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# **TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) DEVICES**

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**OFFICE OF INSPECTOR GENERAL**  
**OFFICE OF ANALYSIS AND INSPECTIONS**

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JULY 1989

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# **TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) DEVICES**

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INSPECTOR GENERAL**

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## EXECUTIVE SUMMARY

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### PURPOSE

This inspection was conducted to identify vulnerabilities in Medicare reimbursement for transcutaneous electrical nerve stimulation (TENS) devices.

### BACKGROUND

The TENS, a low-voltage electrical impulse generator used as a pain-control device, usually looks like a portable transistor radio and can be attached to one's belt. Properly trained, patients are able to use this device as they go about their daily activities.

Medicare covers long-term use of TENS when it provides significant therapeutic benefit to patients with chronic pain and short-term use for acute post-operative pain.

Medicare coverage guidelines for treating chronic pain require that TENS be used for a 1 month trial period and its effectiveness monitored by the physician or physical therapist. The device may be rented during the assessment period and then purchased if beneficial.

Reimbursement for TENS has increased substantially over the past few years. Allowed Medicare charges in 1985 were \$12,802,927; they increased by 55 percent in 1986 to \$20,381,751 and by an additional 97 percent in 1987 to \$40,111,359.

The Office of Inspector General's (OIG) concerns about Medicare reimbursing for TENS were generated by beneficiary complaints. A Medicare Fraud Alert was issued in July 1988 reporting on aggressive selling techniques by suppliers of TENS.

### ISSUES AND METHODOLOGY

The primary issues addressed were: (1) to what extent are carriers reimbursing for TENS claims which do not meet Medicare coverage guidelines, and (2) how useful are Medicare beneficiaries actually finding TENS in alleviating pain?

A random sample of 210 cases was selected from 1986 HCFA data for both renting and purchasing TENS. Sixty were dropped because the beneficiary was either deceased or could not be located. Claims and supporting documents were obtained from the carriers for each of these beneficiaries.

Telephone discussions were held with 126 of the remaining 150 sample beneficiaries to gather pertinent information on whether they had received the TENS, their impressions as to its effectiveness, and whether they had a trial period. A subsample of 26 physicians who authorized TENS was contacted by telephone, along with several physical therapists with expertise in using TENS. Additionally, information was collected from 26 Medicare carriers for whom

sample beneficiary claims were submitted to determine their policies relating to TENS. Forty-eight State Medicaid programs and the Veterans Administration provided information regarding their reimbursement of TENS.

## **FINDINGS**

### ***One-third Of Claims For Beneficiaries Contacted Were Inappropriately Reimbursed***

Medicare carriers should not have paid for 33 percent of the TENS because they were either possibly fraudulent or failed to meet the Medicare coverage requirements for a trial period. This resulted in an estimated loss of \$4,394,500 to Medicare (appendix I).

Nine percent (11 of 126) of claims for the beneficiaries contacted are possibly fraudulent. These 11 beneficiaries denied ever having a TENS. (These cases have been referred to the OIG's Office of Investigations.) Additionally, 24 percent (30 of the 126) of the beneficiaries contacted did not have the required trial period of at least 1 month. Typically these people immediately purchased a TENS.

Medicare carrier procedures to enforce the trial period need strengthening. Although the supporting documentation submitted with the 85 sample purchase claims mentioned a trial period in three-quarters of the cases, only half of those indicated a successful trial period.

Only half of the physicians contacted knew the Medicare guidelines for reimbursing TENS, and only half of the carriers had sent any educational information about TENS coverage to providers.

### ***Most Purchased Tens Units Were Found Helpful; Trial Period Plays Major Role In Assuring Appropriate Use***

Nearly 80 percent (67 of 85) of beneficiaries who purchased and received a TENS found it beneficial. Eighty-four percent of the beneficiaries who had the TENS recommended by a medical practitioner found it helpful; in contrast, only 56 percent of those who did not have it so recommended found it helpful.

Use of the required trial period is critically important in assuring the most effective use of TENS. Of the 55 beneficiaries who purchased a TENS and had a trial period, virtually all (53 of 55) found the TENS helpful. In contrast, only 47 percent of those who purchased a TENS without a trial period (14 of 30) were helped.

Most of the 26 physicians contacted view the TENS favorably. Two-thirds of the physicians said it was their idea to prescribe a TENS and most thought the TENS helpful in relieving the patient's pain. More than half said the patient was seen during the trial period by either themselves or a physical therapist to teach the patient to use the TENS and evaluate its effectiveness.

