RICK SNYDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
Christopher Seppanen
Executive Director

SHELLY EDGERTON
DIRECTOR

[redacted]

Date Mailed: December 22, 2016
MAHS Docket No.: 16-014891
Agency No.: [redacted]
[redacted]

**ADMINISTRATIVE LAW JUDGE: Steven Kibit**

## DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge (ALJ) pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.,* and upon the Petitioner's request for a hearing.

After due notice, a telephone hearing was held on December 8, 2016. Petitioner appeared and testified on his own behalf. [redacted], Appeals Review Officer, represented the Respondent, Department of Health and Human Services (DHHS or Department). [redacted] a registered nurse and analyst in the Department's Program Review Division, testified as a witness for the Department.

## ISSUE

Did the Department properly deny Petitioner's authorization request for a wearable cardioverter defibrillator?

## FINDINGS OF FACT

The Administrative Law Judge, based upon the competent, material and substantial evidence on the whole record, finds as material fact:

1. On or about September 1, 2016, the Department received an authorization request submitted on Petitioner's behalf and requesting a wearable cardioverter defibrillator for Petitioner. (Exhibit A, pages 11-28).

2. While identified as a prior authorization request, the request was actually for a retroactive approval for use of a wearable cardioverter defibrillator between June 17, 2016 and July 17, 2016. (Exhibit A, page 11).

3. During its review of the supporting documentation submitted along with the request, the Department determined that Petitioner only wore his wearable cardioverter defibrillator 67% of the time between June 18, 2016 and July 17, 2016. (Exhibit A, pages 13-14; Testimony of Department's witness).

4. On September 16, 2016, the Department sent Petitioner written notice that the authorization request was denied. (Exhibit A, pages 9-10).

5. Regarding the reason for the denial, the notice stated in part:

> The policy this denial is based on is Section 2.47, 1.10 of the Medical Supplier chapter of the Medicaid Provider Manual. Specifically:
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> - Wear-time data submitted shows the beneficiary wore the LifeVest approximately 67% from 06/18/2016-07/17/2016. This does not meet Medicaid policy specifications of 92% and above.

6. On October 18, 2016, the Michigan Administrative Hearing System (MAHS) received the request for hearing filed in this matter regarding that denial. (Exhibit A, page 6).

7. In that request, Petitioner stated that he was hospitalized between June 26, 2016 and July 3, 2016 and could not wear his wearable cardioverter defibrillator during that hospitalization. (Exhibit A, page 6).

8. Following receipt of the request for hearing, the Department reviewed the supporting documentation submitted along with Petitioner's request and determined that, even after excluding the dates Petitioner was hospitalized, the data submitted only demonstrated that Petitioner wore his wearable cardioverter defibrillator 82% of the time, which still did not meet the criteria for approval. (Exhibit A, pages 13-14; Testimony of Department's witness).

## CONCLUSIONS OF LAW

The Medical Assistance Program is established pursuant to Title XIX of the Social Security Act and is implemented by Title 42 of the Code of Federal Regulations (CFR). It is administered in accordance with state statutes, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

Medicaid covered benefits are addressed for the practitioners and beneficiaries in the Medicaid Provider Manual (MPM). Regarding the specific request in this case, the applicable version of the MPM states:

**2.47 WEARABLE CARDIOVERTER-DEFIBRILLATORS**

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| **Definition** | A wearable cardioverter-defibrillator (WCD) is an external device intended to perform the same tasks as an implantable cardioverter-defibrillator (ICD) without requiring an invasive procedure. It is considered a bridge to permanent ICD placement.<br><br>The WCD consists of a vest, worn continuously underneath clothing, and contains cardiac monitoring electrodes that deliver a counter shock. The vest is connected to a monitor with a battery pack and alarm module that interprets the cardiac rhythm and determines when a counter shock is necessary. An alarm module alerts the patient to certain conditions by lights or voice messages. |
| **Standards of Coverage** | The WCD may be considered medically necessary only as an interim treatment for patients at high risk of sudden cardiac arrest who:<br><br>▪ Have a left ventricular ejection fraction of 35% or less;<br><br>▪ Have a temporary contraindication to |

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| | receiving an ICD (i.e., a systemic infection) at the current time; and<br><br>▪ Have experienced a documented episode of ventricular fibrillation or sustained (lasting 30 seconds or longer) ventricular tachyarrhythmia that was not due to a transient or reversible cause and did not occur during the first 48 hours of an acute myocardial infarction; and<br><br>▪ Are tentatively scheduled for an ICD placement procedure based on one of the following:<br><br>➢ Received treatment with the goal of an ICD placement and have been<br><br>➢ scheduled for the ICD placement within three months; or<br><br>Had an ICD removed and have been scheduled for placement of another ICD once the contraindication has been treated.<br>WCDs will not be covered for investigational procedures or patient preference. |
| **Documentation** | Documentation must include the following and be made available upon request unless otherwise |

