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# THE JOURNAL OF FEDERAL AGENCY ACTION



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# The Journal of Federal Agency Action

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# Editor's Note

# Are We All Agency Subjects Now?

Victoria Prussen Spears*

It sometimes seems that all areas of our work and personal lives and perhaps especially that all businesses—and all aspects of every business—are subject to federal agency actions. If you doubt that, consider the broad scope of topics explored in the articles in this issue of *The Journal of Federal Agency Action*.

## Wages and Jobs

Our lead article, "Antitrust Agencies Remain Undeterred Despite Repeated Setbacks in Criminal Prosecutions of Wage-Fixing and No-Poach Agreements," is by Betty Graumlich, Michelle Mantine (a member of our Board of Editors), and Danielle Stewart of Reed Smith LLP.

Here, the authors advise that, in this era of heightened antitrust scrutiny, it is critical that companies review their antitrust compliance programs to ensure that they are comprehensive, effective, and up-to-date.

## Food

Next, Sharon Lindan Mayl, Bethany J. Hills (a member of our Board of Editors), and Matthew Piscitelli of DLA Piper discuss the long-awaited final Food Traceability Rule issued recently by the Food and Drug Administration, and explain why industry should be paying attention. Their article is titled, "Food and Drug Administration's Final Food Traceability Rule: What It Says and What It Means for the Future."

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## Chemicals

Manufacturers and importers of products containing PFAS will face new and substantial costs for recordkeeping and reporting if an Environmental Protection Agency rule designed to collect comprehensive data on PFAS is finalized as proposed.

In our next article, "What Is in the Environmental Protection Agency's Billion Dollar PFAS Reporting Rule?," Victor Y. Xu and James B. Pollack of Marten Law LLP discuss the proposed reporting rule and its implications—and the costs for U.S. manufacturers and importers.

## Telemedicine

The Centers for Medicare & Medicaid Services recently issued a final rule that contains significant changes for telehealth, digital remote therapeutic monitoring, and behavioral health providers. Jamie Ravitz, David Hoffmeister, Georgia Ravitz, Eva Yin, Paul Gadiock, Kathleen Snyder, and Jeff Weinstein of Wilson Sonsini Goodrich & Rosati analyze the rule in their article, "New Reimbursement Rules from Centers for Medicare & Medicaid Services Will Likely Impact Digital Health and Telemedicine."

## Privacy

For years, patients and healthcare companies have been wrestling with privacy issues relating to cookies, pixels, and other tracking technologies. The U.S. Department of Health and Human Services' Office of Civil Rights (OCR), which enforces the Health Insurance Portability and Accountability Act (HIPAA), has not substantially involved itself in this prolonged and public debate—until now.

As Paul Bond, Shannon Britton Hartsfield, Ilenna J. Stein, and Mark S. Melodia of Holland & Knight LLP explain in their article, "Department of Health and Human Services Offers HIPAA Guidance on Online Tracking Technologies," the OCR has just issued a bulletin that may profoundly impact this debate. The authors also discuss the steps that healthcare companies can take both to comply with the new guidance and to mitigate litigation and regulatory risk.

## Climate

"Federal Acquisition Regulatory Council's Proposed Rule on Greenhouse Gas Emissions Would Impose Significant Compliance Obligations on Federal Contractors" is by Richard B. Oliver, Matt Carter, Alex D. Tomaszczuk, Michael S. McDonough, and Jeffrey A. Knight of Pillsbury Winthrop Shaw Pittman LLP.

The authors explain that the Federal Acquisition Regulatory Council recently issued a far-reaching proposed rule that includes significant compliance obligations for contractors related to their greenhouse gas emissions.

## Compliance

Then, Christopher D. Durham and Zev L. Grumet-Morris of Duane Morris LLP summarize key proposed changes requested by the Department of Labor for documents that initiate audits by the Office of Federal Contract Compliance Programs in their piece, "Department of Labor's Office of Federal Contract Compliance Programs Proposes Significant Changes to Compliance Review Scheduling Letter and Itemized Listing."

## Property Ownership

As we learn from Jeff C. Dodd, Kevin E. Gaunt, Carleton Goss, Eric R. Markus, and Elizabeth P. White of Hunton Andrews Kurth in their article, "Treasury Department Issues Final Rule on Beneficial Ownership Reporting Requirements Under the Corporate Transparency Act," there are new regulations implementing beneficial ownership reporting requirements under the Corporate Transparency Act.

Once the regulations go into effect, tens of millions of existing companies will have to make a report under the Act and approximately two million new entities created each year (and individuals and businesses that routinely facilitate the creation of these entities) will potentially be subject to the regulations. Failure to comply with the new reporting regime could result in civil and criminal penalties.

## Bank Fees

"Consumer Financial Protection Bureau Signals Stricter Enforcement of 'Unfair' Banking Fees" is our next article. Clifford S. Stanford, Brendan Clegg, and Caroline K. Eisner of Alston & Bird LLP explain how the Consumer Financial Protection Bureau plans on regulating bank fees and outline what banks can do to prepare for agency scrutiny.

## Mortgages

Fannie Mae and Freddie Mac seller/servicers and Ginnie Mae issuers must take note of the new financial eligibility requirements they now face. The new rules, and their impact on consumers and investors, are considered by Amy McDaniel Williams, Edward L. Douma, Brit Mohler Dufilho, William J. Van Thunen, and Claudia H. Fendian of Hunton Andrews Kurth LLP in their article, "Robust Financial Guidelines on Tap for Fannie Mae and Freddie Mac Seller/Servicers and Ginnie Mae Issuers."

## And, of Course, the SEC

The Securities and Exchange Commission continues to be active, as you can read in "Securities and Exchange Commission Alleges That Investment Adviser Failed to Adequately Disclose ESG Investment Policies and Procedures," by Alan R. Friedman, Andrew Otis, Steven S. Sparling, Arielle Warshall Katz, Daniel M. Ketani, and David Richards of Kramer Levin Naftalis & Frankel LLP.