## **RECOMMENDATIONS**

To reduce inappropriate payments for TENS, HCFA should:

- Evaluate and strengthen, as needed, carrier implementation of Medicare and Omnibus Reconciliation Act of 1987 (OBRA 1987) requirements to:
  - ensure a trial period prior to purchasing a TENS by assuring an appropriate certification form is submitted by the physician which indicates information on training in using the device and its effectiveness;
  - prohibit payment unless the supplier receives a written order from the physician prior to delivering the device to the patient.
- Publicize Medicare coverage requirements to the medical community; and
- Add TENS to the categories of services to be considered by carriers when conducting postpayment reviews of providers.

## **HCFA RESPONSE**

The HCFA concurred with the OIG recommendations and made some general comments (see appendix II).

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## INTRODUCTION

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### **PURPOSE**

The purpose of this inspection was to identify vulnerabilities in Medicare reimbursement for transcutaneous electrical nerve stimulation devices.

### **BACKGROUND**

When senior citizens get together, the talk frequently turns to the subject of pain, particularly chronic pain. Many different therapies have been tried for relieving chronic pain with varying degrees of success. A relatively new modality is a transcutaneous electrical nerve stimulation device, hereafter referred to as TENS.

The TENS is a low-voltage electrical impulse generator used as a non-pharmacological pain-control device. It usually looks like a portable transistor radio and can be attached to one's belt. Properly trained, patients are able to use this device as they go about their daily activities. There are multiple brands and models on the market, each slightly different but all having wires leading to either two or four electrodes. The electrodes are placed on the patient's body at positions selected by a physician or physical therapist based on various factors such as the anatomical location of peripheral nerves and/or the area of greatest pain. However, an element of trial and error is always present when determining placement. After the electrodes are placed with conducting jelly between them and the patient's skin, the controls are set, the unit is turned on, and a pulsating current passes through the area providing a mild-to-moderate stimulation. Some practitioners prefer low frequency/high intensity stimulation while others favor high frequency/low intensity application. The literature and clinicians both report variations in treatment time, ranging from 15 or 20 minutes daily to use throughout the day. They also stress the importance of evaluating patients.

Exactly how relief is achieved is not fully known, but there are two prevalent theories: one, the Gate Control Theory, suggests that the pulsating current overloads the nerve circuitry and blocks pain signals to the brain; another theory says that electrical stimulation causes the brain to react by releasing natural pain-suppressing substances called enkephelins and endorphins.

A literature review indicates that TENS does not cure a disease and does not work in all cases, but may give symptomatic relief of pain. Most clinicians agree that TENS applied properly can be effective, regardless of the brand or model, although one model may be more effective for a particular patient than another. However, in untrained hands TENS is not an effective or valuable modality. Although some clinicians report as much as a 90 percent success rate with carefully selected patients, most report about a 40-50 percent success rate.

## ***Medicare Coverage***

Medicare reimburses for both long-term use of TENS when they provide significant therapeutic benefit to patients with chronic pain and for short-term use for post-operative pain. When used for the treatment of acute post-operative pain, TENS are covered as supplies. The TENS are covered, however, as prosthetic devices when used for the treatment of chronic intractable pain (MCM Chapter II-Coverage Issues Appendix, Section 65-8 A1).

Medicare coverage guidelines require that, when used for the treatment of chronic intractable pain, TENS must be used by the patient on a trial basis and its effectiveness monitored by the physician or physical therapist. Section 35-46 of the same appendix addresses the use of the trial period to determine the patient's suitability for electrical nerve stimulation therapy:

*...It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally the physician or physical therapist should be able to determine whether the patient is likely to derive significant therapeutic benefit from continuous use of a TENS within a trial period of one month; in a few cases this determination may take longer to make...when the physician or physical therapist advises the patient to rent the TENS during the trial period program payment may be made.*

Based on the Omnibus Budget Reconciliation Act (OBRA) of 1987, the rental period for TENS was increased (effective January 1, 1989) to a period of not more than 2 months. If the item is then determined to be appropriate, it is reimbursed as routinely purchased equipment.

The OBRA 1987 also requires payment to be made for certain equipment such as TENS only if the physician has communicated a written order for the equipment prior to delivery. This requirement is designed to curtail some aggressive marketing strategies.

