

# **Mammography Facility Adverse Event and Action Report – November 17, 2017: Summers County Appalachian Regional Healthcare**

## **Background**

As part of the Mammography Quality Standards Act (MQSA), Congress mandated there be annual reporting of adverse actions taken against mammography facilities. Congress stipulated that the report be made available to physicians and the general public and that it should include information that is useful in evaluating the performance of mammography facilities nationwide. In order to provide this information in the timeliest manner, we now post the following information in “real time,” as actions taken against mammography facilities are concluded:

## **Mammography Facility Against Which There Was An Adverse Action**

### **The State of West Virginia**

#### **Facility Name and Address:**

Summers County Appalachian Regional Healthcare  
1500 Terrace Street  
Hinton, WV 25951

#### **Facility ID Number:**

199257

#### **Adverse Event:**

On January 24, 2017, The American College of Radiology (ACR) initiated a Full Additional Mammography Review (AMR) of mammograms performed by this facility based on deficiencies noted with the clinical images submitted by the facility for a Random Image Check, a clinical image review process required to be performed by accreditation bodies under the MQSA.

The ACR notified the facility on March 2, 2017, that the AMR failed.

#### **Action Taken:**

Based on the failed AMR results, on March 13, 2017, the ACR revoked the facility’s accreditation.

After evaluating the reasons for the accreditation revocation, on March 14, 2017, the Food and Drug Administration (FDA) declared the facility's MQSA certificate to be no longer in effect until such time as the facility's accreditation was reinstated and the facility had complied with all the requirements of the FDA.

**Corrective Action:**

Based on the serious image quality deficiencies noted during the AMR, the FDA declared the mammography performed at this facility to be a serious risk to human health and therefore required the facility to perform a Patient and Referring Healthcare Provider Notification (PPN) to alert all at-risk patients and their providers of the mammography quality problems at the facility.

The facility successfully completed the PPN and was notified of such by the FDA on May 25, 2017.

As part of the ACR's post-revocation protocol, the facility was required to participate in a post-revocation follow-up AMR, a more extensive clinical image review for accreditation reinstatement. On June 22, 2017, the FDA issued a provisional certificate to the facility for the facility to lawfully obtain the clinical images needed to complete the accreditation reinstatement process.

On August 24, 2017, the ACR informed the facility and the FDA that the facility's accreditation was revoked for a second time based on the failure of the follow-up AMR.

The FDA again declared the mammography performed at this facility to be a serious risk to human health and therefore required the facility to perform a second PPN to alert all at-risk patients and their providers of the mammography quality problems at the facility. On October 2, 2017, the FDA suspended the facility's certificate until such time as the facility's accreditation is reinstated and the facility has complied with all the requirements of the FDA.

The facility successfully completed the second PPN and was notified as such by the FDA on November 2, 2017.

**Status of the Facility:**

The facility is currently not practicing mammography.