Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

PRESSURE REDUCING SUPPORT SURFACES

JUNE GIBBS BROWN
Inspector General

JUNE 1997
OEI-02-95-00370

OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

PURPOSE

To determine the extent of inappropriate Medicare payments for pressure reducing support surfaces and to assess the effect of new 1996 Durable Medical Equipment Regional Carrier (DMERC) medical policies and coverage guidelines.

BACKGROUND

Pressure reducing support surfaces are a kind of durable medical equipment (DME) used for the care of pressure sores. These sores are lesions caused by unrelieved pressure resulting in damage of underlying tissue. Support surfaces are coded under one of 16 different HCFA Common Procedure Coding System (HCPCS) codes and categorized into three groups. A major distinction between support surfaces is that some are powered by electricity and others are not.

In an effort to clarify and improve existing support surface medical policies, new Durable Medical Equipment Regional Carrier guidelines became effective January 1, 1996. These changes had the greatest impact on alternating pressure mattresses by no longer allowing reimbursement for these mattresses if used for preventive treatment, as they had been before 1996. The new guidelines also no longer require certificates of medical necessity (CMNs) for support surface equipment, with the exception of air-fluidized beds.

In conducting this inspection, we used the following combination of methods: a mail survey to a sample of Medicare beneficiaries who had claims paid for support surface equipment; a medical record review for a subsample of these Medicare beneficiaries; an examination of their support surface billing histories; and a review of Medicare reimbursement data for support surface codes. In order to assess the effect of new 1996 DMERC support surface medical policies, we selected two beneficiary samples for this inspection - the first from the last quarter (October, November, and December) of 1995, and the second from the second quarter (April, May, and June) of 1996.

FINDINGS

While New 1996 DMERC Guidelines Appear To Be Having A Positive Impact On Controlling Medicare Costs For Support Surfaces, Inappropriate Payments Are Still Noted

Medicare reimbursement for alternating pressure mattresses has been decreasing, dropping from $183,358,943 in 1995, to $148,894,337 in 1996. In 1996, 29 percent of sample beneficiaries used support surfaces that were medically unnecessary, fewer than the 47 percent of beneficiaries who used a medically unnecessary support surface in 1995. Finally, 12 percent of beneficiaries in 1996, down from 22 percent in 1995, report receiving upcoded equipment or no equipment at all, or had duplicate support surface billings. Because of the

small sample size, we cannot demonstrate that these differences are statistically significant. However, these trends are consistent with recent actions taken by the Health Care Financing Administration (HCFA).

A Variety of Other Problems Continue To Adversely Affect Medicare Support Surface Reimbursement

These problems are due to a lack of adherence to existing DMERC guidelines, and were not impacted in any way by the establishment of new 1996 DMERC policies. They include: the use of group 2 equipment before a trial of less expensive and complex group 1 equipment; the continued use of support surface equipment after sores have healed completely; an apparent lack of physician involvement in and documentation for beneficiary use of support surfaces; and improper use of support surfaces by beneficiaries who do not plug in their electrical equipment.

Most Beneficiaries With Appropriately Paid Claims Report Positive Experiences With Their Support Surface Equipment

Of the beneficiaries in 1995 and 1996 who received electrical equipment which was both medically necessary and properly used, a majority (79 percent and 89 percent respectively) report that their pressure sores healed completely or improved because of their support surface use.

RECOMMENDATIONS

While the new 1996 DMERC guidelines appear to be having a positive impact on controlling Medicare costs for support surfaces, inappropriate payments are still being made and other problems continue to adversely affect Medicare reimbursement for this equipment. We therefore believe that additional steps can be taken to reduce the extent of inappropriate support surface payments. In particular, we recommend that:

HCFA establish the requirement for periodic review and renewal of the medical necessity for beneficiaries' use of group 2 support surface equipment.

We recognize that establishing such a requirement may be cumbersome to both the DMERCs in processing claims and to the suppliers in obtaining the necessary information. However, we believe that this requirement should help to eliminate problems identified in this report. These include beneficiaries' inappropriate and improper use of support surfaces, provision of upcoded equipment, and poor documentation of support surface use. Periodic recertifications could be done every 3 months and completed by a healthcare practitioner.

We estimate that implementing this requirement would save as much as $12 million annually. Actual savings could be considerably larger than this amount.

COMMENTS

We received comments on the draft report from HCFA and the Assistant Secretary for Planning and Evaluation. We also solicited and received comments from 3 industry groups, the Health Industry Manufacturers Association (HIMA), the National Association for Medical Equipment Services (NAMES), and the Health Industry Distributors Association (HIDA).

The HCFA does not concur with our recommendation that it establish the requirement for periodic review and renewal of the medical necessity for beneficiaries' use of group 2 support surface equipment. It does not believe such a requirement is necessary since group 2 support surface claims must have a ZX modifier, which indicates the supplier has documentation that medical policy requirements have been met. Furthermore, the HCFA is concerned about the timeliness and costs associated with utilizing a certificate of medical necessity (CMN) for group 2 equipment.

In response, we point out that our recommendation did not specifically state that a CMN be used for periodic review and renewal of medical necessity. In fact, we deliberately did not recommend that a CMN be used because of the same concerns of timeliness and costs. However, we feel strongly that some other mechanism be used to review and renew medical necessity. We do not believe the ZX modifier is sufficient to do this, since there is no requirement for additional medical evidence to support it beyond the initial medical necessity determination. Currently, there is no mandate for any additional, ongoing review of medical necessity. Furthermore, the findings of our report indicate inappropriate utilization which warrants, in our opinion, some type of corrective action.

We believe that the Statement of the Ordering Physician, which must be filled out prior to delivery of the equipment and is kept on file with the supplier, could be used to implement our recommendation. This would assure that the equipment continues to be medically necessary. Such a review could also assure that the beneficiary is using the equipment appropriately and using equipment that is properly coded.

All three industry groups support, on some level, our recommendation. The HIMA is in "complete agreement" and states that this is a position they have held for the past several years. The NAMES supports using the Statement of the Ordering Physician, but on a 6 month basis; HIDA agrees with the 6 month timeframe. We believe a 3 month time requirement for review and renewal, as suggested by HIMA, is the best option, and have changed the recommendation accordingly.

Both HCFA and ASPE raised questions about our cost savings estimate of $12 million. We have added a further explanation as to how we derived this estimate in the report's methodology. The ASPE suggests we conduct a cost-benefit analysis for implementing our recommendation. While we acknowledge that certain costs would be incurred by implementing this recommendation, we believe that these costs are likely to be minimal, particularly since the Statement of the Ordering Physician is already kept on file by the supplier.

The HCFA also states that it is unaware of any new support surface coding verification process by the SADMERC. During discussions with SADMERC staff, however, they indicated that they had improved their existing coding verification process to accommodate changes in support surface policies and new support surface codes and now send out a sheet with guidelines for suppliers wanting written coding verification. As HCFA notes, this process is optional to suppliers requesting assistance.

Finally, in response to HCFA's other technical comments, we have made additional clarifications to the text in both the background and findings sections. The full text of all comments are included in Appendix D.

TABLE OF CONTENTS

INTRODUCTION

PURPOSE

To determine the extent of inappropriate Medicare payments for pressure reducing support surfaces and to assess the effect of new 1996 Durable Medical Equipment Regional Carrier (DMERC) medical policies and coverage guidelines.

BACKGROUND

Medicare Program

Medicare provides health insurance for approximately 37 million elderly and disabled beneficiaries under two parts. The first, Part A, is hospital insurance which covers services furnished by providers, such as hospitals, home health agencies, and skilled nursing facilities. The second, Part B, is supplementary medical insurance which covers physician services, outpatient hospital services, and other medical services and supplies. The Health Care Financing Administration (HCFA) administers the Medicare program and contracts with carriers and fiscal intermediaries to process, review, and pay claims for covered services.

DME

One benefit covered under Medicare Part B is durable medical equipment (DME). Home health agencies can also bill for DME under the Part A home health benefit if such equipment is part of their patient's home health plan of care. In order for DME to be covered, it must: withstand repeated use; be used primarily and customarily to serve a medical purpose; generally not be useful to a person in the absence of illness or injury; and be appropriate for home use.