In this article, the authors discuss an enforcement action brought recently by the Securities and Exchange Commission that highlights the agency's growing interest in environmental, social, and governance–related disclosures and alleged "greenwashing" by asset managers.

Enjoy the issue!

## Note

* Victoria Prussen Spears, Editor of *The Journal of Federal Agency Action*, is a writer, editor, and law firm marketing consultant for Meyerowitz Com-

munications Inc. A graduate of Sarah Lawrence College and Brooklyn Law School, Ms. Spears was an attorney at a leading New York City law firm before joining Meyerowitz Communications. Ms. Spears, who also is Editor of *The Journal of Robotics, Artificial Intelligence & Law*, can be reached at vpspears@meyerowitzcommunications.com.

# Antitrust Agencies Remain Undeterred Despite Repeated Setbacks in Criminal Prosecutions of Wage-Fixing and No-Poach Agreements

Betty Graumlich, Michelle Mantine, and Danielle Stewart*

*In this article, the authors advise that, in this era of heightened antitrust scrutiny, it is critical that companies review their antitrust compliance programs to ensure that they are comprehensive, effective, and up-to-date.*

In a collaborative effort to further intensify antitrust scrutiny, federal regulators are joining forces to advance their competition-related initiatives with greater efficiency and transparency. On July 19, 2022, Lina M. Kahn, Chair of the Federal Trade Commission (FTC), and Jennifer A Abruzzo, General Counsel of the National Labor Relations Board (NLRB), signed a Memorandum of Understanding that outlines their agencies' intention to collaborate through information sharing, cross-agency training, coordinated outreach, and investigations to further their common regulatory interest—"to protect workers against unfair methods of competition, unfair or deceptive acts or practices, and unfair labor practices." That common interest touches key labor market issues, including the "gig economy," restrictive covenants, such as verbal and written non-compete and nondisclosure agreements, and labor market concentration.[1] The FTC, which does not ordinarily weigh in on workers' rights issues, has become increasingly active in this area, making one of its key strategic goals in its most recent strategic plan to "protect the public from unfair methods of competition in the marketplace and promoting fair competition."[2]

This recent wave of activity is not the first time the federal agencies have joined forces to combat anticompetitive practices in labor markets. On October 20, 2016, the Antitrust Division of the Department of Justice (DOJ) and the FTC issued antitrust guidelines[3] for human resources professionals to educate them on how

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antitrust laws apply to hiring and other human resource decisions.[4] The guidelines warn employers that in addition to civil actions, the agencies may bring criminal charges against both individuals and companies relating to wage-fixing and no-poach agreements among competitors. While many criminal prosecutions did not materialize until 2020, they are now on the rise with no end in sight.[5]

## Enforcement of the Antitrust Laws in Labor Markets—An Uphill Battle

The DOJ has, and continues to face, an uphill battle in establishing criminal liability for wage-fixing and no-poach agreements. While the DOJ has gained few footholds during its initial prosecutions, it remains aggressive in pursuing such actions.

### DOJ's First Criminal Wage-Fixing and No-Poach Prosecutions

Two DOJ criminal prosecutions for wage-fixing and no-poach agreements went to trial during the same week in April 2022. The first to reach a conclusion was *United States v. Jindal* in the U.S. District Court for the Eastern District of Texas.[6] Neerraj Jindal, owner of a physical therapy staffing company, and his clinical director, John Rodgers, were indicted for price fixing employee wages, conspiring to wage fix, and obstructing proceedings before the FTC.[7] After an eight-day trial, the jury acquitted Rodgers of all charges, and acquitted Jindal of the antitrust charges, but found him guilty of obstruction. Shortly thereafter, in *United States v. DaVita Inc.*, the jury reached a verdict in a similar case in the U.S. District Court in Colorado.[8] That indictment accused a dialysis company and its former chief executive officer (CEO) of two counts of conspiracy to restrain trade to allocate employees, by allegedly agreeing with rival companies not to poach each other's employees. After two days of deliberation, the jury acquitted both the company and its former CEO.

The press release issued by the DOJ following the *Jindal* verdict did not focus on the antitrust allegations, but on the obstruction verdict and the court's November 2021 ruling denying Jindal's motion to dismiss the wage-fixing charge.[9] The tone of the press release, coupled with comments made by Assistant Attorney

General Jonathan Kanter in a keynote speech later the same month,[10] emphasize that the DOJ remains undeterred by those losses. In fact, these case outcomes seem to have further incited the DOJ to pursue per se liability for wage-fixing and no-poach agreements, even when it means intervening in other civil litigation.[11]

## DOJ Sees Some Forward Progress

The DOJ recently secured a victory of sorts under its new theory of criminal liability for wage-fixing and no-poach agreements. In March 2021, a federal grand jury indicted VDA OC LLC (VDA), formerly Advantage On Call LLC, a healthcare staffing company, and its former manager with one count of conspiracy to allocate nurses and fix their wages in violation of the Sherman Act.[12] On June 24, 2022, the parties filed a stipulation requesting to continue a scheduled evidentiary hearing in part because they "had reached a preliminary resolution as to both defendants that now needs to be confirmed in writing."[13] The parties requested the evidentiary hearing be delayed 30 days, and the court granted that request.[14] In early August, the parties requested additional time beyond the added 30 days. Again, the court granted the parties' request.[15] On September 1, 2022, VDA entered its notice of intent to change its plea to guilty.[16] On October 20, 2022, the DOJ filed its sentencing memorandum, which coincided with a later-filed plea agreement, consisting of a criminal fine of $62,000, restitution to the nurses of $72,000, and a $400 special assessment.[17] The DOJ quickly announced this result as a win despite the low volume of commerce affected and low penalty amounts.[18]