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| | noted in the Standards of Coverage and PA Requirements sections of this policy:<br><br>▪ Diagnosis/medical condition related to the need for the item.<br><br>▪ Specific item(s) required.<br><br>▪ Medical reason why receiving an ICD is not currently plausible.<br><br>▪ Current treatment plan and updated recommendations.<br><br>▪ Tentative scheduled date for ICD placement and/or date other ICD removed. |
| **PA Requirements** | Food and Drug Administration (FDA)-registered WCDs are covered under the Medicaid and CSHCS programs with prior authorization (PA). Requests for PA (form MSA-1653-B) may only be submitted by the beneficiary's managing cardiologist and must include a current treatment plan and updated recommendations.<br><br>PAs are approved for 30 days at a time for a maximum of three months.<br><br>For continued medical need beyond 30 days, a new PA request must be submitted documenting all of the |

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| | following:<br><br>▪ The beneficiary's response to and continued need for the WCD;<br><br>▪ The anticipated date of the ICD procedure; and<br><br>▪ Documentation of the beneficiary's compliance with wearing the WCD. The compliance report should demonstrate a compliance rate of at least 92% for the previous 30-day period.<br><br>Requests for continued PA beyond the maximum of three months will be considered on a case-by-case basis. |
| **Payment Rules** | WCDs are rental only items. The rental fee includes the vest, monitoring electrodes, therapy electrodes and batteries. The batteries, garments and electrodes may be replaced due to normal use and wear of the WCD and require PA. |

*MPM, July 1, 2016 version*
*Medical Supplier Chapter, pages 91-92*

Here, the Department denied Petitioner's request for a wearable cardioverter defibrillator pursuant to the above policy. Specifically, the Department's witness testified in support of the decision and stated that, while the above policy requires, among other things, that a beneficiary had complied with wearing the wearable cardioverter defibrillator at a rate of at least 92% for the previous thirty day period, the review of Petitioner's documentation demonstrated that he only wore his 67% of the time during the requested time period. She also testified that, after receiving the request for hearing and learning of Petitioner's claim that he was hospitalized during the

requested time period, she re-reviewed his request; excluded the days Petitioner said he was hospitalized from her analysis; and determined that Petitioner's compliance rate was still only 82%, which is insufficient to meet the above requirements.

In response, Petitioner testified regarding his hospitalization and why it was too difficult for him to wear his wearable cardioverter defibrillator while hospitalized. He further testified that the condition that led him to a hospitalization also affected the way he felt both before entering and after leaving the hospital, and that the way he felt made it difficult to wear the wearable cardioverter defibrillator as well.

Petitioner bears the burden of proving by a preponderance of the evidence that the Department erred in denying his authorization request.

Given the record and applicable policies in this case, Petitioner has failed to meet that burden of proof and the Department's decision must therefore be affirmed. While the above policy only speaks to a prior authorization and Petitioner was seeking a retroactive authorization, the Department nonetheless considered his request and took into account the specific criteria that must be met in order for the continued use of a wearable cardioverter defibrillator to be approved, including a requirement that a beneficiary both provide documentation of the beneficiary's compliance with wearing the wearable cardioverter defibrillator and that the compliance report demonstrate a compliance rate of at least 92% for the previous 30-day period. Here, there is no documentation in the record regarding compliance in the thirty days prior to the requested period, but Petitioner did submit documentation regarding his compliance rate during the requested thirty days. However, while provided to the Department, that documentation clearly demonstrated that Petitioner was not sufficiently compliant with wearing the wearable cardioverter defibrillator.

Moreover, to the extent Petitioner argues that his lack of compliance should be excused because his health and hospitalization prevented him from wearing the wearable cardioverter defibrillator, his argument must be rejected. Petitioner's authorization request and supporting documentation did not specifically identify any such basis for noncompliance and, even when the hospitalization was considered, Petitioner was still not sufficiently compliant.

To the extent that Petitioner's circumstances have changed or he has new or updated information he wants to provide, he and his doctor are free to submit a new prior authorization request at any time. The denial at issue in this case, however, must be affirmed given record in this case.

## DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that the Department properly denied Petitioner's authorization request for a wearable cardioverter defibrillator.

**IT IS, THEREFORE, ORDERED** that:

The Department's decision is **AFFIRMED**.

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**Steven Kibit**
Administrative Law Judge
for Nick Lyon, Director
Department of Health and Human Services

**NOTICE OF APPEAL**: A party may appeal this Order in circuit court within 30 days of the receipt date. A copy of the circuit court appeal must be filed with the Michigan Administrative Hearing System (MAHS).

A party may request a rehearing or reconsideration of this Order if the request is received by MAHS within 30 days of the date the Order was issued. The party requesting a rehearing or reconsideration must provide the specific reasons for the request. MAHS will not review any response to a request for rehearing/reconsideration.

A written request may be mailed or faxed to MAHS. If submitted by fax, the written request must be faxed to (517) 335-6088; Attention: MAHS Rehearing/Reconsideration Request.

If submitted by mail, the written request must be addressed as follows:

Michigan Administrative Hearings
Reconsideration/Rehearing Request
P.O. Box 30763
Lansing, Michigan 48909-8139

**DHHS Department Rep.**

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