In October, 1993, HCFA began processing DME claims through four regional carriers called the Durable Medical Equipment Regional Carriers (DMERCs). These four carriers cover the entire country, using common medical policies and coverage guidelines for DME.

Support Surfaces

Pressure reducing support surfaces are a kind of DME used for the care of decubitus ulcers or pressure sores. These sores are lesions caused by unrelieved pressure resulting in damage of underlying tissue. They form when patients are not able to shift their weight from one part of their body to the other, thus resulting in pressure being applied to only one area where the sore then develops. Individuals with limited mobility who are confined to a bed or wheelchair for long periods of time, as well as those with impaired sensation, are susceptible to pressure sores. Thus, patients with conditions such as multiple sclerosis or spinal cord injuries, as well as the frail elderly, are particularly vulnerable. Pressure sores are classified into four stages, with stage I being the mildest and stage IV the most severe.

Support surfaces are coded under one of 16 different HCFA Common Procedure Coding System (HCPCS) codes and categorized into three groups. A major distinction between support surfaces is that some are powered by electricity and others are not. Equipment in group 1 are generally less expensive than equipment in groups 2 and 3.

Group 1 includes both powered and non-powered mattress overlays made of gel, air, water or foam. Group 2 includes two air mattress overlays, one powered and the other not, both of which were given their own codes in April 1996. It also includes a powered air flotation bed and an alternating pressure mattress. The only support surface included in group 3 is the air-fluidized bed, which uses the circulation of filtered air through silicone coated ceramic beads, thus simulating the movement of fluid.

Medicare Coverage of Support Surfaces

In an effort to clarify and improve existing support surface medical policies and coverage requirements, new DMERC guidelines became effective January 1, 1996. These changes had the greatest impact on alternating pressure mattresses (code E0277), by no longer allowing reimbursement for these mattresses if used only for preventive treatment, as they had been before 1996. The new policies also no longer require certificates of medical necessity (CMN) for support surface equipment, with the exception of air-fluidized beds. Additionally, the Statistical Analysis DMERC (SADMERC) improved its existing process of support surface coding verification for suppliers with questions about which code to use for their equipment.

For all three support surface groups, patients should have a care plan established by their physician or home care nurse, which is documented in their medical records. This plan generally should include, among other things, education of the patient and regular assessment by a healthcare practitioner. Coverage for all three groups continues until the patient's pressure sore is healed.

In addition to the above common requirements, coverage for specific groups of support surfaces varies as follows:

GROUP 1. A group 1 support surface is covered if the patient is completely immobile. Otherwise, he or she must be partially immobile, or have any stage pressure sore, and demonstrate one of the following conditions: impaired nutritional status; incontinence; altered sensory perception; or compromised circulatory status. A physician order must be obtained prior to delivery of the equipment and should be kept on file by the supplier.

GROUP 2. A group 2 support surface is covered if the patient has a stage II pressure sore located on the trunk or pelvis, has been on a comprehensive pressure sore treatment program (which has included the use of an appropriate group 1 support surface for at least one month), and has sores which have worsened or remained the same over the past month. A group 2 support surface is also covered if the patient has large or multiple stage III or IV pressure sores on the trunk or pelvis, or if he or she has had a recent mycutaneous flap or skin graft for a pressure sore on the trunk or pelvis and has been on a group 2 or 3 support

surface immediately prior to recent discharge from a hospital or nursing facility. A physician order must be obtained prior to delivery and kept on file by the supplier.

GROUP 3. Air-fluidized beds, the sole group 3 support surface, are covered if seven criteria are met. These are stage III or IV pressure sores; severely limited mobility; an unsuccessful conservative treatment trial; a trained adult caregiver who is available to assist the patient; physician direction of the home treatment regimen; and the consideration and ruling out of alternative equipment. For air-fluidized beds, an order and certificate of medical necessity (CMN) must be signed and dated by the ordering physician prior to delivery. These beds must have their medical necessity recertified on a monthly basis.

Operation Restore Trust

The Office of Inspector General (OIG) has over the past few years issued several reports on durable medical equipment (DME) which have documented problems with inappropriate Medicare payments. In response to these and other concerns with Medicare fraud and abuse, the Department of Health and Human Services designed an anti-fraud initiative called Operation Restore Trust (ORT) to target fraud, waste and abuse related to home health agencies, nursing homes and DME suppliers. Recent reports and investigations by the OIG showed that these areas are particularly vulnerable to fraud, waste, and abuse. The ORT initiative targets California, Florida, New York, Illinois, and Texas. These five States account for 40 percent of the nation's Medicare beneficiaries and program expenditures.

METHODOLOGY

Multiple Methods

In conducting this inspection, we used the following combination of methods: a mail survey to a sample of Medicare beneficiaries who had claims paid for support surface equipment; a medical record review for a subsample of these Medicare beneficiaries; an examination of their support surface billing histories; and a review of Medicare reimbursement data for support surface codes.

In order to assess the effect of new DMERC support surface medical policies which started on January 1, 1996, we selected two beneficiary samples for this inspection - the first from the last quarter (October, November, and December) of 1995, and the second from the second quarter (April, May, and June) of 1996. Both samples were selected from the HCFA National Claims History 5 percent file.

See Appendix A for further discussion of our sample selection. Also see Appendix B for confidence intervals on key survey questions and medical record review results, and Appendix C for non-respondent analyses.

1995 Sample

For the 1995 sample, we selected a stratified random sample of 300 Medicare beneficiaries

who had a support surface claim paid during the last three months of 1995. We selected 50 beneficiaries from each of the five ORT States and the remaining 50 from the rest of the country. We included the following five codes in this sample: E0194 (air-fluidized bed), E0193 (powered air flotation bed), E0277 (alternating pressure mattress), E0180 (alternating pressure pad), and E1399 (miscellaneous durable medical equipment). These five codes accounted for over 90 percent of all support surface reimbursement in the last 3 months of 1995.

After our sample was selected, we determined that most of the claims (110 of 130) for the E1399 code were for equipment that was not a support surface. We therefore excluded these 110 beneficiaries from our sample, leaving us with a usable sample size of 190. After allowing 2 months for data collection, during which time we conducted a second mailing to non-respondents, 136 beneficiaries returned their mail questionnaire, for a response rate of 72 percent.

We also selected a subsample of 150 beneficiaries for a medical record review - 25 from each of the six strata. From these, we had to exclude 58 beneficiaries with E1399 claims, leaving a usable sample size of 92. For each of these 92 beneficiaries, we requested medical records from the physician listed as the ordering physician on the claim. In some cases, the physician referred us to the patient's home health agency for the medical records. After at least two efforts to obtain accurate addresses, we were unable to locate five of the 92 physicians.

After allowing 2 months for data collection, during which time non-responding physicians were sent a second follow-up request, we received responses from 58 physicians. Of these 58 physicians, 55 sent us a medical record or other patient specific response (such as a detailed letter), two said they had never seen the beneficiary, and one said he had never ordered the support surface equipment.

Once we obtained a medical record or other patient specific response, we used a medical review contractor to review the documents to determine whether the support surface equipment the beneficiary had a claim paid for was medically necessary. The contractor developed a screening document, based on DMERC medical guidelines, Agency for Health Care Policy and Research (AHCPR) pressure sore guidelines, and with input from one of the DMERC medical directors. Nurse reviewers then used this screening document to review the records. Any records which failed this initial screening were referred to a physician reviewer who then made a final determination of medical necessity.

Due to the big difference between weights used in our analysis of 1995 sample data, the same number of responses may result in different percentages, depending on the strata from which those responses come.

1996 Sample

Due to revised DMERC medical policy changes effective 1996, we stratified our 1996 beneficiary sample differently than our 1995 sample. For 1996, we stratified by HCPCS

code rather than by ORT State, in order to assure a large enough number of the one code (E0277) that was most affected by the new policies. Additionally, we determined that it was necessary to stratify our sample by codes because of the wide variance in frequency of support surface codes.

Therefore, we selected 420 Medicare beneficiaries for our 1996 sample: 290 from stratum 1 (code E0277), 75 from stratum 2 (code E0180), and all 55 from stratum 3 (E0193 and E0194). These four codes accounted for over 85 percent of all Medicare support surface reimbursement during the second 3 months of 1996. With the exception of E1399, these four codes were the same codes included in our 1995 sample. After allowing 2 months for data collection, during which time we conducted a second mailing to non-respondents, 286 beneficiaries returned their mail questionnaire, for a response rate of 68 percent.