## Hurricane Ian's Impact on No-Poach Cases

Hurricane Ian frustrated the DOJ's efforts in another wage-fixing case. On September 20, 2020, the DOJ charged Dr. William Harwin with participating in a conspiracy to allocate the provision of medical and radiation oncology services in Southwest Florida.[19] This trial began September 6, 2022, in the U.S. District Court for the Middle District of Florida.[20] After a ten-day jury trial, the parties presented closing arguments on September 21, 2022.[21] The court closed for several days because of the impending hurricane and planned to resume jury deliberations on October 3, 2022; however,

on September 30, 2022, after an oral motion during a status conference, the court declared a mistrial[22] and set a new trial date for during the November 2022 trial term.[23] The parties requested and the court has now granted the new trial date to be set during the January 2023 term.[24]

## The Devil Is in the Details

One of the critical factors in the success or failure of wage-fixing and no-poach actions has undoubtedly been which party won the battle over jury instructions. As is typical, both parties submit draft jury instructions as well as objections[25] to the other parties' proposed instructions.[26] Given that criminal no-poach and wage-fixing actions are an evolving area of the law, it remains to be seen how the court will decide these issues, but the fundamental difference in the jury instructions relates to the specific elements that the government must prove in its case. Key differences between the parties' instructions often include whether or not the government must establish an unreasonable restraint on trade, proof of a relevant market, and whether an agreement must seek to end meaningful competition for the services of the affected employees in order to establish a conspiracy to allocate the market via a no-poach or wage-fixing agreement.[27]

## Conclusion

As we await further guidance from the courts on the standard for these agreements, companies would be well served by continuing to conduct regular antitrust compliance training, helping executives and key human resources personnel understand what wage-fixing and no-poach agreements are, and training them on best practices to stay clear of conduct that may spark an inquiry or investigation. With the DOJ actively pursuing cases in this area, and the FTC and NLRB signaling increased cooperation by and among their agencies, federal scrutiny of hiring practices will only increase in the near future. In this era of heightened antitrust scrutiny, it is critical that companies review their antitrust compliance programs to ensure that they are comprehensive, effective, and up-to-date. This includes making staffing decisions a high priority when addressing antitrust compliance efforts.

## Notes

* Betty S.W. Graumlich, a partner in Reed Smith LLP, leads the firm's Virginia Labor & Employment team. Michelle Mantine, a partner in the firm and a member of the Board of Editors of *The Journal of Federal Agency Action*, leads the firm's global Antitrust & Competition team. Danielle Stewart is an associate in the firm's Regulatory & Investigations group. The authors may be contacted at bgraumlich@reedsmith.com, mmantine@reedsmith.com, and daniellestewart@reedsmith.com, respectively.

1. *See* Press Release, Fed. Trade Comm'n, Federal Trade Commission, National Labor Relations Board Forge New Partnership to Protect Workers from Anticompetitive, Unfair, and Deceptive Practices (July 19, 2022), www.ftc.gov/news-events/news/press-releases/2022/07/federal-trade-commission-national-labor-relations-board-forge-new-partnership-protect-workers?utm_source=govdelivery ("The FTC is responsible for combatting unfair and deceptive acts and practices and unfair methods of competition in the marketplace. The NLRB is responsible for protecting employees from unfair labor practices which interfere with the rights of employees to join together to improve their wages and working conditions, to organize a union and bargain collectively, and to engage in other protected concerted activity."); Rules Concerning Unfair Methods of Competition (proposed Jan. 5, 2023) (to be codified at 16 C.F.R. pt. 910) (FTC proposed new legislation preventing employers from entering into non-compete clauses with workers and requiring employers to rescind existing non-compete clauses).

2. Fed. Trade Comm'n, Strategic Plan for Fiscal Years 2022-2026, https://www.ftc.gov/system/files/ftc_gov/pdf/fy-2022-2026-ftc-strategic-plan.pdf. *See also* Press Release, Fed. Trade Comm'n, FTC Cracks Down on Companies That Impose Harmful Noncompete Restrictions on Thousands of Workers (Jan. 4, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/01/ftc-cracks-down-companies-impose-harmful-noncompete-restrictions-thousands-workers. (The FTC has already filed three complaints this year, the first against two Michigan-based security companies and their owners, alleging they exploited their superior bargaining power over employees, requiring them to agree to employment terms that would prohibit employees from working for competing businesses for a period of two years within a 100-mile radius. In two additional complaints, the FTC alleged the two largest manufacturers of glass food and beverage containers in the United States imposed one- to two-year non-compete restrictions on employees across a variety of positions in an industry, which is already a highly concentrated industry with substantial barriers to entry, due in part to difficulty in finding skilled employees).

3. U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidance for Human Resource Professionals (Oct. 2016), www.justice.gov/atr/file/903511/download.

4. This guidance was issued in the wake of three civil enforcement actions against technology companies that resulted in consent judgments against the companies (eBay and Intuit, Lucasfilm and Pixar, and Adobe, Apple, Google, Intel, Intuit, and Pixar) for allegedly entering into no-poach agreements with competitors.

5. Additionally, the DOJ continues to prosecute this type of conduct under its civil enforcement ability. *See, e.g.*, Press Release, U.S. Dep't of Justice, "Justice Department Requires Knorr and Wabtec to Terminate Unlawful Agreements Not to Compete for Employees" (Apr. 3, 2018), www.justice.gov/opa/pr/justice-department-requires-knorr-and-wabtec-terminate-unlawful-agreements-not-compete; *see also* Complaint, *U.S. v. Knorr-Bremse AG*, No. 1:18-cv-00747 (D.D.C. Apr. 3, 2018) (ECF No. 1). More recently, DOJ filed a civil indictment and consent decree against various poultry producers for engaging in a decade's long conspiracy to share wage and benefit information and suppressing competition to poultry processing plant workers. Complaint, *U.S. v. Cargill Meat Solutions Corp.*, No. 1:22-cv-01821-EHL (D. Md. July 25, 2022) (ECF No. 1); *see also* U.S. Dep't of Justice, *U.S. v. Cargill Meat Solutions Corp. et al.* (July 25, 2022), www.justice.gov/atr/case/usv-cargill-meat-solutions-corp-et-al. Interestingly, although the companies allegedly engaged in a conspiracy to share wage and benefit information, the companies were not accused of reaching any agreement with regard to wages or benefits during their conspiracy.

