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OFFICE OF INSPECTOR GENERAL
OFFICE OF AUDIT SERVICES
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JAN 4 2006

Report Number: A-03-04-00001

Mr. Dennis Conroy, SPHR
Raytel Medical Corporation
Director, Human Resources/Compliance Officer
7 Waterside Crossing
Windsor, Connecticut 06095-0727

Dear Mr. Conroy:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG) final report entitled "Review of Trans-telephonic Cardiac Monitoring Services Provided By Raytel Cardiac Services, Inc. for Calendar Year 2002." The Office of Counsel to the Inspector General requested this review. A copy of this report will be forwarded to the action official noted below for review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official named below. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C § 552, as amended by Public Law 104-231, Office of Inspector General reports are made available to members of the press and general public to the extent the information contained therein is not subject to exemptions in the Act which the Department chooses to exercise (See 45 CFR part 45).

If you have any questions or comments about this report, please do not hesitate to contact me, or your staff may contact Eugene Berti, audit manager, at (215) 861-4474, or through e-mail at Gene.Berti@oig.hhs.gov. Please refer to report number A-03-04-00001 in all correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen Virbitsky", with a long horizontal flourish extending to the right.

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosures – as stated

Direct Reply to HHS Action Official:

Charlotte S. Yeh, MD, Regional Administrator
Centers for Medicare & Medicaid Services – Region I
U.S. Department of Health and Human Services
JFK Federal Building, Room 2325
Boston, MA 02203

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF TRANS-TELEPHONIC
CARDIAC MONITORING SERVICES
PROVIDED BY
RAYTEL CARDIAC SERVICES, INC.
FOR CALENDAR YEAR 2002**



**Daniel R. Levinson
Inspector General**

**JANUARY 2006
A-03-04-00001**

Office of Inspector General

<http://oig.hhs.gov>

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In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information contained therein is not subject to exemptions in the act. (See 45 CFR Part 5.)

OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.



EXECUTIVE SUMMARY

BACKGROUND

General

Medicare, established by Title XVIII of the Social Security Act (the Act), as amended, is a national health insurance program for people age 65 or older, some people under age 65 with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Raytel Cardiac Services, Inc.

Raytel is a major provider of cardiac diagnostic services, including remote trans-telephonic pacemaker monitoring, in the United States. Trans-telephonic pacemaker monitoring tests implanted pacemakers remotely, using a standard telephone at the offsite location.

Settlement Agreement Between Raytel and the Federal Government

In October 2001, the United States Attorney's Office for the District of Connecticut and the Office of Inspector General (OIG) entered into a settlement agreement (settlement) with Raytel. As part of the settlement, OIG and Raytel also entered into a comprehensive 5-year corporate integrity agreement (CIA) beginning October 2001.

OBJECTIVE

The objective of our review was to determine whether Medicare payments to Raytel for trans-telephonic cardiac monitoring services were allowable and made in accordance with applicable Federal regulations and guidelines.

SUMMARY OF FINDINGS

Raytel received improper payments totaling \$12,315 in calendar year 2002. These improper payments included:

- \$11,666 in duplicate payments for 374 services reimbursed under both a local procedure code and a Common Procedural Terminology (CPT) code, and
- \$649 for 26 services that did not comply with Medicare requirements.

We did not question Medicare reimbursements for the services in our sample performed by Raytel technicians who lacked certification or licenses from a State or national accreditation body. The States in which Raytel operated did not require licenses for pacemaker technicians, and the carrier did not issue guidelines for certification until after our audit period. However, Raytel stated that Charter Oak State College reviewed and

approved its pacemaker-training program and its pacemaker technicians and technologists have received college credit for completing the training. Raytel also stated that its Board certified cardiologist and supervising physicians have certified the training program.

RECOMMENDATIONS

We recommend that Raytel:

1. refund to the Medicare carrier \$12,315 for duplicate payments received for billing the same service using both a local procedure code and a CPT code, and for services that did not comply with Federal regulations or Medicare guidelines;
2. examine the errors identified in our review and develop additional controls and training to ensure that these types of errors do not occur in the future; and
3. work with the carrier to ensure that its pacemaker-training program is in compliance with the carrier guidelines for trans-telephonic monitoring personnel.