We also selected a subsample of 250 of the 420 beneficiaries for the medical review - 145 from stratum 1, 50 from stratum 2, and all 55 from stratum 3. Despite at least two efforts to obtain accurate addresses, we were unable to locate 11 physicians. After allowing 2 months for data collection, during which time non-responding physicians were sent a second follow-up request, we received responses from 127 physicians for a response rate of 51 percent. Of the 127 responding physicians, 113 sent us a medical record or other patient specific response, 10 said they had never seen the beneficiary, and four said they never ordered the equipment. The same contractor and review procedures used to conduct the 1995 medical record review were also used for the 1996 subsample.

Determining Inappropriate Reimbursement

In determining inappropriate Medicare reimbursement for support surface equipment, we looked at the following four categories of beneficiary use: equipment that was not medically necessary; equipment beneficiaries report they never received; equipment beneficiaries report was less what than Medicare paid for; and duplicate billings for support surface equipment.

While percentages are given for the different categories of inappropriate reimbursement, we report numbers when discussing individual medically unnecessary claims. Reporting percentages for these claims would be imprecise, due to their relatively small number.

Estimating Inappropriate Medicare Reimbursement Costs

Estimates for inappropriate Medicare payments were based on allowed Medicare support surface charges for beneficiaries falling into one of the above four categories. These estimates are conservative, however, since we assumed Medicare payments were appropriate for the records not reviewed in the medical record subsample and for the beneficiaries who did not respond to the mail questionnaire. Additionally, due to relatively small sample sizes, especially in 1995, the confidence intervals for some estimates are considerably wide.

The medically unnecessary 1996 claims represent $3 million in inappropriate Medicare payments in the second 3 months of 1996, or $12 million if projected to the entire year, assuming the rest of the year was comparable to that quarter. Of the 33 beneficiaries who

used medically unnecessary support surfaces in 1996, a large majority (88 percent) used a group 2 surface. Only four beneficiaries did not use a group 2 surface: three used an air-fluidized bed and the other a mattress overlay. Furthermore, costs associated with the latter are minimal, since monthly rental costs for mattress overlays are significantly lower than those for group 2 equipment.

This inspection was conducted in accordance with the **Quality Standards for Inspections** issued by the President's Council on Integrity and Efficiency.

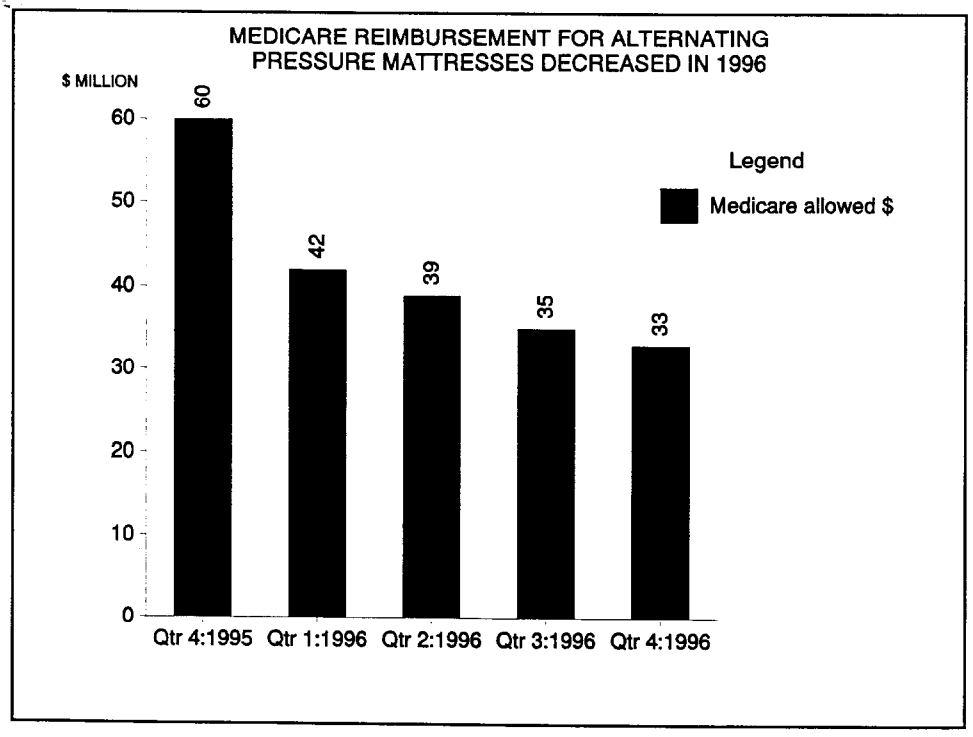
FINDINGS

WHILE NEW 1996 DMERC GUIDELINES APPEAR TO BE HAVING A POSITIVE IMPACT ON CONTROLLING MEDICARE COSTS FOR SUPPORT SURFACES, INAPPROPRIATE PAYMENTS ARE STILL NOTED

Medicare Reimbursement for Alternating Pressure Mattresses Has Been Decreasing

Up until 1996, Medicare reimbursement for support surfaces had been increasing significantly, due specifically to a dramatic growth in reimbursement for alternating pressure mattresses. Payment for these mattresses climbed from $2,777,056 in 1992 to $183,358,943 in 1995. The 1996 DMERC medical policies, which stopped reimbursement for this equipment if used for prevention, was an attempt to control utilization of these mattresses. The support surface industry was well aware before the new policy became effective that such a change would occur.

Since the beginning of 1996, reimbursement for alternating pressure mattresses has been decreasing. Reimbursement for these mattresses dropped from $183,358,943 in 1995 to $148,894,337 in 1996. Graph One below illustrates decreases in quarterly reimbursement amounts, from the last quarter of 1995 through all four quarters of 1996. However, despite this decrease, alternating pressure mattresses still rank highly in terms of overall Medicare DME costs. These mattresses were the 12th highest of all DME codes in terms of overall reimbursement in the third quarter of 1996.



Graph 1

Despite the new 1996 DMERC medical policies which no longer allow reimbursement for the alternating pressure mattress solely for the purpose of prevention, 13 percent of our sample beneficiaries in that year report using their mattress for prevention only.

Twenty-nine percent of beneficiaries in 1996 used medically unnecessary support surface equipment, fewer than did so in 1995

In 1996, 29 percent of beneficiaries used medically unnecessary support surface equipment, fewer than the 47 percent who did so in 1995. Due to the small 1995 sample size, we cannot demonstrate that this difference is statistically significant; however, this trend is consistent with recent actions taken by HCFA. The beneficiaries used one of four different types of support surfaces, ranging from an inexpensive mattress overlay to a much more costly alternating pressure mattress. For 113 documents in the 1996 medical record review, half (50 percent) were medical records. The other half consisted of physician letters, office notes, and other patient specific responses. The medical review contractor was able to make a final decision on the question of medical necessity for 91 of the 113 beneficiaries. Insufficient medical documentation prevented such a decision from being made for the other 22 beneficiaries.

The medically unnecessary 1996 claims represent $3 million in inappropriate Medicare payments in the second 3 months of 1996, or $12 million if projected to the entire year. However, the amount for the year is probably considerably larger than $12 million, since we were only able to review approximately half of the 250 records in the medical review subsample. Since we assumed that all of the other half we were unable to review were medically necessary, our projection of $12 million is a conservative estimate.

The 33 beneficiaries who used a support surface that was medically unnecessary in 1996 are categorized as follows:

- 12 used an alternating pressure mattress despite having no pressure sores. This contradicts the new 1996 DMERC medical policies for this support surface, which state that these mattresses must be used for treatment only.

- 15 beneficiaries were using a group 2 support surface (mostly an alternating pressure mattress) before first trying a group 1 mattress overlay.

- four beneficiaries had insufficient medical evidence to warrant use of their support surface.

- two beneficiaries used a support surface for pressure sores on their limbs.

