessary for the safety of beneficiaries. Therefore, for CY 2009 only, we will make payments when the supplier performs a routine maintenance and servicing visit following each period of continuous use of 6 months after the 36-month rental period ends. Determining a period of continuous use is governed by §414.230, which we discussed in section III.J.2.a. above.

Payments for a routine maintenance and servicing visit in CY 2009 will be made when the beneficiary is at home or at a temporary residence (for example, a vacation residence). For each visit, we believe that it is appropriate to provide payment for 30 minutes of labor for general maintenance and servicing of oxygen equipment other than liquid or gaseous equipment (stationary and portable). As we indicated in the November 9, 2006 final rule for implementing section 5101(b) of the DRA (71 FR 65917), we believe that payment for 30 minutes of labor will adequately compensate suppliers for general maintenance and servicing visits based on findings by the OIG in their September 2006 report (OEI-09-04-00420) that many routine maintenance activities performed by suppliers on concentrators could be performed within that timeframe.

We expect that the primary purpose of the periodic visit would be to check the supplier-owned oxygen equipment to ensure that it will continue to function properly for the succeeding 6-month period of continuous use and does not need to be replaced. We are revising §414.210(e)(2) to permit payment in CY 2009 for general maintenance and servicing of supplier-owned oxygen equipment beginning 6 months after the end of the 36-month rental period.

As a result, we will make payments under §414.210(e)(2) only for an actual visit to the beneficiary's home or temporary residence. This provision is generally consistent with the additional maintenance and servicing payments established at §414.210(e)(2) after the enactment of the DRA, except that, in light of the repeal of transfer of title for oxygen equipment provisions, separate payment will not be made for parts replaced during the routine maintenance and servicing visit. If parts need to be replaced in order to make supplier-owned equipment suitable for the beneficiary, we believe that the supplier should be responsible for replacing the parts on equipment from their inventory in order to meet the beneficiary's medical need for oxygen.

We will make payments for general maintenance and servicing of oxygen concentrators and transfilling equipment as discussed above. However, we welcome comments from interested parties on this issue, especially regarding whether these payments should continue past CY 2009 in light of the OIG's findings that only minimal maintenance and servicing of oxygen equipment is necessary and that suppliers continue to own the equipment.

K. Section 145: Clinical Laboratory Tests