

including for defining the term business day. The Board believes that these parties will be able to adapt their contracts after the Fedwire Funds Service and NSS operating hours are expanded.

Several commenters asked about the potential regulatory impact of expanded hours, particularly with respect to liquidity regulations such as Regulation WW and Regulation YY.³⁴ The Board notes that its decision on expanded hours does not change the legal standards for liquidity risk management. Institutions remain responsible for ensuring that their liquidity risk management reflects their operational reality if they opt in to expanded hours. The Board's timeline for expanding operating hours is intended to provide institutions with time to evaluate and, if needed, adapt their organization to account for this and other considerations discussed in this notice.³⁵

Some commenters suggested that the Federal Reserve impose regulatory or contractual requirements on Fedwire Funds Service participants to report, share, investigate, and mitigate fraud. Others asked about potential changes to Fedwire Funds Service and National Settlement Service operational practices (for example, planned outages, cutoff times, or the closing time for the service's business day). As noted in section IV, the Board is assessing public comments following publication of a separate Request for Information related to fraud considerations. In addition, the Reserve Banks will continue to collect input and consider enhancements to address the needs of Fedwire Funds Service and NSS participants through the Reserve Banks' regular engagement with its participants.

V. Competitive Impact Analysis

Board policy requires that the Board conduct a competitive impact analysis when considering changes to a service. The policy requires the Board to first determine whether there will be a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services

³⁴ A few commenters also raised questions about the impact of expanded hours on rules applicable to futures and securities, including the Board's Regulation T and the Security and Exchange Commission's Rule 15c3-3. Changes to rules applicable to futures and securities are outside the scope of this **Federal Register** notice. Nevertheless, the Board has not identified a reason that expanding the hours of the Fedwire Funds Service and NSS into the weekend would affect these rules.

³⁵ For example, institutions may need to factor expanded hours into their internal models for Regulation YY internal liquidity stress testing.

and then, if such an adverse effect is identified, to determine if that effect is due to differing legal powers or the Federal Reserve's dominant market position deriving from such legal differences. Next, if such legal differences exist, the proposed change would be further evaluated to assess its benefits and determine if the proposal could be modified.³⁶

The Board continues to believe that an expansion of Fedwire Funds Service and NSS operating hours would not have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve. In particular, the Federal Reserve provides the only large-value payment services in the United States that allow settlement in central bank money.

While some commenters questioned the need for expanding Fedwire Funds Service and NSS operating hours given the availability of instant payment system (see section III.B), none of the commenters raised concerns about the effect expanding Fedwire Funds Service and NSS operating hours would have on other service providers' ability to compete effectively with the Federal

³⁶ See The Federal Reserve in the Payments System, *supra* note 13. The policy states, "The Board will also conduct a competitive impact analysis when considering an operational or legal change, such as a change to a price or service, or a change to Regulation J, if that change would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services due to differing legal powers or constraints or due to a dominant market position of the Federal Reserve deriving from such legal differences. All operational or legal changes having a substantial effect on payments-system participants will be subject to a competitive-impact analysis, even if competitive effects are not apparent on the face of the proposal. In conducting the competitive-impact analysis, the Board would first determine whether the proposal has a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services. Second, if such an adverse effect on the ability to compete is identified, the Board would then ascertain whether the adverse effect was due to legal differences or due to a dominant market position deriving from such legal differences. Third, if it is determined that legal differences or a dominant market position deriving from such legal differences exist, then the proposed change would be further evaluated to assess its benefits, such as contributing to payments-system efficiency or integrity or other Board objectives, and to determine whether the proposal's objectives could be reasonably achieved with a lesser or no adverse competitive impact. Fourth, the Board would then either modify the proposal to lessen or eliminate the adverse impact on competitors' ability to compete or determine that the payments-system objectives may not be reasonably achieved if the proposal were modified. If reasonable modifications would not mitigate the adverse effect, the Board would then determine whether the anticipated benefits were significant enough to proceed with the change even though it may adversely affect the ability of other service providers to compete with the Federal Reserve in that service."

Reserve. Where commenters raised competitive considerations, they were supportive of expanding the Fedwire Funds Service operating hours. The main private-sector provider of large-value payment services and the large majority of commenters from large banks, financial market utilities, and fintech companies offered comments on the 2024 Notice explaining that they would benefit from an expansion of Fedwire Funds Service operating hours. In particular, these organizations indicated that an expansion of Fedwire Funds Service operating hours would improve efficiency and reduce risk in conducting U.S. dollar payments and settlements and would support private-sector payments efforts in the United States. For instance, expanding Fedwire Funds Service operating hours could improve liquidity risk management for payment systems that rely on the Fedwire Funds Service for prefunding (for example, a private-sector instant payment service, a large-value payment service, and a foreign exchange settlement system). Accordingly, an expansion of Fedwire Funds Service and NSS operating hours is not expected to adversely impact any other service provider that competes with Federal Reserve payment services and could instead support their efficiency and resilience.

By order of the Board of Governors of the Federal Reserve System.

Benjamin W. McDonough,

Deputy Secretary of the Board.

