Mammography Facility Adverse Event and Action Report – December 16, 2016: DeQueen General Hospital Inc. dba DeQueen Medical Center

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

Facility Name and Address:

DeQueen General Hospital Inc.
dba DeQueen Medical Center
1306 West Collin Raye Drive
DeQueen, AR 71832

Facility ID Number:

187039

Adverse Event:

On July 15, 2016, The State of Arkansas Accreditation Body (SAR AB) initiated a Limited Additional Mammography Review (LAMR) of mammograms performed by this facility based on reviewer comments made about the clinical images that the facility submitted during the accreditation renewal process.

On July 25, 2016, the SAR AB informed the facility of the results of the LAMR. The mammograms reviewed did not meet the SAR AB's criteria for clinical image quality and therefore the SAR AB required the facility to participate in a Full Additional Mammography Review (FAMR) in order to evaluate an expanded sample of clinical images performed at the facility.

On August 22, 2016, the SAR AB notified the facility and the Food and Drug Administration (FDA) that the mammograms reviewed during the FAMR did not meet the SAR AB's criteria for clinical image quality and that the deficiencies suggested a serious risk to human health (SRHH).

Action Taken:

On August 22, 2016, the SAR AB revoked the facility's accreditation.

After evaluating the reasons for the accreditation revocation, on August 24, 2016, the FDA declared the facility's MQSA certificate to be no longer in effect until such a time as the facility's accreditation is reinstated and the facility has complied with all the requirements of the FDA.

Corrective Action:

Based on the serious image quality deficiencies noted during the FAMR, the FDA declared the mammography performed at this facility to be a SRHH 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 November 14, 2016.

Status of the Facility:

The facility is currently not performing mammography pending completion of the SAR AB accreditation reinstatement process.