Mammography Facility Adverse Event and Action Report – March 13, 2020: The Breast Institute at JFK Medical Center North Campus

Background
As part of the Mammography Quality Standards Act (MQSA), Congress mandated that 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 Florida

Facility Name and Address:

The Breast Institute at JFK Medical Center North Campus
4631 N.Congress Ave Suite 100
West Palm Beach, FL 33407

Facility ID Number:

210740

Adverse Event:

On July 29, 2019, the Food and Drug Administration (FDA) initiated an Additional Mammography Review (AMR) of mammograms performed by this facility, to be conducted by the facility's accreditation body, the American College of Radiology (ACR). The AMR was initiated due to quality control deficiencies noted during the annual MQSA inspection performed on June 20, 2019, by the State of Florida.

On October 16, 2019, the ACR notified the FDA and the facility that the AMR revealed serious deficiencies with clinical image quality and that the facility failed to meet the ACR's clinical image evaluation criteria.

Action Taken:

Based on the failed AMR results, on October 29, 2019, the ACR revoked the facility's mammography accreditation.

After evaluating the reasons for the accreditation revocation, on October 30, 2019, the FDA declared the facility's MQSA certificate to be no longer in effect until such time as the facility's accreditation is reinstated and the facility has complied with all the requirements of the FDA.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 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 February 13, 2020.

Status of the Facility:

The facility has not applied for re-instatement of its mammography accreditation and is currently not authorized to perform mammography.