RAYTEL COMMENTS

In a response dated September 22, 2005, Raytel did not concur with our audit findings as stated in the draft report. Raytel agreed that it received a duplicate payment of \$11,599, but stated that it properly billed for these services and refunded the unsolicited duplicate payments immediately upon discovering them. Two of the services were not duplicates. Raytel states that its records met the documentation requirements for the “not documented” services. It agreed that it billed in excess of the frequency guidelines for five services and that it should only have billed for the technical component on two of the three questioned claims, and refunded the payment for them.

Raytel’s response is included as an Appendix to the report.

OFFICE OF INSPECTOR GENERAL RESPONSE

The Office of Inspector General acknowledges that, as a result of its audit, Raytel refunded \$11,788 of the \$12,315 it received in duplicate payments and payments for services improperly billed.

We do not agree that 16 services met documentation requirements. The Program Safeguard Contractor determined that the services were not documented. Raytel should work with the Carrier to resolve these findings.

As stated in our report, the carrier did not issue guidelines for certification of technicians until after our audit period. Therefore, we did not question the Medicare reimbursement for the services in our sample. We acknowledge that Charter Oak State College gave college credit to Raytel technicians and technologists who complete the training program,

but we believe that Raytel should work with the carrier to ensure that its pacemaker-training program is in compliance with the new guidelines for trans-telephonic monitoring personnel. We have revised our report, where necessary, to take into account Raytel's comments.

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INTRODUCTION

BACKGROUND

General

Medicare, established by Title XVIII of the Social Security Act (the Act), as amended, is a national health insurance program for people age 65 or older, some people under age 65 with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Raytel Cardiac Services, Inc.

Raytel is a major provider of cardiac diagnostic services, including remote trans-telephonic pacemaker monitoring, in the United States. Trans-telephonic pacemaker monitoring tests implanted pacemakers remotely, using a standard telephone at the offsite location.

Settlement Agreement Between Raytel and the Federal Government

In October 2001, the United States Attorney's Office for the District of Connecticut and the Office of Inspector General (OIG) entered into a settlement agreement (settlement) with Raytel. As part of the settlement, OIG and Raytel also entered into a comprehensive 5-year corporate integrity agreement (CIA) beginning October 2001.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our review was to determine whether Medicare payments to Raytel for trans-telephonic cardiac monitoring services were allowable and made in accordance with applicable Federal regulations and guidelines.

Scope

We reviewed Medicare payments made to Raytel for trans-telephonic monitoring services provided during calendar year (CY) 2002. Fieldwork was performed at Raytel's offices in Windsor, CT. A program safeguard contractor (PSC) conducted the medical review.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, CMS guidelines, and carrier local medical review policies;
- reviewed the settlement agreement and CIA;

- extracted from CMS's National Claims History File all trans-telephonic cardiac monitoring services paid to Raytel in CY 2002;
- reviewed a random statistical sample of 594 trans-telephonic cardiac monitoring services totaling \$17,801 provided to 100 Medicare beneficiaries during CY 2002;
- compared all trans-telephonic cardiac monitoring claims in CY 2002 reimbursed under local carrier codes against trans-telephonic cardiac monitoring claims reimbursed under Common Procedure Terminology (CPT) codes;
- gained an understanding of Raytel's internal controls and their procedures for performing, and submitting claims for trans-telephonic cardiac monitoring services;
- obtained medical records and other documentation from Raytel and the ordering physicians for each beneficiary in the sample;
- reviewed PSC's medical review results; and
- reviewed the licensing or credentialing status for each technician who performed a sampled service.

We did not review the overall internal control structure of Raytel or of the Medicare program because the objective of our review was accomplished through substantive testing.

Our audit was conducted in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

Raytel received improper payments totaling \$12,315 in CY 2002. These improper payments included:

- \$11,666 in duplicate payments for 374 services reimbursed under both local procedure codes and CPT codes, and
- \$649 for 26 services that did not comply with Medicare requirements.

We did not question Medicare reimbursements for the services in our sample performed by Raytel technicians who lacked certification or licenses from a State or national accreditation body. The States in which Raytel operated did not require licenses for pacemaker technicians, and the carrier did not issue guidelines for certification until after our audit period. However, Raytel stated that Charter Oak State College reviewed and approved its pacemaker-training program and its pacemaker technicians and technologists have received college credit for completing the training. Raytel also stated that its Board certified cardiologist and supervising physicians have certified the training program.