More beneficiaries in 1995 than in 1996 used medically unnecessary support surfaces. Of the 55 beneficiaries in our 1995 medical record review subsample, 47 percent (21 beneficiaries) had claims paid for a support surface that were determined to be not medically necessary. This represents $14 million in inappropriate Medicare payments in the last 3 months of 1995. Of the 55 physicians, home health agencies, or nursing homes which

provided us with some medical documentation, more than half (57 percent) provided complete medical records. The remaining 43 percent provided some other patient specific response, such as a detailed letter or office notes. Despite poor documentation for many cases, however, the medical review contractor was able to make a determination on the question of medical necessity for all but three of the 55 beneficiaries. The contractor was unable to make a decision on medical necessity for these three beneficiaries because of insufficient medical documentation.

The 21 beneficiaries who used a support surface that was medically unnecessary in 1995 can be categorized as follows:

- 13 beneficiaries used a group 2 support surface (almost always an alternating pressure mattress for pressure sore care or prevention) before first trying a group 1 support surface as required. None of the 13 met the DMERC medical policy criteria that would have allowed use of a group 2 support surface without first trying a group 1 surface. Included in this 1995 group are beneficiaries who would not qualify for support surface reimbursement under the new 1996 guidelines, since many had no pressure sores.

- three beneficiaries used a support surface for pressure sores on their limbs, not allowed by DMERC medical policy.

- three beneficiaries had insufficient medical evidence to warrant use of a support surface.

- one beneficiary was using a support surface for a diabetic foot infection, a noncovered medical condition.

- one beneficiary's ordering physician stated that while the support surface he ordered for his patient was medically necessary, it was delivered after the patient died and therefore was never used.

Twelve percent of beneficiaries in 1996, down from 22 percent in 1995, report receiving upcoded equipment or no equipment at all, or had duplicate billings

Fewer beneficiaries in 1996 (12 percent) than in 1995 (22 percent) report problems with upcoded or undelivered equipment, or had duplicate billings. Again, due to the small 1995 sample size, we are unable to determine if this difference is statistically significant. While the new 1996 DMERC guidelines do not directly address these problems, the SADMERC's improvement of its existing coding verification process for suppliers with questions about which code to use for their equipment may be having some positive effect here. The inappropriate 1996 claims represent $922,000 in allowed Medicare payments in the second quarter of 1996.

The 12 percent in 1996 are categorized as follows:

- 7 percent of 286 beneficiaries report receiving equipment that was less than what Medicare paid. Seven beneficiaries had claims paid for alternating pressure mattresses, and another seven for alternating mattress overlays. While the claims paid for these 14 beneficiaries used codes for electrically powered equipment, they all report that their equipment does not have an electric plug.

- 4 percent of beneficiaries report never receiving support surface equipment. Seven claims were paid for alternating pressure mattresses, two for alternating mattress overlays, and another two for powered air flotation beds.

- 1 percent of beneficiaries had duplicate support surface billings, two for the same equipment and the third for two different types of equipment, all within the same month.

In 1995, 22 percent of 136 Medicare beneficiaries report receiving either upcoded equipment or no equipment at all, or had duplicate support surface billings. These claims represent $6.6 million in allowed Medicare payments in the fourth quarter of 1995.

The 22 percent in 1995 are categorized as follows:

- 13 percent of beneficiaries report receiving equipment that was less than what Medicare paid for. These beneficiaries report that the equipment they are using for the care of their pressure sores does not have an electric plug. However, all of the claims paid for these individuals used codes for electrically powered equipment - eight for alternating pressure mattresses, one for a powered air flotation bed, and one for an alternating mattress overlay.

- 4 percent of beneficiaries report never receiving any kind of support surface equipment. All of these beneficiaries, however, had a Medicare claim paid for some type of support surface equipment. Four claims were for alternating pressure mattresses, and three were for alternating mattress overlays.

- 5 percent of beneficiaries had duplicate billings. In all of these cases, more than one support surface was billed and paid for under Medicare within the same month, which Medicare coverage policy does not permit. Two beneficiaries had two claims paid for the same equipment, while five had claims paid for two different types of support surfaces, usually a support surface overlay and a support surface mattress, within the same month.

A VARIETY OF OTHER PROBLEMS CONTINUE TO ADVERSELY AFFECT MEDICARE SUPPORT SURFACE REIMBURSEMENT

The following problems are due to a lack of adherence to existing DMERC guidelines, and were not impacted in any way by the establishment of new 1996 DMERC policies.

Some Beneficiaries Are Using Group 2 Support Surface Equipment Before First Trying A Less Expensive Support Surface From Group 1; 9 Out Of 10 Have No Documentation Of A Comprehensive Pressure Sore Treatment Program

As noted in the medical record reviews for both years, some beneficiaries are using a support surface from group 2 without first trying equipment from group 1. These beneficiaries include those without any pressure sores as well as those with stage II pressure sores, all of whom should have first tried a lesser, group 1 support surface as part of their comprehensive treatment plan before moving to a group 2 support surface. Only 10 percent of beneficiaries in the 1996 medical record review had documentation which demonstrated the existence of a comprehensive pressure sore treatment program.

Other Beneficiaries Report Continuing Use of Their Support Surface After Their Pressure Sore Healed

In both 1995 and 1996, more than one-third (37 percent and 38 percent, respectively) of beneficiaries report continuing to use their group 2 support surface equipment after their pressure sores healed completely. While DMERC medical policies do not allow continued coverage of support surfaces once the patient's pressure sore has healed completely, Medicare continued to pay rental for 63 percent of beneficiaries with healed sores in 1995 and 81 percent in 1996.

Physicians Play A Limited Role

Based on the limited medical documentation of beneficiaries' pressure sore treatment in both years, physicians appear to be playing a limited role in their patients' use of support surfaces. In 1995, plans of care were submitted to us for just 23 percent of beneficiaries, only four of which included a reference to pressure sore treatment. Documentation showing the patient tried preventative treatment prior to the use of a support surface was available for only 38 percent of beneficiaries. Furthermore, according to the medical record review, just 37 percent were educated on the management of their pressure sores, and only 23 percent were regularly assessed by a healthcare practitioner; both of these practices are listed in DMERC medical policies as being part of a patient's plan of care.

In 1996, we received plans of care for just 30 percent of beneficiaries, only one-third of which specifically addressed pressure sore treatment. Furthermore, documentation of preventive treatment tried prior to use of a support surface was available for only 23 percent of beneficiaries. According to the medical record review, only one-third of beneficiaries were educated on the management of their pressure sores, and just one-third were regularly assessed by a healthcare practitioner.

Finally, on a related note, in 1995, 5 percent of physicians report either having no record of the patient for whom they were listed as the ordering physician or report never ordering support surface equipment for their patients. Even more physicians in 1996 - 14 percent - report the same problems.

Some Beneficiaries Report Using Their Equipment Improperly

Five percent of beneficiaries in each year appear not to be using their electrical equipment properly. This improper use reduces the medical efficacy of their equipment. Some of these beneficiaries report never plugging in their support surface bed, mattress or mattress overlay, despite the fact that their equipment has a plug that must be used in order for it to work. Others plug it in only occasionally when using it.

Such improper use of equipment may suggest a lack of adequate patient education. However, most of all beneficiaries in both 1995 and 1996 (72 and 77 percent respectively) report that the supplier taught them how to use their equipment. Only 2 percent in 1995 and 3 percent in 1996 report having to teach themselves how to use their equipment by reading a manual. Furthermore, more than one-third of all beneficiaries in both years report contacting their supplier when they have any questions about their support surface equipment.

Place Of Service Coding Is Not Always Accurate

Twelve percent of beneficiaries in 1995 and 4 percent in 1996 report living in a nursing home on their survey questionnaire. However, more than half of these beneficiaries in 1995 and all of them in 1996 had claims with "home" coded as the place of service. These cases may not necessarily be problematic. However, a supplier billing for the equipment in this way makes a greater profit: they would be paid 15 months of a high rental price by the DMERC and beneficiary, as opposed to being paid a lower purchase price by the nursing home.

