DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	2/28/2018-3/8/2018* FEI NUMBER 3010521294

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Williiam H. Schofield, Director of Operations

FIRM NAME	STREET ADDRESS
OptumHealth Care Solutions Inc.	1100 King St Bldg 6 Ste 300
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rye Brook, NY 10573-1057	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for design verification have not been adequately established.

Specifically, the firm has no established procedure that requires the firm to review the results of the verification activities performed by the contract firm ((b) (4)) responsible for the software coding and verification testing of the software.

Additionally, the following were noted:

- the firm has no documentation to show that they reviewed the design verification performed by (b) (4) in 6/2017 for the Optum TeleHealth Application software Version 2.2 for iOS and Android applications. The software was commercially released on 7/2017 for the Android application and on 8/2017 for the iOS application.

- for the Optum TeleHealth Application server software Version 4.2.0, Portal performed the software verification testing, on 10/26/2017, to ensure that the Unique Device Identification (UDI) was correctly

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Gregson A Joseph, Investigator	X Gregson A Joseph Investigator Signed By: Gregson A. Joseph -S Date Signed: 03-08-2018 11:43:14	3/8/2018

added to the software, but they created the test plan for the verification testing on 11/27/2017 (after the testing was completed). This was not caught by the firm (Optum Health Care Solutions, Inc.).

OBSERVATION 2

Procedures for design change have not been adequately established.

Specifically, the firm manufactures the Optum TeleHealth Application, which is a software designed to retrospectively monitor vital signs, and when a revision is made to the software (in other words, a design change), the revision is classified as major or minor. However, the firm has not itself defined in its own procedure what is considered a "major" or a "minor" change; the firm relies on the definitions of the firm that it contracts with ((b) (4)) to create the software code and to do verification testing. However, the contract firm's definition of a major and a minor change is not adequately defined. In the contract firm's procedure, entitled "(b) (4) release date - March 2, 2015, a major change/revision is noted as (b) (4) ", and a minor change/revision is noted as "(b) (4) ".

OBSERVATION 3

Design input requirements were not reviewed and approved by designated individual(s).

Specifically, for the Optum TeleHealth Application software for Version 2.3.0 for the iOS application and for Version 2.4.0 for the Android application, the design input for these software Versions, was for the support of the (b) (4) . However, the design input,

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initially, indicated these software Versions were to support the (b) (4), and there is no documentation of the firm's review and approval for the change to the aforementioned (b) (4) which occurred in 2017.

OBSERVATION 4
Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, the firm's complaint handling procedure, PR4119, Rev. 5.0, effective 11/14/2017, does not accurately specifies who is responsible for certain complaint handling functions and for making certain complaint determinations. For example, the procedure specifies that the "(b) (4) In actuality, however, these tasks are performed by (b) (4).

Additionally, the firm has no procedure that states the job titles or list the individuals who comprise the (b) (4).

OBSERVATION 5
Procedures for quality audits have not been adequately established.

Specifically, the firm's quality audit procedure, PR4131, Rev. 5.0, effective - 11/14/2017, does not specify the frequency in which audits will be conducted.

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OBSERVATION 6

Procedures for management review have not been adequately established.

Specifically, the firm's management review procedure, PR4117, Rev. 5.0, effective 11/14/2017, states (b) (4) but the procedure does not state or define the job titles or individuals who comprise (b) (4)

Annotations to Observations

Observation 1: Annotation Intentionally Left Blank
Observation 2: Annotation Intentionally Left Blank
Observation 3: Annotation Intentionally Left Blank
Observation 4: Promised to correct
Observation 5: Promised to correct
Observation 6: Promised to correct

*DATES OF INSPECTION

2/28/2018(Wed), 3/01/2018(Thu), 3/02/2018(Fri), 3/05/2018(Mon), 3/06/2018(Tue), 3/08/2018(Thu)

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