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GULF COAST ECOSYSTEM RESTORATION COUNCIL

[Docket No.: 111132025-1111-02]

Notice of Proposed Subaward Under a Council-Selected Restoration Component Award

AGENCY: Gulf Coast Ecosystem Restoration Council.

ACTION: Notice.

SUMMARY: The Gulf Coast Ecosystem Restoration Council (Council) publishes notice of a proposed modification of the subaward from the Texas Commission on Environmental Quality to the Armand Bayou Nature Preserve, a non-government organization, for the purpose of land acquisition in accordance with the Council's Texas Land Acquisition Program for Coastal Conservation Award set forth in the Council's 2021 Funded Priorities List.

FOR FURTHER INFORMATION CONTACT:

Please send questions by email to Bridget Zachary by email bridget.zachary@restorethegulf.gov or call (504) 232-3750.

SUPPLEMENTARY INFORMATION: Section 1321(t)(2)(E)(ii)(III) of the *Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies Act of 2012* (33 U.S.C. 1321(t) and *note*) (RESTORE Act) and the Department of the Treasury's implementing regulation at 31 CFR 34.401(b) set forth certain notice and publication requirements. They require that for purposes of awards made under the Comprehensive Plan Component of the RESTORE Act, a State or Federal award recipient may make a subaward to or enter into a cooperative agreement with a nongovernmental entity that equals or exceeds 10 percent of the total amount of the award only if at least 30 days before the State or Federal award recipient enters into such an agreement, the Council publishes in the **Federal Register** and delivers to specified Congressional committees the name of the recipient and subrecipient; a brief description of the activity, including its purpose; and the amount of the award. This notice fulfills the **Federal Register** publication requirement.

Description of Proposed Action

As specified in the Council's 2021 Funded Priorities List, which is available on the Council's website at <https://www.restorethegulf.gov/our-work/fpl/fpl-3/>, RESTORE Act funds in the amount of \$24,300,000 will support the Texas Land Acquisition Program for Coastal Conservation Award to the Texas Commission on Environmental Quality. Under the Texas Land Acquisition Program for Coastal Conservation Award, Texas Commission on Environmental Quality will provide a subaward increase in the amount of \$1,500,000 to Armand Bayou Nature Center, a non-government organization, to acquire and preserve approximately 106 acres of habitat along Armand Bayou. This amount is added to the previous subaward of \$3,000,000 used for the purchase of 1,160 acres.

Keala J. Hughes,

Director of External Affairs & Tribal Relations, Gulf Coast Ecosystem Restoration Council.

[FR Doc. 2025-19981 Filed 11-14-25; 8:45 am]

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GULF COAST ECOSYSTEM RESTORATION COUNCIL

[Docket No.: 111132025-1111-03]

Senior Executive Service Performance Review Board Membership

AGENCY: Gulf Coast Ecosystem Restoration Council (GCERC).

ACTION: Notice of Performance Review Board (PRB) appointments.

SUMMARY: This notice announces the members of the Senior Executive Service (SES) Performance Review Board. The PRB is comprised of a chairperson and a mix of state representatives and career senior executives that meet annually to review and evaluate performance appraisal documents and provide a written recommendation to the Chairperson of the Council for final approval of each executive's performance rating, performance-based pay adjustment, and performance award.

DATES: The board membership is applicable beginning on 5/01/2025 and ending on 12/31/25.

FOR FURTHER INFORMATION CONTACT: Mary S. Walker, Executive Director, Gulf Coast Ecosystem Restoration Council, telephone 504-210-9982.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c)(4), the persons named below have been selected to serve on the PRB:

Gulf Coast Ecosystem Restoration Council

Walker, Mary S., Executive Director, Mary.Walker@restorethegulf.gov, 504-210-9982

Department of Interior

Blanchard, Mary Josie, Deputy Director, Environmental Protection Compliance, MaryJosie_Blanchard@ios.doi.gov, 202-208-3406

State of Florida

Blalock, Adam, Deputy Secretary for Ecosystem Restoration, Adam.Blalock@floridadep.gov, 850-245-2118

State of Texas

Schar, Steven, Deputy Executive Director, Texas Commission on Environmental Quality, steven.schar@tceq.texas.gov, 512-239-3900

Environmental Protection Agency

Fotouhi, David, Deputy Administrator, EPA, Atkinson.Emily@epa.gov, 202-564-4700

Keala J. Hughes,

Director of External Affairs & Tribal Relations, Gulf Coast Ecosystem Restoration Council.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2013-D-0446]

Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers." This guidance finalizes the revised draft guidance issued on November 2, 2022, and replaces the final guidance of the same title issued in June 2016 and updated in October 2017. The guidance addresses frequently asked questions, including those related to the implementation of FDA's regulations on expanded access to investigational drugs and other topics related to expanded access that are promulgated through the 21st Century Cures Act (Cures Act) and the FDA Reauthorization Act of 2017 (FDARA). Upon publication of this guidance, FDA is withdrawing the 1998 information sheet guidance, entitled "Emergency Use of an Investigational Drug or Biologic," for institutional review boards and clinical investigators because the information provided in the 1998 guidance is included in this final guidance.

DATES: The announcement of the guidance is published in the **Federal Register** on November 17, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the