MOST BENEFICIARIES WITH APPROPRIATELY PAID CLAIMS REPORT POSITIVE EXPERIENCES WITH THEIR SUPPORT SURFACE EQUIPMENT

Beneficiaries Report Benefitting From Their Support Surface Use

Of the beneficiaries in 1995 and 1996 who received electrical equipment which was both medically necessary and properly used, a majority report positive experiences with their equipment. More specifically, in 1995, 79 percent of these beneficiaries report that their pressure sores healed completely or improved because of their support surface. Of these, 47 percent say it took 1 month or less for this healing or improvement to occur, while the remaining 53 percent say it took longer than 1 month (for 20 percent, more than 6 months). One beneficiary reports that his equipment is "a very good product. I would have trouble without it." Another says "my mattress does wonders."

In 1996, 89 percent of beneficiaries with appropriately paid claims report a complete recovery from or improvement of their pressure sores since using their support surface equipment. Almost half (46 percent) say this took 1 month or less, while the remaining 54 percent say it took longer than 1 month (longer than 6 months for 9 percent of beneficiaries).

RECOMMENDATIONS

While the new 1996 DMERC guidelines appear to be having a positive impact on controlling Medicare costs for support surfaces, inappropriate payments are still being made and other problems continue to adversely affect Medicare reimbursement for this equipment. We therefore believe that additional steps can be taken to reduce the extent of inappropriate support surface payments. In particular, we recommend that:

HCFA establish the requirement for periodic review and renewal of the medical necessity for beneficiaries' use of group 2 support surface equipment.

We recognize that establishing such a requirement may be cumbersome to both the DMERCs in processing claims and to the suppliers in obtaining the necessary information. However, we believe that this requirement should help to eliminate problems identified in this report. These include beneficiaries' inappropriate and improper use of support surfaces, provision of upcoded equipment, and poor documentation of support surface use. Periodic recertifications could be done every 3 months and completed by a healthcare practitioner.

We estimate that implementing this requirement would save as much as $12 million annually. Actual savings could be considerably larger than this amount.

COMMENTS

We received comments on the draft report from HCFA and the Assistant Secretary for Planning and Evaluation. We also solicited and received comments from 3 industry groups, the Health Industry Manufacturers Association (HIMA), the National Association for Medical Equipment Services (NAMES), and the Health Industry Distributors Association (HIDA).

The HCFA does not concur with our recommendation that it establish the requirement for periodic review and renewal of the medical necessity for beneficiaries' use of group 2 support surface equipment. It does not believe such a requirement is necessary since group 2 support surface claims must have a ZX modifier, which indicates the supplier has documentation that medical policy requirements have been met. Furthermore, the HCFA is concerned about the timeliness and costs associated with utilizing a certificate of medical necessity (CMN) for group 2 equipment.

In response, we point out that our recommendation did not specifically state that a CMN be used for periodic review and renewal of medical necessity. In fact, we deliberately did not recommend that a CMN be used because of the same concerns of timeliness and costs. However, we feel strongly that some other mechanism be used to review and renew medical necessity. We do not believe the ZX modifier is sufficient to do this, since there is no requirement for additional medical evidence to support it beyond the initial medical necessity determination. Currently, there is no mandate for any additional, ongoing review of medical necessity. Furthermore, the findings of our report indicate inappropriate utilization which warrants, in our opinion, some type of corrective action.

We believe that the Statement of the Ordering Physician, which must be filled out prior to delivery and is kept on file with the supplier, could be used to implement our recommendation. This would assure that the equipment continues to be medically necessary. Such a review could also assure that the beneficiary is using the equipment appropriately and using equipment that is properly coded.

All three industry groups support, on some level, our recommendation. The HIMA is in "complete agreement" and states that this is a position they have held for the past several years. The NAMES supports using the Statement of the Ordering Physician, but on a 6 month basis; HIDA agrees with the 6 month timeframe. We believe a 3 month time requirement for review and renewal, as suggested by HIMA, is the best option, and have changed the recommendation accordingly.

Both HCFA and ASPE raised questions about our cost savings estimate of $12 million. We have added a further explanation as to how we derived this estimate in the report's methodology. The ASPE suggests we conduct a cost-benefit analysis for implementing our recommendation. While we acknowledge that certain costs would be incurred by implementing this recommendation, we believe that these costs are likely to be minimal, particularly since the Statement of the Ordering Physician is already kept on file by the supplier.

The HCFA also states that it is unaware of any new support surface coding verification process by the SADMERC. During discussions with SADMERC staff, however, they indicated that they had improved their existing coding verification process to accommodate changes in support surface policies and new support surface codes and now sends out a sheet with guidelines for suppliers wanting written coding verification. As HCFA notes, this process is optional to suppliers requesting assistance.

Finally, in response to HCFA's other technical comments, we have made additional clarifications to the text in both the background and findings sections. The full text of all comments are included in Appendix D.

APPENDIX A

SAMPLE SELECTION

I. Defining the Universe

We selected two samples of beneficiaries for this inspection, one from 1995 and the other from 1996. We also selected subsamples from each of the two samples. Using HCFA's National Claims History (NCH) 5 percent sample file, we extracted all Medicare Part B line items meeting the following five criteria:

1. Processed by DMERCs
2. HCFA had received and posted the claims as of 12/31/95 for the 1995 sample and 06/30/96 for the 1996 sample
3. HCPCS code of E0180, E0193, E0194, E0277, or E1399 for the 1995 sample and HCPCS code of E0180, E0193, E0194, E0277 for the 1996 sample.
4. Allowed dollar amount greater than zero
5. An ending date for line item services (TDT) between 10/01/95 and 12/31/95 for the 1995 sample, and between 04/01/96 and 06/30/96 for the 1996 sample.

II. 1995 Sample Selection

The original universe consisted of 7,454 line items attributable to 4,178 beneficiaries. After removing the line items of 648 beneficiaries whom HCFA's Enrollment Database (EDB) show to be deceased, and by selecting the most recent line item for each beneficiary, we were left with a final universe of 3,530 line items, each attributable to a unique beneficiary.

We stratified the universe by ORT State and an "all other" category based on beneficiaries' zip codes. We then randomly selected 50 beneficiaries from each of the six strata, for a total original sample size of 300. Our original subsample was then constructed by randomly selecting 25 beneficiaries from each stratum, for an initial subsample of 150.

Once it became clear that only 20 of the 130 beneficiaries with HCPCS code E1399 claims had used support surface equipment, we dropped them from the original sample. This reduced the original sample size from 300 to a final sample size of 190 and the original subsample size from 150 to a final sample size of 92.

1995 SAMPLE

Strata	Universe	Original Sample	Final Sample
1. (FL)	285	50	33
2. (NY)	125	50	46
3. (CA)	441	50	15
4. (IL)	99	50	32
5. (TX)	272	50	31
6. (Other States)	2308	50	33
TOTAL	3530	300	190

1995 SUBSAMPLE

Strata	Universe	Original Subsample	Final Subsample
1. (FL)	285	25	16
2. (NY)	125	25	23
3. (CA)	441	25	8
4. (IL)	99	25	12
5. (TX)	272	25	15
6. (Other States)	2308	25	18
TOTAL	3530	150	92

III. 1996 Sample Selection

The original universe consisted of 3,225 line items attributable to 1,701 beneficiaries. After removing the line items of 228 beneficiaries whom HCFA's Enrollment Database (EDB) show to be deceased, and by selecting the most recent line item for each beneficiary, we were left with a final universe of 1,473 line items, each attributable to a unique beneficiary.

We stratified the 1996 sample by HCPCS code, one stratum for E0277, one for E0180,

and one for both E0193 and E0194. We then randomly selected 290 cases from stratum 1, 75 from stratum 2, and 55 from stratum 3, to form a sample of 420 beneficiaries. Our subsample was then constructed by randomly selecting 145 cases from stratum 1, 50 from stratum 2 and 55 from stratum 3, yielding a subsample of 250 beneficiaries.

1996 SAMPLE

Strata	Universe	Sample
1. (HCPCS E0277)	800	290
2. (HCPCS E0180)	618	75
3. (HCPCS E0193/E0194)	55	55
TOTAL	1473	420

1996 SUBSAMPLE

Strata	Universe	Subsample
1. (HCPCS E0277)	800	145
2. (HCPCS E0180)	618	50
3. (HCPCS E0193/E0194)	55	55
TOTAL	1473	250

APPENDIX B

CONFIDENCE INTERVALS FOR KEY QUESTIONS

We calculated confidence intervals for 14 key questions (seven from the beneficiary mail questionnaire and seven from the medical record review). The response estimate and 95 percent confidence interval are given for each of the following:

From the mail questionnaire

1. Have you ever received medical equipment, such as a special bed, mattress or mattress overlay, for the care of pressure sores?