DUPLICATE PAYMENTS

Raytel was improperly paid \$11,666 for 374 services billed twice to the carrier – once under local procedure codes and once under CPT codes. Prior to January 1, 2003, the carrier required providers to submit claims for trans-telephonic cardiac monitoring services using local procedure codes. These local codes started with “W96” and were followed by two numbers. When the carrier discontinued using local codes in January 2003, Raytel changed its billing system to bill using CPT codes. Any unpaid claims submitted in 2002 under local codes were resubmitted using the applicable CPT code (93733 or 93736). The carrier paid both claims, which resulted in duplicate payments for 374 services.

SERVICES NOT IN COMPLIANCE WITH FEDERAL REGULATIONS OR MEDICARE GUIDELINES

Raytel was reimbursed \$649 for 26 services that were:

Not Documented

Raytel was paid \$470 for 16 services that did not comply with the documentation requirements set forth in Section 50-1 of the Medicare Coverage Issues Manual (MCIM). Raytel did not document the three minimum 30 seconds of readable electrocardiogram strip as required. The third required monitoring strip was not found with the report or was not readable.

Billed In Excess Of Frequency Guidelines

Raytel was paid \$150 for five services that exceeded the frequency guidelines set forth in the Section 50-1 MCIM or the ordering physician’s requested monitoring schedule. The errors occurred because Raytel entered an incorrect pacemaker implant date (one service) or the wrong frequency guideline (four services) into its system.

Not Performed

Raytel was paid \$23 for both the technical and professional component for three services when only the technical component was performed by Raytel.

Reimbursed at the Wrong Rate by the Carrier

Raytel was paid \$6 for two services that were incorrectly reimbursed by the carrier.

RAYTEL’S TECHNICIAN TRAINING PROGRAM

42 CFR § 410.33 (c) states that any non-physician personnel used to perform tests must demonstrate the basic qualifications to perform the tests in question, and have training and proficiency as evidenced by licensure or certification by the appropriate State health

or education department. In the absence of a State licensing board, an appropriate national credentialing body must certify the technician. The provider must maintain documentation that these requirements are met.

Raytel performed cardiac monitoring services in three states: Connecticut, New York, and New Jersey. These states did not require technicians to be licensed. Federal regulations, therefore, require that a national association credential the technicians.

Section 5.4(B) of the Medicare Program Integrity Manual, however, states that for trans-telephonic and electronic monitoring services ...“We currently do not have specific certification standards for their technicians; technician credentialing requirements for them are at carrier discretion.”

During the audit period the carrier did not have certification standards or guidelines in place. However, in March 1998 Charter Oak State College, Connecticut’s external degree program, began offering college credit for Raytel’s employees completing the pacemaker-training program. Charter Oak reevaluated the program in February 2004. Raytel stated that its pacemaker technicians complete over 300 hours of comprehensive college level training in anatomy and physiology, ECG strip interpretation, and pacemaker functionality. Each of the three levels of training earns the employees three college credits towards an associate degree for a total of nine college credits. In a letter dated May 9, 2005, Charter Oak advised Raytel that transcripts have been mailed showing credit for pacemaker rhythm interpretation training for 96 Raytel employees.

Subsequent to our audit period, in December 2004, the carrier issued Medicare Guidelines for independent diagnostic testing facilities. The guidelines provided coverage requirements and the basic qualifications that non-physician personnel must demonstrate to perform diagnostic tests. For trans-telephonic pacemaker monitoring, the guidelines state that non-physician personnel must be certified by Cardiovascular Credentialing International as a certified cardio graphic technician, or must be a registered nurse or a paramedic.

RECOMMENDATIONS

We recommend that Raytel:

1. refund to the Medicare carrier \$12,315 for duplicate payments received for billing the same service using both a local procedure code and a CPT code, and for services that did not comply with Federal regulations or Medicare guidelines;
2. examine the errors identified in our review and develop additional controls and training to ensure that these types of errors do not occur in the future; and
3. work with the carrier to ensure that its pacemaker-training program is in compliance with the carrier guidelines for trans-telephonic monitoring personnel.

RAYTEL COMMENTS

In a response dated September 22, 2005, Raytel did not concur with our audit findings as stated in the draft report. Raytel agreed that it received a duplicate payment of \$11,599, but stated that it properly billed for these services and refunded the unsolicited duplicate payments immediately upon discovering them. Two of the services were not duplicates. Raytel stated that its records met the documentation requirements for the “not documented” services. It agreed that it billed in excess of the frequency guidelines for five services and that it should only have billed for the technical component on two of the three questioned claims, and refunded the payment for them. Raytel stated that Charter Oak State College provides college credits to technicians who complete the course. Raytel also stated that its Board certified cardiologist and supervising physicians have certified the training program.

