professionally acceptable standards of practice.

++ Section 416.51(b)(3) to ensure that the ASC's infection control program provides a plan of action for infections and communicable diseases and immediately implements corrective and preventive measures.

++ Section 416.52 to ensure that each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are done.

We also reviewed DNV's comparable survey processes, which were conducted as described in section III. of this final notice, and yielded the following areas where, as of the date of this notice, DNV has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Ensuring DNV's policies allow for the survey team to include at least one RN or Physician with hospital or ASC survey experience.

++ Updating DNV's policy and procedures to include 488.26(b) for determining manner and degree, when evaluating multiple standards and elevating to a higher deficiency level.

++ Providing clarification to DNV's policy on timeframes for notifying CMS of terminations and withdrawals.

++ A process to ensure that during survey, an Infection Control Worksheet is completed to confirm safe injection practices.

B. Term of Approval

Based on our review described in section III. and section V. of this final notice, we approve DNV as an initial national accreditation organization for ASCs that request participation in the Medicare program. The decision announced in this final notice is effective December 8, 2025 to December 10, 2029. In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years. Generally, when an AO is seeking an initial approval for a specific program type, CMS may approve for a term no greater than 4 years.

VI. Collection of Information and Regulatory Impact Statement

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Center for Medicare & Medicaid Services.

[FR Doc. 2025–22203 Filed 12–5–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6461]

Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) is announcing its Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot (''TEMPO pilot''), in connection with the Center for Medicare and Medicaid Innovation (CMMI) Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model, to promote access to certain digital health devices while safeguarding patient safety.

DATES: FDA is seeking statements of interest for participation in the TEMPO pilot beginning January 2, 2026. See below for instructions on how to submit a statement of interest for participation in the TEMPO pilot.

FOR FURTHER INFORMATION CONTACT: Jessica Paulsen, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–6883, *FDA-TEMPOPilot@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. TEMPO Pilot

FDA is announcing its TEMPO pilot, in connection with the CMMI ACCESS model (Ref. 1), to promote access to certain digital health devices while safeguarding patient safety. Through the CMMI ACCESS model, the Centers for Medicare and Medicaid Services (CMS) will test a new payment option that emphasizes patient outcomes, enabling clinicians to offer innovative technology-supported care to improve patients' health and prevent and manage chronic disease (Ref. 1). The CMMI ACCESS model introduces Outcome-Aligned Payments, which are recurring payments for managing a patient's qualifying condition, with payment tied to achieving measurable health outcomes (Ref. 1). CMS has designed the CMMI ACCESS model to include several safeguards to support clinical quality and accountability; under the CMMI ACCESS model, CMS will monitor performance and may terminate organizations who fail to meet quality, safety, or outcome standards, and will publish risk-adjusted outcomes in a public directory (Ref. 1).

In general, if the manufacturer of a digital health device wishes to offer its device for an intended use to improve patient outcomes (*e.g.,* measurable changes in chronic disease outcomes), the device must, among other things, be authorized by FDA for that use. If a manufacturer seeks to offer its device for an intended use to improve patient outcomes such that it may be used to provide care covered by the CMMI ACCESS model, FDA generally expects the device to be FDA-authorized for that use. However, manufacturers of certain digital health devices that are not already authorized by FDA for such use may request to participate in FDA's TEMPO pilot by following the procedures described in this notice and requesting that FDA exercise enforcement discretion and not enforce certain applicable requirements when their device is offered to or by CMMI ACCESS participants [1] for an intended use to improve patient outcomes, to be used in providing care expected to be covered by the CMMI ACCESS model. For example, such manufacturers might request that FDA exercise enforcement discretion and not enforce premarket authorization requirements, investigational device exemption (IDE) requirements, requirements under 21 CFR parts 50 and 56, or other applicable requirements. As is often the case when FDA exercises enforcement discretion and informs a manufacturer that FDA does not intend to enforce certain applicable requirements, FDA will work with participants in the TEMPO pilot to identify the circumstances when enforcement discretion may be appropriate for that manufacturer's device, including, for example, when the labeling includes appropriate cautions, and when FDA requests that certain records be maintained (as may

[1] This may include, for example, when the manufacturer is itself a participating organization under the CMMI ACCESS model, or when the manufacturer offers the device to other entities that are participants under the CMMI ACCESS model for an intended use to improve patient outcomes.

be informed by certain types of documentation described in 21 CFR 812.140 and 812.150).

FDA recognizes that real-world data (RWD) may be collected in the course of clinical practice during the treatment and management of patients, particularly with the use of digital health devices. Under certain circumstances, RWD may be used to generate real-world evidence (RWE) that can help inform or augment FDA's understanding of the benefit-risk profile of devices at various points in their life cycle. These data may also be supportive of FDA's review of devices, along with other information needed in a marketing submission. FDA expects that manufacturers participating in the TEMPO pilot will collect RWD relating to the intended uses of their devices to improve patient outcomes while offering the devices for use in providing care covered by the CMMI ACCESS model, share the data with FDA during their participation in the TEMPO pilot, and, using the data collected during their participation in the TEMPO pilot (along with other information), seek appropriate marketing authorization from FDA.

As the TEMPO pilot is a pilot, FDA plans to limit participation, and currently expects to select up to about ten manufacturers based in the United States [2] in each of the four clinical use areas identified in this notice (see below). To further help us gain insights, we hope to have broad representation among participants, with manufacturers of all sizes, types, and maturities.