	1995	1996
"Yes" response estimate:	96%	96%
Lower interval:	90%	93%
Upper interval:	100%	99%

2. Was the support surface paid inappropriately (i.e., was the support surface never received, was the equipment upcoded, or were duplicate billings paid)?

	1995	1996
"Yes" response estimate:	22%	12%
Lower interval:	10%	8%
Upper interval:	34%	16%

3. Have you ever had a pressure sore?

	1995	1996
"No" response estimate:	N/A	13%
Lower interval:	N/A	8%
Upper interval:	N/A	18%

4. Who taught you how to use your special bed, mattress or mattress overlay?

	1995	1996
"The company that supplies the product" response estimate:	72%	77%
Lower interval:	58%	71%
Upper interval:	86%	84%

5. Since using your special bed, mattress or mattress overlay, have your pressure sore(s) healed completely, improved, remained the same, or gotten worse?

	1995	1996
"Healed completely" response estimate:	37%	38%
Lower interval:	21%	31%
Upper interval:	54%	45%

6. Who do you talk to when you have questions about using your special bed, mattress or mattress overlay?

	1995	1996
"Someone from the company that supplies the product" response estimate:	37%	57%
Lower interval:	23%	50%
Upper interval:	52%	64%

7. Where do you live?

	1995	1996
"In a nursing home" response estimate:	12%	4%
Lower interval:	22%	2%
Upper interval:	2%	7%

From the medical record review

8. Was support surface medically indicated?

	1995	1996
"No" response estimate:	47%	29%
Lower interval:	24%	20%
Upper interval:	70%	38%

9. Information source

	1995	1996
"Medical record" response estimate:	56%	50%
Lower interval:	34%	39%
Upper interval:	78%	61%

10. Was there a written plan of care that addressed patient risk?

	1995	1996
"Yes" response estimate:	33%	30%
Lower interval:	12%	20%
Upper interval:	54%	40%

11. Did the plan of care address pressure ulcer treatment?

	1995	1996
"Yes" response estimate:	25%	31%
Lower interval:	5%	21%
Upper interval:	45%	41%

12. Was preventative treatment initiated prior to ordering surface?

	1995	1996
"Yes" response estimate:	38%	23%
Lower interval:	16%	31%
Upper interval:	54%	15%

13. Was there documentation of education of the patient and caregiver on the prevention and/or management of pressure ulcers?

	1995	1996
"Yes" response estimate:	37%	31%
Lower interval:	15%	21%
Upper interval:	59%	41%

14. Was there documentation of regular assessment by a nurse, physician, or other licensed healthcare practitioner at least weekly?

	1995	1996
"Yes" response estimate:	23%	33%
Lower interval:	5%	23%
Upper interval:	41%	43%

APPENDIX C

NON-RESPONDENT ANALYSES

When surveys are used to collect data, the results may be biased if non-respondents differ from respondents. For this inspection, a beneficiary for whom a survey was not received is a non-respondent.

1995 Sample

For the 1995 beneficiary sample, due to the relatively small sample size and resulting small cell sizes in the two-variable tables, we were only able to analyze one variable. To test for the presence of any non-response bias in the 1995 survey data, we obtained information from HCFA's National Claims History 5 percent file for all 190 beneficiaries who were sent a questionnaire. A total of 136 surveys were returned, for a response rate of 72 percent. The following table illustrates the number of responses and the response rate by strata:

STRATA	NUMBER	RESPONSE RATE
1 (FL)	33	73
2 (NY)	46	61
3 (CA)	15	67
4 (IL)	32	75
5 (TX)	31	84
6 (U.S.)	33	73
Total Respondents	190	72

The survey data are analyzed as a whole and not by strata. However, we did exceed the desired minimum 60 percent response rate for each stratum.

For the 190 individuals in our sample, we looked at their sex. This categorical variable was tested using the Chi-Square with the appropriate degrees of freedom. The results are presented in Table A.

TABLE A

SEX						
	Respondents		**Non-respondents**		**Total**	**Response Rate**
Male	41	30%	15	28%	56	73%
Female	95	70%	39	72%	134	71%
Total	**136**		**54**		**190**	**72%**
CHI-SQ = .104 Degree of Freedom = 1						

1996 Sample

To test for the presence of any non-response bias in the 1996 survey data, we obtained information from HCFA's National Claims History 5 percent file for all 420 beneficiaries who were sent a questionnaire. A total of 287 surveys were returned, for a response rate of 68 percent. The following table illustrates the number of responses and the response rate by strata:

STRATA	NUMBER	RESPONSE RATE
1 (HCPCS E0277)	196	68
2 (HCPCS E0180)	54	72
3 (HCPCS E0193/E0194)	37	67
Total Respondents	287	68

The survey data are analyzed as a whole and not by strata. However, we did exceed the desired minimum 60 percent response rate for each strata.

To test for the presence of any non-respondent bias, we analyzed the variables that might influence whether an individual would respond to the survey or that might affect his or her responses. For the 420 individuals in our sample, we looked at their sex, support surface used, and place of service. These categorical variables were tested using the Chi-square with the appropriate degrees of freedom.

The results of this analysis are presented in tables A, B and C. The Chi-square values given in the tables provide a test of the difference between the distribution of the respondents and that of the non-respondents for the variable of interest. Also provided in the tables are the response rates by the different values of the variables.

These tables show no statistically significant difference between respondents and non-respondents for any of the variables tested. Given the results of this analysis, we believe that the original results fairly represent the opinions of the sample of beneficiaries to whom the questionnaires were sent. We therefore believe that our survey results can be generalized to the universe of Medicare beneficiaries who had a support surface claim paid during the second 3 months of 1996.

TABLE A

SEX						
	Respondents		**Non-respondents**		**Total**	**Response Rate**
Male	105	37%	46	35%	151	70%
Female	182	63%	87	65%	269	68%
Total	**287**		**133**		**420**	**68%**
CHI-SQ = .158 Degree of Freedom = 1						

TABLE B

SUPPORT SURFACE BILLED						
	Respondents		**Non-respondents**		**Total**	**Response Rate**
Alternate pressure mattress (E0277)	196	68%	94	71%	290	68%
Other sample equipment (E0180, E0193, E0194)	91	32%	39	29%	130	70%
Total	**287**		**133**		**420**	**68%**
CHI-SQ = .242 Degree of Freedom = 1						

TABLE C

PLACE OF SERVICE						
	Respondents		**Non-respondents**		**Total**	**Response Rate**
Home	273	95%	128	96%	401	68%
Not Home	14	4%	5	5%	19	73%
Total	**287**		**133**		**420**	**68%**
CHI-SQ = .263 Degrees of Freedom = 1						

APPENDIX D

In this appendix, we present in full the comments from the Health Care Financing Administration and the Assistant Secretary for Planning and Evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: MAY 16 1997

TO: June Gibbs Brown
Inspector General

FROM: Bruce C. Vladeck
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Pressure Reducing Support Surfaces," (OEI-02-95-00370)

We reviewed the above-referenced report that describes the extent of inappropriate Medicare payments for pressure reducing support surfaces and assesses the effect of new 1996 durable medical equipment regional carrier medical policies and coverage guidelines.

Our detailed comments on the report's recommendation are attached for your consideration. Thank you for the opportunity to review and comment on this report.

Attachment

IG	✓
EAIG	
SAIG	✓
PDIG	
DIG-AS	
DIG-EC	✓
DIG-EI	
DIG-OI	
DIG-MP	
AIG-LC	
OGC/IG	✓
ExecSec	✓
Date Sent	5-19

Comments of the Health Care Financing Administration (HCFA)
on Office of Inspector General (OIG) Draft Report:
"Pressure Reducing Support Surfaces,"
(OEI-02-95-00370)

OIG Recommendation

HCFA should re-establish the requirement for periodic review and renewal of the medical necessity for beneficiaries' use of group 2 support surface equipment.

