



## **Regulatory Status Assessment – ADAMM-RSM Wearable and HCO Respiratory Care (RC) Mobile Application**

### **1. Purpose**

The purpose of this memorandum is to document the regulatory assessment of the following components of Health Care Originals' Respiratory Care Program ("RC Program"):

1. HCO RC Mobile Application (Android, iOS, Web)
2. ADAMM-RSM body-worn wearable (ages 7+)

This assessment is based on the products' intended use, functionality, risk profile, and alignment with applicable FDA guidance documents.

### **2. Scope**

This memorandum covers:

- Program positioning and intended use
- Functional description of each component
- Assessment of whether the app and wearable constitute regulated medical devices
- FDA guidance alignment rationale
- Claims/communications guardrails to preserve non-regulated / enforcement discretion posture

### **3. Program Overview**

The RC Program delivers self-management education for members who have been diagnosed with asthma and/or COPD. Self-management education has established benefits and expected outcomes. However, patient understanding and consistent utilization are often limited, resulting in poor symptom control, exacerbations ("flare-ups"), and avoidable emergency care utilization.

The RC Program addresses this by delivering education in a manner tailored to the member and paced according to member engagement and assimilation. Timely access to respiratory care professionals supports member understanding and adherence to education.

Important Program Limitation: The RC Program is not intended to diagnose, treat, cure, mitigate, or prevent disease, and program participants must have an existing diagnosis of asthma and/or COPD.

### **4. Components Covered**

#### **4.1 Non-Traditional / Unfamiliar Program Components:**

- HCO RC Mobile Application (Android, iOS, Web) – encouraged for all members; alternative accommodations exist.
- ADAMM-RSM wearable (ages 7+) – optional use; program outcomes are not dependent on wearable use.



#### 4.2 Additional Non-Content Components (As Needed):

- Access to respiratory care professionals
- Spacers and/or medication delivery support devices
- Peak flow meters
- OPEP airway clearance devices
- Action plans
- HEPA air filters, Wi-Fi hotspots, and residential home-use rated pesticides

### 5. Product Descriptions

5.1 HCO RC Mobile Application: Centralized platform for education, engagement, self-reporting, and communications including symptom/trigger tracking, action plans, medication usage tracking (member-reported), messaging/calls/documents.

5.2 ADAMM-RSM Wearable: Non-invasive wearable collecting physiological and activity-related data to support self-awareness and engagement with respiratory self-management education. Not intended for emergency detection or clinical decision-making.

### 6. Intended Use Statements (Recommended Internal Language)

6.1 HCO RC Mobile Application – Intended Use: The HCO RC Mobile Application is intended to provide educational content and support tools for individuals with an existing diagnosis of asthma and/or COPD. The application enables members to access education, record self-reported symptoms and triggers, document action plans, and communicate with program support resources.

6.2 ADAMM-RSM Wearable – Intended Use: ADAMM-RSM is intended to collect and display physiological and activity-related data to support general wellness, self-awareness, and engagement with respiratory self-management education for individuals with an existing diagnosis of asthma and/or COPD.

### 7. Explicit Exclusions (Not Intended Use / Not Indications for Use)

7.1 HCO RC Mobile Application – Not Intended: Diagnose, predict exacerbations with clinical certainty, recommend medication changes, provide clinician-directed treatment decisions, provide emergency alarms.

7.2 ADAMM-RSM Wearable – Not Intended: Detect or diagnose attacks/exacerbations, detect emergencies, replace clinical monitoring devices, provide clinical decision support, function as stand-alone disease management device.

### 8. Regulatory Assessment

8.1 HCO RC Mobile Application: Aligned with FDA Policy for Device Software Functions and Mobile Medical Applications. Primarily education/logging/communications; advanced trending features may be subject to enforcement discretion when positioned as low-risk and not driving diagnosis/treatment/emergency response.



8.2 ADAMM-RSM Wearable: Aligned with FDA General Wellness: Policy for Low Risk Devices. Non-invasive, low-risk, supports self-awareness and education without diagnosis/treatment claims.

### **9. Risk Rationale / Low-Risk Justification**

Low-risk profile due to non-invasive wearable, no direct intervention, no emergency response, no diagnostic outputs, no automated clinical decision-making, member-driven use. Residual risk of misinterpretation mitigated through disclaimers, education-based positioning, access to respiratory care professionals, and claims guardrails.

### **10. Claims and Marketing Guardrails**

Acceptable/Recommended language includes: supports self-management education, helps members understand trends, allows logging of symptoms/triggers, promotes general wellness and self-awareness.

Avoid/Prohibited language includes: diagnoses asthma/COPD, treats or prevents attacks, predicts exacerbations, recommends medication changes, emergency alert system, clinical-grade monitoring device.

### **11. Regulatory Conclusion**

Both the HCO RC Mobile Application and ADAMM-RSM wearable align with FDA frameworks indicating they are not regulated medical devices and/or subject to enforcement discretion (where applicable). Neither currently requires FDA classification (Class I/II) nor clearance/approval such as 510(k), provided claims remain within education and general wellness boundaries.

### **12. References**

1. FDA – Policy for Device Software Functions and Mobile Medical Applications (latest): <https://www.fda.gov/media/80958/download>
2. FDA – General Wellness: Policy for Low Risk Devices (latest): <https://www.fda.gov/media/90652/download>

### **13. Contact**

For questions or requests for supporting documentation, please contact:

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