In selecting participants, FDA intends to evaluate whether the digital health device would not present a potential for serious risk to the health, safety, or welfare of patients. Given the nature of the pilot, FDA will select digital health products that meet the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 321(h)) (including those that are artificial-intelligence-enabled), and are intended to be used in conjunction with clinician-supervised outpatient treatment to patients with conditions in one of the following four CMMI ACCESS clinical use areas: early cardio-kidney-metabolic (hypertension, dyslipidemia, obesity or overweight with marker of central obesity, or prediabetes), cardio-kidney-metabolic (diabetes, chronic kidney disease, or atherosclerotic cardiovascular disease), musculoskeletal (chronic musculoskeletal pain), or behavioral health (depression or anxiety). These digital health devices may rely on off-the-shelf platforms such as general-purpose computing platforms or wearable products (that may or may not be regulated wearable devices).

To request to participate in the TEMPO pilot, a manufacturer should contact FDA at *FDA-TEMPOPilot@fda.hhs.gov.* This communication should be titled ''Statement of Interest for Participation in the TEMPO Pilot,'' and should identify the manufacturer and the manufacturer's device, including any current authorizations or prior FDA interactions (*e.g.,* relevant submission numbers) related to the device; include a proposed indications for use statement identifying the intended use to improve patient outcomes in a clinical use area consistent with participation in the CMMI ACCESS program; and include a request that FDA give the manufacturer a statement that FDA does not intend to enforce certain legal requirements (*e.g.,* a statement that FDA does not intend to enforce premarket authorization requirements, IDE requirements, and requirements under 21 CFR parts 50 and 56). FDA will collect statements of interest for participation in the TEMPO pilot beginning [January 2, 2026]. Upon receipt of the statement of interest, FDA will follow up with certain potential pilot participants who reflect a broad spectrum of manufacturers to request additional information to help enable FDA to make a decision concerning participation. FDA expects to begin to send follow-up requests around [March 2, 2026]. The types of information that would be helpful to submit may vary depending on the specific device, but we believe the following general types of information may be helpful:

1. A device description, including proposed indications for use and proposed claims clearly describing the intended use to improve patient outcomes for which the manufacturer wishes to offer the device in connection with the CMMI ACCESS model;

2. Data to demonstrate the device is adequately safe and can function as designed, and to support a reasonable expectation that the device could provide patient benefit (*e.g.,* a bibliography and copies of publications and a summary of unpublished information relevant to an evaluation of the safety of the device, and to justifying a reasonable expectation that the device could provide patient benefit);

3. Information about the manufacturer's quality management system;

4. A plan that sufficiently mitigates risks to patients and provides for the collection, monitoring, analysis, and reporting of real-world performance data;

5. Proposed performance goals and a statistical analysis plan for patient outcomes;

6. A proposed timeline for data collection and submission to FDA of a premarket notification (510(k)) or other type of marketing submission (as applicable) for the device for the intended use for which the manufacturer offers the device in connection with the CMMI ACCESS model; and

7. A proposed interim reporting plan, including frequency (such as every 6 months), to report (for example) adverse events, new risks, and progress with respect to timelines.

FDA will inform manufacturers who have submitted a statement of interest about FDA's decision. As part of the TEMPO pilot, FDA will offer and encourage pilot participants to engage in ''sprint'' discussions with the goal of reaching mutual agreement on a specific topic within a set time period (*e.g.,* 45 days) that may relate to the planned marketing submission.[3] The number, format, and duration of interactions within a sprint discussion may vary based on project needs. Although data collected during participation in the TEMPO pilot are intended to be supportive of a marketing submission to FDA, additional data may also be needed to support a marketing submission. Participation in the TEMPO pilot is not an indication of whether FDA will issue a positive decision for any future marketing submission.

II. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 820 (Quality System Regulation) and relating to device master files have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 (Investigational Device Exemptions)

[2] FDA intends to select manufacturers based in the United States for participation in the TEMPO pilot to facilitate FDA's oversight of participating manufacturers, for example, to facilitate inspections and/or access to records.

[3] For additional information regarding sprint discussions, see Section IV.A of FDA's guidance document entitled ''Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff,'' September 15, 2023, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program.*

have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E (Premarket Notification Procedures), have been approved under OMB control number 0910–0120; the collections of information under 21 CFR part 801 (Device Labeling) have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR 860, subpart D (De Novo Classification) have been approved under OMB control number 0910–0844.

III. References

The following reference is on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. CMS, ''ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model,'' available at *https://www.cms.gov/priorities/innovation/innovation-models/access* (last accessed on December 1, 2025).

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22190 Filed 12–5–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–5791]

Revocation of Emergency Use of a Drug Product During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Genentech, Inc. (Genentech) for Actemra (tocilizumab). FDA revoked this Authorization on August 8, 2025, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, including an explanation of the reasons for the revocation, are reprinted in this document.

DATES: The authorization is revoked as of August 8, 2025.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Andrea Gormley, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., 2nd Floor, Silver Spring, MD 20993–0002, 301–796–2210 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations.

On June 24, 2021, FDA issued an Authorization to Genentech for Actemra (EUA 099), subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on August 5, 2021 (86 FR 42850), as required by section 564(h)(1) of the FD&C Act.

The authorization of a drug for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. The Revocation

On August 8, 2025, the Agency approved a supplemental Biologics License Application (BLA) to BLA 125276, which expanded the approved indication for COVID–19 to the following: ACTEMRA® (tocilizumab) is an interleukin–6 (IL–6) receptor antagonist indicated for the treatment of: Coronavirus Disease 2019 (COVID–19), Hospitalized adult and pediatric patients aged 2 years and older with coronavirus disease 2019 (COVID–19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Based on this approval, FDA concluded that BLA 125276 for Actemra is an adequate, approved, and available alternative to Actemra's emergency use for the treatment of COVID–19 for the purposes of section 564(c)(3) of the Act. Accordingly, FDA revoked EUA 099 for Actemra, pursuant to section 564(g)(2) of the Act. The revocation in its entirety follows and provides explanations of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at: *https://www.regulations.gov/.*

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