

■ 2. Add § 892.2070 to subpart B to read as follows:

**§ 892.2070 Medical image analyzer.**

(a) *Identification.* Medical image analyzers, including computer-assisted/aided detection (CADe) devices for mammography breast cancer, ultrasound breast lesions, radiograph lung nodules, and radiograph dental caries detection, is a prescription device that is intended to identify, mark, highlight, or in any other manner direct the clinicians' attention to portions of a radiology image that may reveal abnormalities during interpretation of patient radiology images by the clinicians. This device incorporates pattern recognition and data analysis capabilities and operates on previously acquired medical images. This device is not intended to replace the review by a qualified radiologist, and is not intended to be used for triage, or to recommend diagnosis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include:

(i) A detailed description of the image analysis algorithms including a description of the algorithm inputs and outputs, each major component or block, and algorithm limitations.

(ii) A detailed description of pre-specified performance testing methods and dataset(s) used to assess whether the device will improve reader performance as intended and to characterize the standalone device performance. Performance testing includes one or more standalone tests, side-by-side comparisons, or a reader study, as applicable.

(iii) Results from performance testing that demonstrate that the device improves reader performance in the intended use population when used in accordance with the instructions for use. The performance assessment must be based on appropriate diagnostic accuracy measures (e.g., receiver operator characteristic plot, sensitivity, specificity, predictive value, and diagnostic likelihood ratio). The test dataset must contain a sufficient number of cases from important cohorts (e.g., subsets defined by clinically

relevant confounders, effect modifiers, concomitant diseases, and subsets defined by image acquisition characteristics) such that the performance estimates and confidence intervals of the device for these individual subsets can be characterized for the intended use population and imaging equipment.

(iv) Appropriate software documentation (e.g., device hazard analysis; software requirements specification document; software design specification document; traceability analysis; description of verification and validation activities including system level test protocol, pass/fail criteria, and results; and cybersecurity).

(2) Labeling must include the following:

(i) A detailed description of the patient population for which the device is indicated for use.

(ii) A detailed description of the intended reading protocol.

(iii) A detailed description of the intended user and user training that addresses appropriate reading protocols for the device.

(iv) A detailed description of the device inputs and outputs.

(v) A detailed description of compatible imaging hardware and imaging protocols.

(vi) Discussion of warnings, precautions, and limitations must include situations in which the device may fail or may not operate at its expected performance level (e.g., poor image quality or for certain subpopulations), as applicable.

(vii) Device operating instructions.

(viii) A detailed summary of the performance testing, including: test methods, dataset characteristics, results, and a summary of sub-analyses on case distributions stratified by relevant confounders, such as lesion and organ characteristics, disease stages, and imaging equipment.

Dated: January 9, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**44 CFR Part 64**

[Docket ID FEMA-2020-0005; Internal Agency Docket No. FEMA-8613]

**Suspension of Community Eligibility**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final rule.

**SUMMARY:** This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at <https://www.fema.gov/national-flood-insurance-program-community-status-book>.

**EFFECTIVE DATES:** The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

**FOR FURTHER INFORMATION:** If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212-3966.

**SUPPLEMENTARY INFORMATION:** The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59.

Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency

Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

**National Environmental Policy Act.** FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

**Regulatory Flexibility Act.** The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain

management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

**Regulatory Classification.** This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

**Executive Order 13132, Federalism.** This rule involves no policies that have federalism implications under Executive Order 13132.

**Executive Order 12988, Civil Justice Reform.** This rule meets the applicable standards of Executive Order 12988.

**Paperwork Reduction Act.** This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

**List of Subjects in 44 CFR Part 64**

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

**PART 64—[AMENDED]**

- 1. The authority citation for Part 64 continues to read as follows:

**Authority:** 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

**§ 64.6 [Amended]**

- 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
<b>Region VI</b>				
Texas:				
Bee Cave, City of, Travis County .....	481610	N/A, Emerg; April 12, 1988, Reg; January 22, 2020, Susp.	January 22, 2020 ...	January 22, 2020.
Creedmoor, City of, Travis County ...	481697	N/A, Emerg; July 20, 2018, Reg; January 22, 2020, Susp.	.....do .....	Do.
Gonzales, City of, Gonzales County	480254	August 6, 1975, Emerg; June 15, 1979, Reg; January 22, 2020, Susp.	.....do .....	Do.
Gonzales County, Unincorporated Areas.	480253	November 8, 1973, Emerg; August 15, 1978, Reg; January 22, 2020, Susp.	.....do .....	Do.
Lakeway, City of, Travis County .....	481303	June 27, 1977, Emerg; November 5, 1980, Reg; January 22, 2020, Susp.	.....do .....	Do.
Mustang Ridge, City of, Caldwell and Travis Counties.	481687	N/A, Emerg; June 15, 2000, Reg; January 22, 2020, Susp.	.....do .....	Do.
Point Venture, Village of, Travis County.	481691	N/A, Emerg; May 29, 2002, Reg; January 22, 2020, Susp.	.....do .....	Do.
Rollingwood, City of, Travis County ..	481029	February 3, 1975, Emerg; September 29, 1978, Reg; January 22, 2020, Susp.	.....do .....	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
San Leanna, Village of, Travis County.	481305	N/A, Emerg; March 11, 1980, Reg; January 22, 2020, Susp.	.....do .....	Do.
The Hills, Village of, Travis County ...	480063	N/A, Emerg; November 15, 2006, Reg; January 22, 2020, Susp.	.....do .....	Do.
Volente, Village of, Travis County .....	481696	N/A, Emerg; April 15, 2004, Reg; January 22, 2020, Susp.	.....do .....	Do.
West Lake Hills, City of, Travis County.	481030	March 10, 1976, Emerg; July 17, 1978, Reg; January 22, 2020, Susp.	.....do .....	Do.
<b>Region VII</b>				
Kansas: Butler County, Unincorporated Areas.	200037	June 23, 1975, Emerg; March 2, 1981, Reg; January 22, 2020, Susp.	.....do .....	Do.
Missouri: Maryville, City of, Nodaway County.	290264	March 7, 1975, Emerg; September 18, 1985, Reg; January 22, 2020, Susp.	January 22, 2020 ...	January 22, 2020.

\* .....do =Ditto.

Code for reading third column: Emerg. —Emergency; Reg. —Regular; Susp. —Suspension.

Dated: January 6, 2020.

**Eric Letvin,**

*Deputy Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration—FEMA Resilience, Department of Homeland Security, Federal Emergency Management Agency.*

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