Home use of TENS by patients is discussed in Section 35-48 of the appendix:

*A patient can be taught how to employ the stimulator, once this is done, can use it safely and effectively without direct physician supervision....Once it is determined that electrical stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that the patient will employ the TENS on a continual basis in his home.*

The most appropriate placement of the electrodes, as well as the intensity and frequency of the current, is established by the physician or physical therapist after an evaluation period of about 1 month. The device may be reimbursed on a rental basis during this assessment period. After the physician or physical therapist is satisfied that the unit performs a therapeutic purpose, the beneficiary must purchase it. The medical necessity for the services furnished beyond the first month must always be documented. Medical policy guidelines regarding medical necessity are left up to each carrier to determine. Medicare carriers are responsible to see that coverage requirements are met before approving payment.

Medicare also reimburses for replacement electrodes, gel and batteries when necessary for the continuing use of TENS for the relief of chronic pain (MCM Section 2130).

### ***Reimbursement***

Claims submitted by suppliers under assignment are paid at 80 percent of the allowable charge recognized by Medicare. The beneficiary is then responsible for paying the 20 percent coinsurance to the supplier unless it is a hardship. The supplier is obligated to make a reasonable effort to collect the coinsurance. Suppliers who do not accept assignment can charge the beneficiary the difference between their total charge and the amount Medicare allows. The HCFA reports a total of \$12,802,927 in allowed Medicare charges for TENS in 1985, a 55 percent increase in 1986 to \$20,381,751, and a 97 percent increase in 1987 to \$40,111,359. (One carrier had an 832 percent increase in allowed charges from 1986 to 1987: \$1,580,524 to \$14,729,627.) The allowed TENS rental charges for the sample claims ranged from \$50 to \$101 a month with an average of \$89 a month while the allowed purchase charges ranged from \$446 to \$640 per unit with an average of \$480 per unit depending on the carrier service area.

### ***OIG Concerns***

The Office of Inspector General (OIG) has had a number of concerns about Medicare's reimbursement for TENS. A Medicare Fraud Alert was issued in July 1988 reporting on aggressive selling techniques by suppliers of TENS. These included door-to-door solicitation, sales presentations to groups of senior citizens and the use of physicians travelling with sales agents to sign the supplier-prepared authorization forms without requiring an evaluation period. There have also been complaints from beneficiaries who never received the units for which Medicare was billed.

### **ISSUES**

- To what extent are carriers reimbursing for TENS claims which do not meet Medicare coverage guidelines?
- How useful are Medicare beneficiaries actually finding TENS in alleviating pain?

### **METHODOLOGY**

This inspection assessed the effectiveness of HCFA policy and guidelines, as well as carrier implementation of them, in assuring appropriate Medicare reimbursement. It also examined Medicare beneficiaries' perceptions of the usefulness of TENS in alleviating pain. Members of the inspection team included a physical therapist and a registered nurse.

A 0.4 percent sample of 210 cases was selected at random from beneficiaries who had Medicare claims reimbursed for TENS in 1986. Sixty were dropped because the beneficiary was ei-

ther deceased or could not be located. This selection was made from 1986 BMAD data for both the rental and purchase of two- and four-lead TENS.

Telephone discussions were held with 126 of the remaining 150 sample beneficiaries. (The remaining 24 could not be reached by telephone or mail.) The 126 were first asked to verify they had received the TENS. They were also asked their impressions as to its effectiveness in relieving their pain (whether acute post-surgical or chronic), their experience with the clinician's evaluation, their perceptions of the marketing practices of suppliers, and other pertinent information.

Claims and supporting documents were requested from the 26 Medicare carriers to whom the 150 sample beneficiary claims were submitted and these were reviewed to see whether a trial period was documented.

A subsample of 30 physicians was selected from those authorizing TENS for the 126 beneficiaries contacted: telephone discussions were held with 26 of them to gain perceptions regarding their patient's use of TENS. The subsample included physicians of different specialties from different parts of the country. In addition, several physical therapists with expertise in TENS were contacted by telephone to gain perspectives on the above issues.

Carrier policy documents were collected from the 26 Medicare carriers to whom sample beneficiary claims were submitted to determine their coverage policies relating to TENS. Lastly, 48 State Medicaid programs and the Veterans Administration provided information regarding their reimbursement of TENS.

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## FINDINGS

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### ***One-third Of The Claims For Beneficiaries Contacted Were Inappropriately Reimbursed***

Medicare carriers should not have paid for 33 percent (41 of 126) of the TENS because they were either possibly fraudulent or they failed to meet the Medicare coverage requirements for a trial period, resulting in an estimated loss of \$4,394,500 to Medicare.