6. U.S. v. Jindal, No. 4:20-cr-00358 (E.D. Tex. Dec. 9, 2021).

7. *Id.* at ECF No. 21.

8. U.S. v. DaVita Inc., No. 1:21-cr-00229 (D. Colo. July 14, 2021).

9. Press Release, U.S. Dep't of Justice, Former Health Care Staffing Executive Convicted of Obstructing FTC Investigation into Wage-Fixing Allegations (Apr. 14, 2022), www.justice.gov/opa/pr/former-health-care-staffing-executive-convicted-obstructing-ftc-investigation-wage-fixing (emphasizing that, in denying the motion to dismiss, "price fixing agreements—even among buyers in the labor market—have been per se illegal for years."); *see also* U.S. v. Patel et. al., No. 3:21-cr-220 (D. Conn. Dec. 2, 2022) (ECF 257) ("While the no-poach agreement alleged in the Indictment does not qualify as a new category of restraint subject to per se treatment, the alleged conduct is subject to per se treatment because it is properly plead as a market allocation.").

10. Jonathan Kanter, Assistant Attorney General, Antitrust Division, Dep't of Justice, Keynote Address at the University of Chicago Stigler Center (Apr. 21, 2022), www.justice.gov/opa/speech/assistant-attorney-general-jonathan-kanter-delivers-keynote-university-chicago-stigler. ("[T]he era of lax enforcement is over, and the new era of vigorous and effective antitrust law enforcement has begun.").

11. *See, e.g.*, Statement of Interest of the United States, Markson v. Crst International Inc., No. 5:17-cv-01261 (C.D. Cal. July 15, 2022) (ECF 637) ("Whether market allocation agreements are based on territory, customers,

or workers, they cause the same harm: they prevent those unhappy with one company from taking their business to another company, and thus reduce the competitive pressure to lower product prices, raise wages, and improve quality. The *per se* rule therefore applies equally in customer-facing and supplier-facing markets, *i.e.*, markets for component parts or labor."); U.S. v. Patel et al., No. 3:21-cr-220 (D. Conn. Dec. 2, 2022) (ECF 257).

12. Press Release, Dep't of Justice, "Health Care Staffing Company and Executive Indicted for Colluding to Suppress Wages of School Nurses" (Mar. 30, 2021), www.justice.gov/opa/pr/health-care-staffing-company-and-executive-indicted-colluding-suppress-wages-school-nurses.

13. Stipulation to Continue Evidentiary Hearing, U.S. v. Hee, No. 2:21-cr-00098 (D. Nev. Jun. 24, 2022) (ECF 92).

14. *Id.* (June 27, 2022, Order) (ECF 93).

15. *Id.*, Stipulation to Continue Evidentiary Hearing (Aug. 2, 2022) (ECF 94); *id.*, Order (Aug. 3, 2022) (ECF 95).

16. *Id.*, Notice of Intent to Change Plea by VDA OC, LLC (Sept. 1, 2022) (ECF 96).

17. United States' Sentencing Memorandum, *id.* (Oct. 20, 2022) (ECF 103) and Plea Agreement, *id.* (Oct. 27, 2022) (ECF 1106).

18. Press Release, Dep't of Justice, "Health Care Company Pleads Guilty and Is Sentenced for Conspiring to Suppress Wages of School Nurses" (Oct. 27, 2022), https://www.justice.gov/opa/pr/health-care-company-pleads-guilty-and-sentenced-conspiring-suppress-wages-school-nurses.

19. U.S. Dep't of Justice, U.S. v. William N. Harwin, www.justice.gov/atr/case/us-v-william-n-harwin.

20. Trial Calendar, U.S. v. Harwin, No. 2:20-cr-00115 (M.D. Fla. Aug. 29, 2022) (ECF 228).

21. *Id.* Minute Entry for In Person proceedings held before Judge Virginia M. Hernandez Covington (Sept. 21, 2022) (ECF 282).

22. During jury deliberations, a juror raised a question about language in the indictment. It is unclear from the record whether that question and the answer thereto played any role in the mistrial.

23. *Id.*, Endorsed order as to William N. Harwin, (Sept. 27, 2022) (ECF 283); Oral Motion for Declaration of Mistrial by William N. Harwin (Sept. 30, 2022) (ECF 287); Oral Order granting 287 Motion for Declaration of Mistrial as to William N. Harwin (Sept. 30, 2022) (ECF 288).

24. *Id.* Endorsed order as to William N. Harwin (Oct. 26, 2022) (ECF 291).

25. Proposed Jury Instructions by USA as to William N. Harwin, *U.S. v. Harwin*, No. 2:20-cr-00115 (M.D. Fla. Aug. 15, 2022) (ECF 220); Proposed Jury Instructions by William N. Harwin, *id.* (Aug. 15, 2022) (ECF 221).

26. *Id.* Objection by USA as to William N. Harwin Proposed Jury Instructions (Aug. 31, 2022) (ECF 231); Objection by William N. Harwin as to Proposed Instructions by the Government (Aug. 31, 2022) (ECF 232).

27. One case has already included such language in its jury instructions. Jury Instructions, U.S. v. DaVita Inc., No. 1:21-cr-00229 (D. Colo. Apr. 13, 2022) (ECF 254).

# Food and Drug Administration's Final Food Traceability Rule: What It Says and What It Means for the Future

Sharon Lindan Mayl, Bethany J. Hills, and Matthew Piscitelli*

*In this article, the authors discuss the long-awaited final Food Traceability Rule issued recently by the Food and Drug Administration, and explain why industry should be paying attention.*

The Food Safety Modernization Act (FSMA) may have been passed more than a decade ago, but it is anything but old news. While the Food and Drug Administration (FDA) has issued many of the "foundational" rules that set forth safety standards for the food industry, the agency continues to issue rules with new requirements and guidance documents to assist industry with compliance.