HCFA Response

We do not concur. Additionally, we do not believe such a requirement would save as much as $12 million annually. We believe use of the ZX modifier will continue to decrease the inappropriate utilization of support surfaces. As noted in the report, the new 1996 durable medical equipment regional carrier (DMERC) guidelines have had significant impact on controlling medically-unnecessary Medicare reimbursement for support surfaces. The downward trends in inappropriate payment for this equipment appear to be continuing.

In order to perform the type of recertification suggested by OIG, the DMERCs would need to utilize a certificate of medical necessity (CMN). However, at this time there is no applicable or appropriate CMN for the DMERCs to use for support surface equipment other than the CMN for air-fluidized beds. CMN changes must be made via the national standard format system. These changes are costly and can only be made once a year. The earliest we could institute this requirement would be July 1998.

In lieu of using a CMN, the DMERCs require suppliers to use a HCFA common procedure coding system ZX modifier for support surface equipment. The ZX modifier indicates the supplier has documentation that medical policy requirements have been met and evidence is available in the supplier's records. The documentation section of the support surface policy requires that an order for a mattress or bed be signed and dated by the ordering physician and kept on file by the supplier. This statement must be supported by information in the patient's medical record which would be available to the DMERC on request. Suppliers are instructed to add the ZX modifier to the code for the equipment only if all of the specified medical necessity and documentation requirements are met. The use of this modifier will allow the DMERCs to monitor and analyze utilization of the modifier for support surface equipment. Consequently, data analysis can be performed consistent with the focused medical review approach and actions can be taken to correct inappropriate billing practices. The policy also states that once the ulcer has healed, the ZX modifier should not be used. If the requirements for use of the modifier are not met, the supplier can submit additional information with the claim to justify coverage, but the ZX modifier should not be used. If a supplier uses the ZX modifier despite the applicable requirements not being met, the supplier is submitting fraudulent claims to the Medicare program.

At this time, we have no way to control whether or not suppliers submit accurate and truthful medical necessity information regardless of the mechanism used to collect the information. This type of fraudulent behavior may only be discovered through a post-payment review of claims.

Therefore, the DMERCs are continuing to require that suppliers substantiate the medical necessity of equipment, but have chosen to do so through the use of the ZX modifier instead of a CMN. The use of the ZX modifier has significantly decreased inappropriate utilization of support surface equipment. However, it should be noted that neither the ZX modifier nor a CMN will solve many of the abuses identified in the OIG report. For example, neither mechanism will be able to discover whether beneficiaries are improperly or inappropriately using their equipment; i.e., beneficiaries never plugging in their equipment. In addition, neither mechanism will be able to determine whether or not the supplier delivered the same equipment that was billed to Medicare or whether the equipment was delivered at all.

Technical Comments

We believe there is incorrect information in the Background section of the report, sub-heading "Medicare Coverage of Support Surfaces." The first paragraph, last two sentences state: "The new guidelines also no longer require monthly recertification for support surface equipment, with the exception of air-fluidized beds. Additionally, the Statistical Analysis DMERC (SADMERC) initiated a new process of coding verification for support surface equipment." These statements are incorrect. Monthly recertification has never been required for all support surface equipment. Air-fluidized beds are the only items that were ever subject to recertification requirements. This requirement continues. Additionally, we are unaware of any new coding verification process that has been developed by the SADMERC. The SADMERC coding verification process is an optional process whereby a supplier may get assistance in identifying the appropriate code for billing. The SADMERC has always been responsible for responding to inquiries from suppliers regarding the appropriate codes to use when billing Medicare. Suppliers are not required to contact the SADMERC for coding guidance for support surface products.

One of the findings states that "13 beneficiaries used a group 2 support surface that was medically unnecessary before first trying a group 1 support surface as required." It should be noted the policy allows for a group 2 support surface to be covered under certain circumstances without first trying a group 1 surface; e.g., if the patient has large or multiple stage III or IV pressure ulcers on the trunk or pelvis or if the patient had myocutaneous flap or skin graft surgery within the past 60 days for a pressure ulcer on the trunk or pelvis.

Another finding states the DMERCs continued to pay the rental of support surface equipment for 63 percent of beneficiaries with healed ulcers despite the policy not allowing "continued coverage of support surfaces once the patient's pressure sore has healed completely." It is not clear whether this statement means that coverage of just the group 2 product would be

discontinued, or if all support surface equipment would not be covered once the ulcer healed. Therefore, it should be noted that if a patient qualified for a group 2 support surface, and the pressure ulcer healed, the DMERCs would cover a Group 1 support surface to prevent the recurrence of the pressure ulcer.

The study also found that "physicians appear to be playing a limited role in their patients' use of support surfaces" and that "nine out of ten beneficiaries have no documentation of a comprehensive pressure sore treatment program." Although this may be true, the DMERC policy requires that patients have a comprehensive care plan established by the patient's physician or home care nurse, and documented in the patient's medical records. In addition, the policy also requires the supplier obtain a signed and dated statement from the physician attesting to the medical necessity of the equipment. Questions pertaining to medical necessity on any form used to collect this information may not be completed by the supplier or anyone in a financial relationship with the supplier. Therefore, we believe the policy goes as far as it can in requiring an active role on the part of the patient's physician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

MAY 2 1997

TO: June Gibbs Brown
Inspector General

FROM: David F. Garrison JM/for
Principal Deputy Assistant Secretary
for Planning and Evaluation

SUBJECT: OIG Draft Report: "Pressure Reducing Support Surfaces," ~~OEI-OE-00370~~ 02-95-00370
CONCUR WITH COMMENT

The Medicare DME benefit includes coverage of three different types of pressure reducing surfaces -- categorized as group 1, group 2, and group 3. These surfaces (e.g., beds, mattresses, and related equipment) are considered durable medical equipment and they are used to reduce decubitus ulcers. Groups 1 and 2 surfaces must be ordered by a physician and the order must be kept on file by the supplier. For group 3 surfaces there is an additional requirement for a certificate of medical necessity, which must be updated monthly. The OIG inspection described in the report found frequent use of more expensive group 2 equipment without prior trial of simpler group 1 devices.

The OIG recommends that HCFA periodically review the medical necessity of group 2 support surfaces for beneficiaries who use these surfaces and indicates that such a review process will produce $12 million in annual savings. However, it was unclear how this amount of savings was determined. The OIG study points out that, in 1996, had all medically unnecessary claims not been paid, $12 million would have been saved. Given that the scope of the OIG's recommendation seems to address only a subset of these medically unnecessary claims, it was unclear how a subset of those claims could also produce $12 million in savings. We recommend the report clarify how it arrived at the $12 million in savings.

In addition, the OIG report does not indicate the costs of implementing a requirement to conduct periodic reviews and the extent to which any savings would be reduced by these costs. Such an estimate should be fairly straightforward since monthly recertifications were previously conducted. We recommend the report estimate the administrative costs of conducting the recommended reviews and recertifications, and emphasize how much the estimated savings would be offset by these added costs.

IG	✓
EAIG	
SAIG	
PDIG	✓
DIG-AS	
DIG-EC	
DIG-EI	✓
DIG-OI	
DIG-MP	
AIG-LC	
OGC/IG	
ExecSec	✓
Date Sent	5-6

HIMA

HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

May 1, 1997

IG ✓
EAIG
SAIG
PDIG ✓
DIG-AS
DIG-EC
DIG-EI ✓
DIG-OI
DIG-MP
AIG-LC
OGC/IG ✓
ExecSec ✓
Date Sent 5/1

The Honorable June Gibbs Brown
Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W.
Room 5246
Washington D.C. 20201

OEI-02-95-00370

Dear Inspector General Brown:

The Health Industry Manufacturers Association (HIMA) is pleased to be asked by your office to respond to the draft report titled " Pressure Reducing Support Surfaces." The Health Industry Manufacturers Association (HIMA) is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 700 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture nearly 90 percent of the $55 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $130 billion purchased annually around the world.

First of all, we appreciate that you addressed our concerns when we suggested in our February 21, 1996 letter to Penny Thompson, Chief, Health Care Branch, that the time period during which you would be collecting the data be changed to take into consideration proper implementation of the support surfaces medical coverage policy. We believe that your data has more validity coming from the second quarter of 1996, rather than retrieving it from the first quarter as you originally intended to do.