- *Nine percent of claims for the beneficiaries contacted are possibly fraudulent.* Eleven beneficiaries denied ever having a TENS. Many added they did not know what a TENS was and certainly had never tried one. These questionable claims, representing seven suppliers nationwide, include both rentals and purchases. Almost all had what appeared to be appropriate signatures and necessary authorization forms. (These cases have been referred to the OIG's Office of Investigations.)
  
- *Twenty-four percent of the beneficiaries contacted did not have the required trial period of at least 1 month.* The MCM requirement for a trial period (MCM Section 30-46) was not met in 30 cases. Typically, in many of these cases, after a TENS had been recommended, a supplier representative would bring the device to the patient's home so the patient could try it; a purchase would then immediately take place without the required trial period. One beneficiary was surprised when the TENS arrived because she had never even heard of it, was never shown how to use it and was afraid to try it. Eight of the 30 beneficiaries returned their TENS to the supplier in spite of the fact that Medicare had reimbursed for it and thus it belonged to them.
  
- *Carrier procedures to enforce trial period need strengthening.* Based on analysis of the 85 purchase claims, the following was noted: although three-quarters of the supporting documentation mentioned a trial period, only half of those had any information to support the fact that a successful trial period had taken place. A review of the carriers' policies and procedures indicated that they all did require such documentation but apparently did not enforce this requirement on an ongoing basis. Some carriers appear to routinely reimburse for the purchase of a TENS after a month's rental without requiring any further information. An additional carrier review weakness is revealed by the fact that 39 percent of the authorization forms were dated after the date of delivery. (OBRA 1987 prohibits payment unless the supplier receives a written order prior to the delivery of the device to the patient.)
  
- *More education of medical community about TENS needed.* Only half of the physicians contacted were aware of TENS guidelines. In addition only half of the Medicare carriers had sent educational information about TENS coverage to physicians and suppliers.

- *Other payors take different approach in approving TENS.* State Medicaid agencies are not required to cover TENS but the majority do. Almost all require prior approval, meaning that a claim must be submitted with documentation of need and effectiveness prior to reimbursement. A few States require that only physicians in certain specialties can authorize TENS. Some States require documentation of patient evaluation during the trial period before the purchase is to be considered. This may include a description of the patient's emotional status and capacity to use a TENS effectively. Some States require a specific TENS form including questions relating to diagnosis, date of onset, duration of medical necessity, treatment plan, and prognosis.

The Veteran's Administration (VA) also uses a prior approval system and requires evaluation during a trial period with follow-up visits by a clinician after the device is procured. The TENS are obtained from contracted suppliers who deal directly with the VA rather than with the patient. Devices are returned to the VA when they are no longer useful and are refurbished if cost effective.

### ***Most Purchased Tens Units Found Helpful; Trial Period Plays Major Role In Assuring Appropriate Use***

*"I really enjoy the relief it gives me because I lived with the agony of back pain for so many years." (a TENS patient)*

- *Nearly 80 percent (67 of 85) of beneficiaries who purchased TENS found it beneficial.* The majority had low-back pain and/or arthritis and had experienced pain for a number of years. Most had taken pain medication with varying results. The duration and frequency of their use differed considerably from leaving it on all day to using it for a few minutes several times a day. Most used four electrodes and placed them wherever they had pain. Some used the TENS on different parts of the body at different times, depending on where their pain was. Many said that they moved the electrodes a bit each time they applied them, a practice which clinicians say is advisable to prevent skin irritation. Most also changed the intensity to a point where it was helpful; some said that point varied depending on the battery strength. Some (9 of 85) had actually used it successfully for acute post-surgical pain, but continued its use for chronic pain.
- *Greater role of medical professionals with TENS helps to assure most appropriate use.* Eighty-four percent (58 of 69) of beneficiaries who had their TENS recommended by a medical practitioner found it helpful, while only 56 percent (9 of 16) of those who did not have it so recommended found it helpful. The remaining 16 beneficiaries became aware of the TENS from TV ads, senior citizens centers, friends, or relatives.
- *Only one-third of the patients reported having follow-up care with their medical practitioner.* Although there are no Medicare guidelines requiring follow-up for users of TENS, many clinicians contacted encouraged it to ensure the most worthwhile use of the device. They believe that following up to ascertain whether the TENS is working

properly and continuing to relieve pain serves a positive role. The data indicate that follow-up does not take place in the majority of cases. However, 17 percent of those beneficiaries that did not find TENS helpful had follow-up after purchase; in contrast, 39 percent of those helped by TENS had such follow-up which supports the helpfulness of keeping in touch with the patient even after the trial period.