Raytel’s response is included as an attachment to this report except for the accompanying schedules. These schedules contained the beneficiaries’ names and other identifying information.

OFFICE OF INSPECTOR GENERAL RESPONSE

The Office of Inspector General acknowledges that, as a result of its audit, Raytel refunded \$11,788 of the \$12,315 it received in duplicate payments and payments for services improperly billed. We do not agree that 16 services met documentation requirements. The PSC determined that the services were not documented. Raytel should work with the carrier to resolve these findings.

As stated in our report, the carrier did not issue guidelines for certification of technicians until after our audit period. Therefore, we did not question the Medicare reimbursement for the services in our sample. We acknowledge that Charter Oak State College offered college credit to Raytel technicians in the absence of Medicare guidelines. However, as stated in our report, the carrier has now issued guidelines that set for the requirements and the basic qualifications that non-physician personnel must demonstrate to perform diagnostic tests. For trans-telephonic pacemaker monitoring, the guidelines state that non-physician personnel must be certified by Cardiovascular Credentialing International as certified cardio graphic technicians, or must be registered nurses or a paramedic. We believe that Raytel should work with the carrier to determine whether its technicians are in compliance with the guideline.

APPENDIX

RAYTEL
CARDIAC SERVICES
The Leader in Remote Cardiac Monitoring
An SHL Telemedicine Company

September 22, 2005

Mr. Stephen Virbitsky
Regional Inspector General for Audit Services
105 S. Independence Mall West Suite 316
Philadelphia, PA 19106-3499

Via: Federal Express

Re: **Report Number: A-03-04-00001**

Dear Mr. Virbitsky:

We received the draft of the above report on July 29, 2005 (the "Draft Report") and thank you for granting us additional time to review this Draft Report and to submit our comments.

FINDING 1 – Duplicate Payments:

1. We do not concur with the stated Summary of "Finding 1" as stated in the Draft Report.
2. We disagree that Raytel received "improper" payments totaling \$11,666 for 374 services billed in calendar year 2002. There was a duplicate payment of \$11,598.92 made to Raytel by the carrier for 372 services properly performed and billed, however these duplicate payments were **immediately refunded** when discovered. The other 2 services in the original finding proved not to be duplicates. The duplicate payments were received unsolicited from the carrier because of the Carrier's confusion over its decision to change from local codes to CPT codes (see Schedule 1). Raytel billed for services properly, but did not detect the duplicate payment immediately because of the uniqueness of the circumstances that led to the carrier initiating the second payment and a Raytel system issue that did not eliminate the re-billing of open unpaid claims under the former local codes. We enclose as schedule 1 a check and transmittal letter to the carrier refunding this overpayment, which was made due to carrier error. Accordingly, we request that any finding on this issue refer to the carrier's error and to Raytel's refunding of the overpayment in the course of its own compliance efforts.

FINDING 2 – Services not in Compliance with Federal Regulations or Medicare Guidelines:

1. We do not concur with the stated Summary of "Finding 2" as stated in the Draft Report.

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2. The \$649 for a total of 26 services were categorized as being incorrectly billed for four reasons: (a) 16 services for \$470 were "not documented"; (b) 5 services for \$150 were "billed in excess of frequency guidelines"; (c) 3 services for \$23 were "not performed"; and (d) 2 services for \$6 were "reimbursed at the wrong rate by the carrier".

(a) Raytel reviewed charts for the "not documented" services noted above and believes in each case that documentation requirements were met, and services were performed. Raytel provided the following documentation for the OIG's review: (1) representative ECG strips for the requested patients; (2) diagnostic reports prepared for the prescribing physicians; (3) the original prescriptions; and (4) any annual prescription renewals. Information substantiating that Raytel complied with the Medicare coverage requirement, commonly referred to as the 30-30-30 rule, can be found by measuring the elapsed time using the grid on the ECG strip, where 5 large boxes of the grid equal 1 second. Attached to this letter as Schedule 2 is a summary of this information taken directly from the documentation referenced above which was reviewed by the OIG and re-reviewed for Raytel by a registered nurse with over 21 years of pacemaker monitoring experience and an advanced pacemaker monitoring technologist with over 26 years experience. Raytel's review clearly found that each of the services at issue was properly documented. The summary is in the form of a spreadsheet that shows the number of seconds of readable ECG strips taken during each mode of the test (demand, magnet and after-magnet). As can be seen from the summary, the Medicare requirements have been met in every case.