On November 21, the FDA published the long-awaited final Food Traceability Rule (or final rule), which establishes additional traceability recordkeeping requirements for those that manufacture, process, pack, or hold certain foods.[1] While the final rule is limited in scope by statute, industry should be paying attention because it sets the stage for the agency's ultimate vision of end-to-end traceability.

The ability to track and trace foods is important for a number of reasons. First, it can protect public health by identifying recipients of unsafe foods more quickly and efficiently, allowing for more rapid recalls and warnings to consumers. Second, and as a consequence to the first, the ability to identify and remove unsafe food quickly can help to reduce a company's risk of liability when food safety events occur. Third, enhanced food system traceability might help anticipate disruptions in the food supply chain and improve inventory control. This could avoid the kind of problems seen with the recent infant formula crisis and during the early days of the COVID-19 pandemic, when foods and other consumer items were not necessarily scarce overall, but in the wrong place at the wrong time (e.g., restaurants and hotels had food that retail stores were lacking, leading to food waste). Finally, being able to quickly

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identify the source of foodborne illness outbreaks and other contamination events can also help prevent food producers from being unfairly affected by recalls and advisories about contaminated foods that have nothing to do with them.[2]

The FDA's final Food Traceability Rule is the first step to achieving end-to-end traceability throughout the supply chain. While many companies have established tracing systems, the systems are not always interoperable, thus hindering the ability to trace foods from farm to table. This final rule creates the foundational components that will allow the food system to speak the same traceability language and can be used by the technology sector to develop software for this rapidly growing market.

## The Final Rule

The final rule establishes additional traceability recordkeeping requirements for those that manufacture, process, pack, or hold certain foods on the FDA's Food Traceability List (FTL). The final rule identifies key activities or Critical Tracking Events (CTEs) along the supply chain where records containing Key Data Elements (KDEs) will have to be created, maintained, and shared for these foods.

### Food Traceability List

Let us begin by understanding what foods are covered by the Food Traceability Rule. Section 204(d)(2) of the FSMA required the FDA to designate high-risk foods for which additional recordkeeping would be required. After soliciting public comments on an approach for developing a list of high-risk food in 2014,[3] the agency developed a risk-ranking model that was used to develop the FTL.[4] The model was designed to be flexible and to consider a wide range of contaminants in FDA-regulated human foods. The agency looked at data associating these contaminants with different commodities and used the model to rank commodity–hazard pairs to develop a proposed FTL in conjunction with the proposed rule.[5]

After receiving public comment on the proposed FTL, the FDA has now issued the final FTL. The final FTL includes:

- All fresh-cut fruits and vegetables;
- Certain other fresh produce: leafy greens, cucumbers, peppers, tomatoes, tropical tree fruits, sprouts, herbs, melons;

- Certain fresh and frozen finfish;
- Fresh and frozen smoked finfish;
- Fresh and frozen crustaceans;
- Fresh and frozen molluscan shellfish, bivalves;
- Certain cheeses;
- Shell eggs;
- Nut butters; and
- Ready-to-eat deli salads.[6]

The Food Traceability Rule's additional recordkeeping requirements will apply not only to foods specifically listed on the FTL but also to foods that contain FTL foods as ingredients, provided the form of the food (e.g., fresh) has not changed. While the FDA considered comments regarding the contents of the FTL, the FTL did not change between the proposed and final rules. In response to stakeholder feedback, however, the FDA added additional descriptions to help industry understand the categories, as well as examples for further clarification.

The FDA recognizes that the FTL may evolve over time and has established a process for updates that includes public input. Based on recommendations in public comments, the agency intends to update the FTL every five years, based on available resources.[7] The agency will review new scientific data or other information that is relevant to the list, as well as the risk-ranking model. The agency may also provide updates sooner than five years, if warranted.[8] When the agency concludes that an update is necessary, it will publish a notice in the Federal Register for comment. After considering additional feedback and information, the agency will publish a second notice in the Federal Register identifying and explaining any changes. Any additions to the list would become effective two years after the date of the second notice, while any deletions would become effective immediately.

## Critical Tracking Events

The Food Traceability Rule focuses on key activities along the supply chain for which KDEs must be established, maintained, and/or shared. The final rule identifies the following CTEs for which records would be required:

- *Harvesting*: Activities that are traditionally performed on farms for the purpose of removing raw agricultural

commodities from the place they were grown or raised and preparing them for use as food.

- *Cooling (Before Initial Packing)*: Active temperature reduction of a raw agricultural commodity using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process.
- *Initial Packing of a Raw Agricultural Commodity Other Than a Food Obtained from a Fishing Vessel*: Packing a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time.
- *First Land-Based Receiving of a Food Obtained from a Fishing Vessel*: Taking possession of a food for the first time on land directly from a fishing vessel.
- *Shipping*: An event in a food's supply chain in which a food is arranged for transport (e.g., by truck or ship) from one location to another location.
- *Receiving*: An event in a food's supply chain in which a food is received by someone other than a consumer after being transported (e.g., by truck or ship) from another location.
- *Transformation*: An event in a food's supply chain that involves manufacturing/processing a food or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the FTL.[9]

In response to comments, the FDA revised the final CTEs significantly from the proposed rule to better align with industry practices and terminology. Among other things, "growing" was removed in favor of more the descriptive "harvesting" and "cooling." Similarly, "first receiver" was replaced with "initial packing" of a raw agricultural commodity (other than food obtained from a fishing vessel) and "first land-based receiver" for food obtained from a fishing vessel. In addition, "creating" was removed in the final rule because "transforming" already adequately captured activities that fell under it.