- *Use of the required trial period is critically important in assuring the most effective use of TENS.* Of the 85 beneficiaries who purchased a TENS, 55 had the benefit of a trial period. Our analysis reveals that virtually all of these beneficiaries with a trial period (53 of 55) found the TENS helpful. In contrast, only 47 percent of those who purchased without a trial period (14 of 30) were benefitted. Clinicians also agreed that a trial period that teaches the patient how to best apply and operate the TENS and allows evaluation of the device's usefulness is essential. Although clinicians suggest trying several different units for best results, almost all beneficiaries only tried one.
- *Beneficiaries' rental experience supports value of trial period.* Eighty percent of those who rented but did not purchase the TENS (24 of 30) found it was not helpful during the 1 month's trial period and returned it to the supplier. These 24 beneficiaries were thus given the opportunity to try the TENS before the clinician reached a decision as to its purchase. By determining that it was not helpful, the trial period served to avoid inappropriate reimbursement of the TENS.

Within this group of 30 beneficiaries who rented but did not eventually purchase, 6 experienced some pain relief while using the TENS. However, they decided not to purchase the TENS after their trial period (1 month rental) for a variety of reasons. One individual died, one had the TENS picked up by the supplier, two no longer experienced pain and two simply disliked using the device. Of the 30 beneficiaries who only rented a TENS, almost all had the device explained to them and also received written instructions on its use.

- *Physicians view TENS favorably.* Most of the 26 physicians contacted felt very positively about TENS. A typical comment was: "TENS units are effective if used properly." This was echoed by many who thought TENS to be an effective treatment for selected patients and preferable to prescribing drugs. Two-thirds of the physicians said it was their idea to prescribe a TENS and almost all denied any pressure from patients, families or suppliers to prescribe one. Sixty-five percent (17 of 26) of the physicians said the TENS was helpful in relieving pain for the patient in the sample. Although the majority of physicians had an ongoing relationship with the patient, one quarter saw the patient only when the TENS was ordered. Most (58 percent) said the patient was seen during the trial period by either themselves or a physical therapist to try the TENS for its effectiveness and teach the patient to use it.

Several physicians suggested that TENS prescribing be limited to certain specialists with expertise in the area. Other physicians mentioned that they refer their patients who are candidates for a TENS to a physical therapist to evaluate the device for its effectiveness and will write a prescription only if there is a positive result.

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## RECOMMENDATIONS

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The following recommendations were presented to HCFA in the draft report. To reduce inappropriate payments for TENS, HCFA should:

***Evaluate And Strengthen, As Needed, Carrier Implementation Of Medicare And Obra 1987 Requirements To:***

- Ensure a trial period prior to purchasing TENS by assuring that a certification form is submitted by the physician which indicates the training of the patient in the use of the device and a certification of its effectiveness for the patient's pain relief.
- Prohibit payment unless the supplier receives a written order from the physician prior to the delivery of the device to the patient.

*HCFA Comments:* Medicare Carriers Manual Transmittal 1284, effective for services rendered on or after January 1, 1989, requires that suppliers have a written physician's order in hand prior to delivery of a TENS device to a Medicare patient. If the written order is not in the supplier's hand prior to delivery, payment may never be made for that item even if a written order is subsequently furnished by a physician. The item, however, may be provided by another supplier to the same patient and, if the appropriate requirements are met, payment may be made under the program.

A draft transmittal which includes a new TENS physician certification form is also in HCFA's clearance process. The new form contains questions regarding patient training, treatment, and expected improvement with a TENS. This certification, required for every beneficiary purchase order for a TENS, will show the results of his/her trial period.

***Publicize Medicare Coverage Requirements To The Medical Community.***

*HCFA Comments:* Medicare Carriers Manual Transmittal 1299, released in April 1989, requires each carrier to notify the State medical society and any applicable specialty societies of the medical guidelines to be used in adjudicating TENS claims.