HIMA is in complete agreement with your recommendation that HCFA re-establish the requirement for periodic review and renewal of the medical necessity for beneficiaries' use of group 2 support surfaces. In fact, this is a position that we have held throughout the development and implementation of the Durable Medical Equipment Regional Carrier (DMERC) medical policy for support surfaces. We would suggest, however, as we did in our October 25, 1995 letter to the DMERC medical directors concerning the support surface policy, that review and renewal of medical necessity documentation should occur every three months.

We would recommend that the current medical necessity document (i.e., the "Statement of the Ordering Physician") and procedures be utilized to initially establish the medical necessity and to renew. Utilizing this document and procedure would achieve the goals outlined in the OIG report, while not making the claims filing and processing tasks more cumbersome. Based on the current DMERC support surface medical coverage policy, the Statement of the Ordering Physician is required before set-up. It is not filed with the claim; but rather it is maintained in the

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patient's chart and provided upon request. In this way, electronic claims filing is available if requested or as part of a post payment audit. This procedure and documentation appears to be working well in initially establishing medical necessity. We believe that it should be fairly easy for the DMERC medical directors to add similar language to the current policy to require it for renewal.

In addition, to reinforce the results of your study, we believe that the "cascading" coverage criteria from overlay to mattress replacement should be reinstated. Again, in our comments to the DMERC medical directors, we noted that in the September 1995 support surfaces medical coverage policy, the coverage criteria for all group 2 products is the same. However, in the August 1994 proposed policy and in the recommendations of the interested associations, a coverage criteria cascade existed from overlay, to mattress replacement, to bed system. The cascade approach allowed for a much clearer selection process based not only on therapeutic wound care benefit, but on the physical needs of the beneficiary; and on their other clinical indicators, (i.e. need for frequent adjustment, weight factors, etc.)

HIMA's recommendation was (and still is) that, for the most part, industry agreed with the "cascading" coverage criterion that was included in the August 1994 proposed policy. This included "bottoming out" as an additional criterion to move from a group 2 overlay to a group 2 mattress replacement. Industry agreed to these parameters. Also, such standards would result in a selection process which is more customized to the patient. Based on this, we believe that it would be advantageous for the DMERC medical directors to reinstate the "cascading" coverage criteria from overlay to mattress replacement in group 2.

Finally, we would like to compliment the staff that were involved in the creation and implementation of this draft report. We have worked closely with your staff in the past and have developed an excellent working relationship. We were delighted to have the opportunity to work with and serve as an educational resource to Demetra Arapakos and her staff concerning support surfaces during the course of the study and at the Medtrade exposition in Atlanta.

Again, as always, we appreciate the opportunity to comment on the draft report.

Sincerely,

Marcia Nusgart R. Ph.

Marcia Nusgart R. Ph.
Associate Vice President, Home Care

HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION
Serving Medical Products Distributors & Home Care Companies Since 1902

April 29, 1997

June Gibbs Brown
Inspector General
Office of the Inspector General
Department of Health and Human Services
Washington, DC 20201

RE: Comments on Draft Inspection Report on Pressure Reducing Support Surfaces
OEI-02-95-00370

Dear Ms. Brown,

Thank you for providing HIDA with a copy of the draft inspection report entitled "Pressure Reducing Support Surfaces." HIDA is the national trade association of home care companies and health and medical product distribution firms. Created in 1902, HIDA now represents approximately 800 home care companies and wholesale and retail medical product distributors with over 2,000 locations.

Subsequent to reviewing the draft report, HIDA recommends that the OIG modify the recommendation that HCFA require periodic recertification of medical necessity for support surface equipment on a monthly or bi-monthly basis. Given that the internal part of a wound often needs greater than three months to properly heal, HIDA believes any requirement of recertification in less than a three month interval is intrusive, and not in the clinical interests of the Medicare beneficiaries. HIDA maintains that six month intervals are a far more reasonable time frame, and should be incorporated in the final version of the report.

Please feel free to contact myself or Mark Hobratschk at (703)-549-4432 with any question or for additional information

Sincerely,

Cara C. Bachenheimer
Executive Director
Home Care and Long Term Care

cc: Mark Hobratschk
S. Wayne Kay

CCB:mh

IG	
EAIG	
SAIG	
PDIG	
DIG-AS	
DIG-EC	
DIG-EI	✓
DIG-OI	
DIG-MP	
AIG-LC	
OGC/IG	✓
ExecSec	
Date Sent	5/2

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NAMES
National Association for
Medical Equipment Services

May 2, 1997 *Via Hand Delivery*

The Honorable June Gibbs Brown
Inspector General
Department of Health and Human Services
Room 5246 Cohen Building
330 Independence Avenue, S. W.
Washington, D. C. 20201

Re: Comments on Draft Report: Pressure Reducing Support Surfaces
OEI-02-95-00370

Dear Inspector General Brown:

The National Association for Medical Equipment Services (NAMES) submits the following comments on the Office of Inspector General's (OIG) draft report, Pressure Reducing Support Surfaces. The draft report, which NAMES received on April 18, 1997, requested comments within fourteen (14) days.

NAMES is a nonprofit trade association comprised of over 1400 home medical equipment (HME) services providers in approximately 4,000 sites across the country. NAMES members furnish a wide variety of equipment, supplies, and services for home use. These items may range from traditional medical equipment such as walkers, oxygen and hospital beds, to highly sophisticated items and services such as enteral and parenteral supplies for complete nutrition support for individuals who can not digest food normally; apnea monitors, which allow parents to closely monitor high risk infants' breathing; and specialized wheelchairs and other technologically advanced equipment which are custom designed for the needs of rehabilitation patients. A substantial portion of HME patients are Medicare beneficiaries or Medicaid recipients.

NAMES has had a sustained commitment to helping eliminate fraud and abuse in the home

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medical equipment (HME) services industry. For example, the NAMES initiative, Operation Build Trust (OBT), was created in response to requests from state Medicaid programs for information about the HME services industry. OBT now serves as a vehicle through which NAMES works with the Medicare and Medicaid programs to identify sources of fraud and abuse within the HME services industry. NAMES also supports anti-fraud and abuse measures proposed by HCFA, such as bonding, and it is advancing a legislative plan that includes accreditation and on site inspections of HME services providers.

NAMES is pleased to have the opportunity to comment on the OIG's draft report. NAMES likewise is pleased to note the favorable trends that the OIG cites in the report, including the following:

- medically unnecessary use of pressure reducing support surfaces has declined;
- fewer beneficiaries report receiving up coded or no equipment;
- fewer beneficiaries report problems with duplicate billings;
- almost all beneficiaries report receiving training in the proper use of the equipment from their HME services provider; and
- patient outcomes are favorable when the support surface is used properly.

Your report also notes that Medicare reimbursement for alternating pressure mattresses has been declining since the beginning of 1996. These outcomes, as you point out, demonstrate the effectiveness of the new guidelines that the DMERCs implemented in 1996. In light of these positive trends, NAMES has serious concerns about reestablishing monthly or bi-monthly certification of the medical necessity for group 2 support surfaces.

As you clearly state in your report, this requirement would be burdensome on the DMERCs and HME services providers. It is our experience that physicians would find this requirement burdensome as well. Wound care patients typically are bedridden and have a severely compromised health status. The healing process may be lengthy and will depend on a number of variables in addition to the use of a support surface, including the patient's nutrition, oxidation, and drug therapy. Consequently, it would be unlikely to see much improvement in these patients' condition on a monthly or bi-monthly recertification schedule.

Documentation of continuing medical necessity could be accomplished in a less burdensome manner by requiring that the physician provide to the HME services provider an updated Statement of Ordering Physician - Group 2 Support Surfaces every six months. This information would not need to be submitted with a claim, but would be kept on file by the HME services

provider. The DMERCs currently require that HME services providers maintain a Statement of Ordering Physician on file for beneficiaries who receive group 2 support surfaces. The requirement to update this form, combined with HCFA's bonding initiative and NAMES legislative proposal to require accreditation and on site inspections, would reduce the problems with group 2 support surfaces cited in your report.

Again, thank you for the opportunity to comment on the draft report. Please feel free to call me if you have any questions, or if NAMES can be of further assistance to you.

Sincerely yours,

Asela M. Cuervo, Esq.
Director of Regulatory Affairs