## Key Data Elements

As discussed above, KDEs are information associated with a CTE for which a record must be established, maintained and, at times, passed on. The KDEs will vary at each CTE but the records

will contain information necessary to effectively trace back a product based on the CTEs a firm performs. Not all KDEs are relevant for each CTE; however, firms that perform multiple CTEs would be required to maintain all the applicable KDEs to the CTEs they perform. The KDEs will link the traceability lot code of the food to the relevant KDE, allowing a food to be traced along the supply chain. This will assist regulators and industry in the case of a food safety event. The agency adopts an approach for maintaining and sharing specific KDEs that it believes aligns with consensus standards for traceability currently used by industry.[10] What follows is a summary of the KDE requirements; not all specific situations are addressed in this table (e.g., sprouts).

| **CTE** | **KDE** |
|---|---|
| Harvesting | • Location description for the immediate subsequent recipient (other than a transporter) of the food<br>• Commodity and, if applicable, variety of the food<br>• Quantity and unit of measure of the food<br>• Location description for the farm where the food was harvested<br>• For produce:<br>  • Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or<br>  • Other information identifying the harvest location at least as precisely as field or growing area name<br>• For aquacultured food:<br>  • Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or<br>  • Other information identifying the harvest location at least as precisely as the container name<br>• Date of harvesting<br>• Reference document type and reference document number |

| **CTE** | **KDE** |
|---|---|
| Harvesting *(continued)* | • Provide to the initial packer:<br>  • Business name<br>  • Phone number<br>  • Harvesting KDEs (except the reference document type and reference document number |
| Cooling | • Location description for the immediate subsequent recipient (other than a transporter) of the food<br>• Commodity and, if applicable, variety of the food<br>• Quantity and unit of measure of the food<br>• Location description for where you cooled the food<br>• Date of cooling<br>• Location description for the farm where the food was harvested<br>• Reference document type and reference document number<br>• Provide to the initial packer:<br>  • Cooling KDEs (except the reference document type and reference document number) |
| Initial Packaging | • Traceability lot code you assign<br>• Commodity and, if applicable, variety of the food received<br>• Date you received the food<br>• Quantity and unit of measure of the food received<br>• Location description for the farm where the food was harvested<br>• For produce:<br>  • Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or<br>  • Other information identifying the harvest location at least as precisely as field or growing area name<br>• For aquacultured food:<br>  • Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or |

| **CTE** | **KDE** |
|---|---|
| Initial Packaging *(continued)* | • Other information identifying the harvest location at least as precisely as the container name<br>• Business name and phone number for the harvester of the food<br>• Date of harvesting<br>• Location description for where the food was cooled (if applicable)<br>• Traceability lot code you assigned<br>• Product description of the packed food<br>• Quantity and unit of measure of the packed food<br>• Location description for where you initially packed the food (i.e., traceability lot code source), and (if applicable) the traceability lot code source reference<br>• Date of initial packing<br>• Reference document type and reference document number |
| First Land-Based Receiver of Food Obtained from a Fishing Vessel | • Traceability lot code you assign<br>• Species and/or acceptable market name for unpackaged food, or the product description for packaged food<br>• Quantity and unit of measure of the food<br>• Harvest date range and locations for the trip during which the food was caught<br>• Location description for the first land-based receiver (i.e., traceability lot code source), and (if applicable) traceability lot code source reference<br>• Date the food was landed<br>• Reference document type and reference document number |
| Shipping | • Traceability lot code for the food<br>• Quantity and unit of measure of the food<br>• Product description for the food<br>• Location description for the immediate subsequent recipient (other than a transporter) of the food<br>• Location description for the location from which you shipped the food |

| CTE | KDE |
|---|---|
| Shipping *(continued)* | • Date you shipped the food<br>• Location description for the traceability lot code source or the traceability lot code source reference<br>• Reference document type and reference document number (maintain only) |
| Receiving[11] | • Traceability lot code for the food<br>• Quantity and unit of measure of the food<br>• Product description for the food<br>• Location description for the immediate previous source (other than a transporter) for the food<br>• Location description for where the food was received<br>• Date you received the food<br>• Location description for the traceability lot code source or the traceability lot code source reference<br>• Reference document type and reference document number |
| Transformation when FTL food is used as an ingredient | • Traceability lot code you assigned<br>• Product description for the food to which the traceability lot code applies<br>• For each traceability lot used, the quantity and unit of measure of the food used from that lot |
| Transformation when a new food is produced | • New traceability lot code for the food<br>• Location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference<br>• Date transformation was completed<br>• Product description for the food<br>• Quantity and unit of measure of the food<br>• Reference document type and reference document number |

Like with the CTEs, the FDA made revisions to the originally proposed KDEs in response to stakeholder feedback. These revisions not only reflected changes to the associated CTEs but also simplified terminology and better aligned the KDEs with industry practices to foster compliance. For example, the final rule allows covered entities to define "lot" according to their business practices rather than creating a universal definition. Several changes

were made in response to comments expressing privacy concerns about information that would need to be shared with others in the supply chain. For example, the agency changed the proposed KDE of a "traceability lot code generator," which would have revealed personal information about an employee, to including in the final KDE for the location description a "traceability lot code source," which will only reveal the place the lot code was assigned. Similarly, the final rule removed "point of contact" as a required KDE and now only requires firms to identify a point of contact in their traceability plan, and that point of contact can be identified as a job title and phone number.

## Traceability Program Records

In addition to requiring records of KDEs, the final rule also requires anyone subject to the rule to establish and maintain a traceability plan. The plan must contain descriptions of how a firm maintains traceability program records (including relevant reference records for the KDEs), lists of food on the FTL that are shipped, description of how traceability lot codes are assigned, a statement identifying a point of contact regarding traceability plans and records, and other information needed to understand data provided within the required records. The traceability plan requirements also include farm maps showing locations and names of fields (or containers for aquaculture farms) where food on the FTL is grown (including geographic coordinates and other location information).

The final rule does not require that records be kept electronically or to communicate electronically, other than to provide an electronic, sortable spreadsheet with relevant tracing information when the FDA is investigating an outbreak, recall, or other threat to public health. Nevertheless, the agency encourages all those subject to the Food Traceability Rule to incorporate electronic recordkeeping and communication procedures into their traceability programs to facilitate and expedite the analysis of data and completion of traceback and traceforward operations.