***Add Tens To The MCM Section 7512E Postpayment Alert List Which Suggests Areas Of Detected Abuse That Should Be Considered When Selecting Cases For The Current Year's Postpayment Review.***

*HCFA Comments:* Medicare Carriers Manual Transmittal 1299 (mentioned above) goes beyond the OIG recommendation that TENS be considered during postpayment reviews. Carriers are now required to manually review each TENS claim on a prepayment basis. We believe that a 100 percent prepayment review of TENS claims is more effective than a postpayment re-

view conducted on a sample basis. Carriers, however, are not precluded from conducting postpayment reviews. They may conduct postpayment reviews of TENS claims to identify the existence of program abuse or fraudulent situations.

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## APPENDIX I

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### METHODOLOGY

The data for this inspection was pulled from the 1986 BMAD data and represents a 0.4 percent sample of all records for that year for whom TENS claims were paid. There were 310 records found representing 210 beneficiaries. According to the analysis, 41 of these individuals had inappropriate payments totaling \$17,578 in allowed charges. This is an average of \$83.70 per sample beneficiary (standard error of 13.69). The total number of beneficiaries in 1986 with bills for TENS is estimated to be 52,500. Based on this universe, it is estimated that there were \$4,394,500 (standard error of \$718,725) in inappropriate allowed payments in 1986. The 90 percent confidence interval of this estimate has a lower cutoff point of \$3,212,197 and an upper cutoff point of \$5,576,803. The overall precision of this estimate is 26.9 percent.

Cost savings can also be projected more conservatively based on the 26 beneficiaries who either did not receive the TENS or did not have a trial period and also did not benefit from the TENS. These 26 beneficiaries had overpayments totaling \$10,743 in allowed charges. This is an average of \$51.16 per sample beneficiary (standard error of 10.868). Cost savings is estimated to be \$2,685,750 (standard error of \$570,570) in 1986. The 90 percent confidence interval of this estimate has a lower cutoff point of \$1,747,162 and a upper cutoff point of \$3,624,338. The overall precision of this estimate is 34.9 percent.

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## APPENDIX II

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The HCFA's comments on our specific recommendations are included in the report's recommendations section. The HCFA's general comments and our responses follow.

### HCFA GENERAL COMMENTS

We do not agree with the OIG's finding that "one-third of the claims for beneficiaries contacted were inappropriately reimbursed." This finding was based on 11 claims of suspected fraud (the beneficiaries denied receipt of a TENS device) and 30 claims where beneficiaries reported that they had no trial period. Improved claims processing requirements would not have resulted in the denial of the potentially fraudulent claims found by the OIG. Therefore, these claims should not be included in the methodology for computing the overpayment. Also, payment for the purchase of TENS units without a trial period is not necessarily indicative of an overpayment or unnecessary program reimbursement. A great percentage of these devices would have been purchased had a trial period been given. Therefore, the existence of inappropriate reimbursement has not been demonstrated. Based on the above comments regarding the OIG's findings, we do not agree that over \$4 million in appropriate payments were made in 1986.

Further, we are unable to reconcile the statistics quoted in paragraph 3, page ii in the Executive Summary, with similar data in the last two paragraphs of this same page. Paragraph 3 states that three-fourths of the 85 beneficiaries receiving a TENS had a trial period, and of these beneficiaries one-half had a successful trial period. These numbers disagree with the last paragraph which states that 53 beneficiaries having a trial period "found the TENS helpful." This difference should either be explained or the third paragraph changed to coincide with the data in the last paragraph.

### OIG RESPONSE

We respond to HCFA's general comments concerning the issue of reimbursement and statistical discrepancies in the following manner:

- HCFA defines inappropriate reimbursement differently than we do. We believe that all payments that are not allowable under law or regulations are inappropriate whether or not contractors are able to identify the problems. Therefore we continue to support finding number one. In the 11 instances where the beneficiaries denied receipt of the TENS, the claims were inappropriately reimbursed.

Relative to the 30 beneficiaries who did not have a trial period, Medicare coverage guidelines require that, when used for the treatment of chronic intractable pain, TENS is used by the patient on a trial basis and its effectiveness is monitored by the physician or physical therapist. This is an important safeguard for preventing inappropriate reimburse-

sement of the TENS. If a TENS unit is purchased without the required trial period and the beneficiary finds the device helpful, the usefulness of the TENS is incidental to the fact that the carrier should not have paid for it without determining that it had been tried and was found helpful in alleviating pain.

- The statistics quoted in paragraph 3 of page ii in the Executive Summary were derived from information provided from the supporting documentation submitted with the 85 sample purchase claims. The figures used in the last paragraph of the same page, however, were derived from actual interviews with the beneficiaries themselves. Therefore, the difference in figures can be explained by the source of data used.