- (b) With regard to the five services that were allegedly billed in excess of the frequency guidelines, Raytel's review revealed the following:

(i) Date of Service 2/04/02 – This test was taken as the age of the pacemaker changed according to the testing frequency one month prior to the actual age of the pacemaker. This was an isolated incident as we have ascertained the problem and corrected going forward. RAYTEL has refunded the payment for this service (see schedule 3).

(ii) Date of Service 5/30/02 and 9/19/02 – This patient should have been tested every 12 weeks instead of every 8 weeks. RAYTEL had the Medicare Guideline frequency loaded in as Guideline I whereas it should have been Guideline II. This was a data entry error and has been corrected. RAYTEL has refunded the payment for this service (see schedule 4).

(iii) Date of Services 9/20/02 and 11/15/02 – This patient was enrolled with a specific schedule of "Every 8 Weeks" regardless of the age of the pacemaker. The two aforementioned tests were as a result of the patient being setup on Guideline I in error. This has since been corrected. RAYTEL has refunded the payments for these services (see schedule 5).

- (c) With regard to the three services alleged not to have been performed, Raytel pulled the "Full Disclosure" from our system in preparation for the OIG audit. A system generated report is not the original that includes the over-reading Physician signature. We went back to the patient' charts for the three services at issue and pulled all of the requested test reports and found that only one of the three claims at issue had the required physician signature and the other two had signatures missing for which we have made refunds (see schedule 6). There were originally 32 files questioned.
- (d) The two services reimbursed at the wrong rate by the carrier were underpayments made by the carrier for which we did not pursue the \$6.00 owed to Raytel. Again, this was a carrier error and was not to Raytel's benefit.

FINDING 3 – Technicians not Licensed or Credentialed:

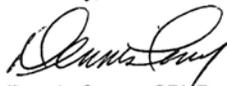
1. We do not concur with the stated Summary of "Finding 3" as stated in the Draft Report referenced above.
2. The statement that "almost all of Raytel's pacemaker technicians were not licensed or credentialed to perform trans-telephonic monitoring services, as required by Federal regulations" is incorrect. 42 CFR 410.33(c) states "In the absence of a state licensing board, the technician must be certified by an appropriate national credentialing body". In Raytel's case technicians are credited by Charter Oak Community College which is accredited by the Connecticut Board of Governors for Higher Education and the New England Association of Schools and Colleges and functions under the degree-granting authority of Connecticut's Board for State Academic Awards.
3. Each of Raytel's pacemaker technicians and technologists complete over 300 hours of comprehensive college level training in anatomy and physiology, ECG strip interpretation, and pacemaker functionality. Each part of the three levels of training earns the employees three college credits towards an associate degree for a total of nine college credits. Additionally, our Board Certified Cardiologist and Supervising Physicians have certified the training program (see letter dated November 20, 2003). We believe this training program is above any industry standard for pacemaker monitoring.
4. With regard to training and credentialing of trans-telephonic pacemaker technicians, it should also be noted that the only carrier recognized accrediting organization, CCI, does not have any training or credentialing program for pacemaker technicians (see attached email correspondence with CCI).
5. We asked for a chance to meet with your reviewers to see where differences existed. As yet, we have not been offered that opportunity.

We would like to reassure your office that Raytel has in place, system and procedure controls to detect errors such as the alleged errors referred to in the report. In fact, these systems and procedures worked and resulted in prompt refund of overpayments, except in the case of the carrier initiating a second payment. Retraining of personnel will correct this issue going forward.

We also kindly request your consideration to the matter of posting your report and our comments on the OIG – HHS web site, taking into consideration the nature of our comments and response with regard to "Finding 3", we strongly believe it would be inappropriate for your office to make this report available to the public prior to allowing us to meet with your representatives, in order to explain our comments and response in this matter. Raytel is servicing, annually, over 70,000 pacemaker patients, most of them Medicare beneficiaries, and over 10,000 physicians. Publishing your report with what we strongly believe to be an incorrect statement, that Raytel's pacemaker technicians are "...not licensed or credentialed..." may potentially cause our patients, as well as prescribing physicians, unnecessary and baseless concerns, and will cause damage to Raytel's impeccable high quality professional service. With that in mind, we request to schedule a meeting with you so that this matter will come under review again. At the very least, we ask that the full extent of Raytel's extensive training and credentialing program be described in the OIG report.

Thank you for your understanding and consideration.

Sincerely,



Dennis Conroy SPHR
Director, Human Resources/
Compliance Officer