## Exemptions

The final Food Traceability Rule includes a number of full and partial exemptions based on the type of entity and the type of food.

These exemptions can get complicated to interpret but include exemptions based on the size of the entity and whether or not the food will be further processed to include a "kill step" to control the potential hazard. While the final rule applies to restaurants and retail establishments, there are some exemptions for restaurants and retail establishments to accommodate business practices. The agency provides a tool to assist businesses in determining whether an exemption applies.[12]

## Providing Records to the FDA

Those subject to the final rule are required to keep records, as original paper or electronic records (or true copies). Records must be provided to the FDA within 24 hours of the agency's request, unless the FDA agrees to additional time.[13] Such a request can be written or by phone. When needed to assist the FDA in the event of an outbreak, recall, or other serious threat to public health, records must be provided to the FDA in an electronic, sortable spreadsheet, unless the firm is subject to a partial exemption from that requirement. Moreover, while the firm can keep its records in any language, they must be translated upon request within a reasonable time, as agreed to by the FDA.[14]

## Oversight and Enforcement

As with other FSMA rules the FDA is taking the "educate before and while it regulates" approach to enforcing this rule. The agency is still developing its compliance program and will work with its state and local regulatory partners to determine the best approach to conducting routine records inspections to ensure compliance. Violation of this rule is a prohibited act under the Federal Food, Drug, and Cosmetic Act and the agency can bring a civil or criminal action against one or more violative firms.[15] The agency can also enforce the rule by refusing entry of imported shipments of food.[16]

## Compliance Dates

The final compliance date for all persons subject to these recordkeeping requirements is January 20, 2026, three years after

the effective date of the final regulation.[17] While Congress directed the FDA to adopt staggered compliance dates based on size, the FDA determined that, because smaller firms and larger firms will potentially have to interact in the event of traceback and traceforward events, having different compliance dates would diminish the rule's effectiveness.[18] While the FDA had initially proposed a two-year compliance date for all firms, the agency added an extra year in the final rule to give industry more time to coordinate information sharing and make any needed changes to tracing systems. The extra year will also provide the FDA with additional time for outreach and training to industry to assist with these efforts.[19]

## The Future of Traceability

FDA Deputy Commissioner Frank Yiannis calls the lack of end-to-end traceability the "Achilles' heel" of the food system, and it is clearly his goal to help industry achieve this through regulatory and voluntary measures.[20] While the FSMA restricted the traceability requirements to certain foods and prevented the agency from prescribing specific technologies for maintaining records, the final rule establishes a framework for data that can be utilized throughout industry beyond the confines of the final rule.

To move toward this goal, the FDA launched the New Era of Smarter Food Safety initiative in July 2020.[21] This initiative seeks to build on the foundational requirements of the FSMA by leveraging technology and other tools and approaches to create a safer and more digital, traceable food system.[22] One component of this initiative specifically focuses on tech-enabled traceability. The Food Traceability Rule is the first step toward this end because it facilitates electronic data sharing by creating common terminology and a standard structure or format for traceability information that can be used by industry and regulatory partners.

Beyond the Food Traceability Rule, the New Era of Smarter Food Safety initiative encourages firms to voluntarily adopt tracing technologies and ways to harmonize tracing activities that will support end-to-end traceability throughout the food system. More specifically, the FDA seeks to create financial models that will enable human and animal food firms of all sizes to participate in a scalable, cost-effective way, focusing not on any particular technology but rather on interoperability across a variety of technology

solutions. This has resulted in the agency interacting with a wider range of stakeholders beyond the food industry itself. One noteworthy example is the FDA's "Low- or No-Cost Tech-Enabled Traceability Challenge" in June of 2021, the goal of which was to encourage participation from new types of stakeholders, including technology providers, entrepreneurs, and innovators to develop traceability hardware, software, or data analytics platforms that can be utilized by small and medium firms.[23]

Looking ahead, the agency will continue to work with all stakeholders, not only to ensure compliance with the Food Traceability Rule (we can expect additional tools for industry assistance) but also to find ways to encourage all stakeholders to embrace the foundational components of that rule to achieve end-to-end traceability. This includes working with international stakeholders to create a global traceability system with common standards and mechanisms for exchanging data that work through complicated supply chains. While this goal will not be reached in the short term, the food industry has a significant economic stake in the long term, as do consumers, who will be better protected if outbreaks and other food safety threats can be identified and contained more quickly.

## Notes

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1. *See* Final Rule 87 FR 70910.

2. Kiesel et al., E. Coli in the Romaine Lettuce Industry: Economic Impacts from the November 2018 Outbreak (July 2021) (estimating total societal losses of $280-$250 million as a result of the outbreak), https://kiesel.ucdavis.edu/Full%20Report.pdf.

3. Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information, 79 FR 6596 (Feb. 4, 2014).

4. FDA Report: Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223) (Aug. 2020), https://www.fda.gov/media/142247/download.

5. *See* Proposed Rule: Requirements for Additional Traceability Records for Certain Foods, 85 FR 59984, 59993 (Sept. 23, 2020).

6. 87 FR 70910, 70916-70917.

7. 87 FR 70910, 71050-71051.

8. *See id.*

9. *See* 21 CFR § 1.1310.

10. 87 FR 70910, 70913.

11. There are different KDEs for entities receiving FTL foods from suppliers that are exempt from the Food Traceability Rule, including assignment of a traceability lot code. 21 CFR 1.1345(b).

12. Traceability Exemptions Flow Chart, https://collaboration.fda.gov/tefcv13/.

13. 21 CFR § 1.1455(c)(1).

14. 21 CFR § 1.1455(c)(4).

15. 21 CFR § 1.1460(a).

16. 21 CFR § 1.1460(b) (citing FSMA § 801(a)).

17. 87 FR 70910, 70915.

18. 85 FR 60020.

19. 87 FR 70910, 71067.

20. Remarks by Frank Yiannas at the International Association for Food Protection 2020 Annual Meeting, Speech Transcript (Oct. 27, 2020), https://www.fda.gov/news-events/speeches-fda-officials/remarks-frank-yiannas-international-association-food-protection-2020-annual-meeting-10272020.

21. FDA web page: New Era of Smarter Food Safety, https://www.fda.gov/food/new-era-smarter-food-safety.

22. *See* FDA Report: New Era of Smarter Food Safety: FDA's Blueprint for the Future at 2 (July 2020), https://www.fda.gov/media/139868/download.

23. *See* FDA web page "Meet the Winners of FDA's Low- or No-Cost Food Traceability Challenge," https://www.fda.gov/food/new-era-smarter-food-safety/meet-winners-fdas-low-or-no-cost-food-traceability-challenge.

# What Is in the Environmental Protection Agency's Billion Dollar PFAS Reporting Rule?

Victor Y. Xu and James B. Pollack*

*In this article, the authors discuss a proposed reporting rule requiring U.S. manufacturers of any product containing per- and polyfluoroalkyl substances—known as PFAS—and any U.S. importer of articles containing any PFAS to investigate and certify to the Environmental Protection Agency the amount of PFAS that they have manufactured or imported into the United States for the past 12 years.*

Manufacturers and importers of products containing per- and polyfluoroalkyl substances—known as PFAS—will face new and substantial costs for recordkeeping and reporting if an Environmental Protection Agency (EPA) rule designed to collect comprehensive data on PFAS is finalized as proposed. The proposed reporting rule requires U.S. manufacturers of any product containing PFAS and any U.S. importer of articles containing any PFAS to investigate and certify to the EPA the amount of PFAS that they have manufactured or imported into the United States for the past 12 years (beginning January 1, 2011).[1] The EPA estimates industry-wide compliance costs to be up to $876 million and up to $1.8 million for each manufacturer or $224,000 for each article importer.[2]

Despite a year-end Congressional deadline,[3] the EPA is still working on the rule and has recently proposed several potential revisions, including revisions to exempt some small businesses and to narrow the set of PFAS covered by the rule. The EPA sought comments on the potential revisions through December 27, 2022.[4]

## EPA's Proposed PFAS Reporting Rule

The proposed PFAS reporting rule, issued June 28, 2021, applies broadly to any businesses that currently or previously manufactured or imported PFAS "between January 1, 2011 and the effective date of the final rule."[5] The rule covers manufacturers

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of PFAS chemicals as well as product manufacturers and product importers of articles containing PFAS. With the ubiquity of PFAS in consumer products—including apparel, food packaging, cookware, carpets, and even automobiles—this rule has the potential to cover large swaths of the economy. There is no exemption for businesses below a certain size. Manufacturers or importers that incidentally produce PFAS as a "byproduct" during the production or disposal of another substance or product are also required to report.[6] The only excluded entities in the proposed rule are manufacturers and importers of PFAS that are regulated under other statutes like the Food, Drug, and Cosmetic Act or the Federal Insecticide, Fungicide, and Rodenticide Act.[7]

The EPA issued the proposed rule under Section 8(a) of the Toxic Substances Control Act (TSCA), which authorizes the EPA to promulgate rules that require businesses to maintain and submit records on the production, import, processing, or mixture of specified chemicals.[8] In December 2019, Congress amended Section 8 of the TSCA to compel the EPA to promulgate a rule requiring PFAS manufacturers and importers to report information on PFAS produced or imported for every year since January 1, 2011.[9] Although Section 8(a)(1) of TSCA—the general grant of authority to the EPA to promulgate these sorts of reporting rules—contains an exemption for "small manufacturer[s] or processor[s],"[10] Congress's directive to the EPA to study PFAS was not so limited.

The EPA's proposed reporting rule raises many questions about how a product manufacturer or importer should collect and report such detailed information. The EPA provides only limited guidance on the topic. The EPA requires a covered business to supply the requested information to the extent any such information is "known to or reasonably ascertainable[.]"[11] When actual data are not available, the EPA will require a "reasonable estimate."[12] This is the same standard used in Chemical Data Reporting (CDR), for which the EPA has provided limited guidance: Information "[k]nown to or reasonably ascertainable by" the submitter means "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know."[13] Most importantly for purposes of compliance, the EPA expects a "case-by-case" and "complete" analysis in light of the submitter's "particular circumstances."[14] In the CDR guidance, the EPA provided several examples of information known or reasonably ascertainable, including marketing, sales, and customer-survey

files maintained by the submitter; information from standard references like material safety data sheets and safety data sheets; and information known to employees or other agents, including those in research and development, manufacturing, and marketing.[15] But in general, the contours of the reporting standard remain opaque. After all, information that is reasonably ascertainable to one business may be quite difficult for others to gather, especially where the source of the PFAS is from foreign or bankrupt suppliers.

## EPA's Recent Updates and Proposed Rule Changes

Although the EPA initially projected minimal costs of complying with the rule,[16] on November 25, 2022, it increased that estimate nearly 100 fold, releasing a report estimating industry-wide costs at $876 million. Small businesses subject to the rule are expected to bear the brunt of these reporting costs—over $863 million. Per-firm costs for manufacturers are estimated to range from $6,553 to $1.8 million, while per-firm costs for article importers are estimated to range from $4,046 to $224,734.

The EPA's new cost estimates were released as part of the EPA's obligations under the Regulatory Flexibility Act, a law designed to provide small businesses with more input on administrative action.[17] Any agency rule having a significant economic impact on a substantial number of small businesses must be accompanied by a report called an initial regulatory flexibility analysis (IRFA).[18] IRFAs must contain, among other things, a description of the number of small businesses that could be affected by the proposed rule and a description of any "significant alternatives to the proposed rule" that "accomplish the stated objectives" while minimizing economic effects on small businesses.[19]

In the PFAS reporting rule IRFA, the EPA proposed several compliance alternatives to the broadly applicable proposed rule. Those alternatives, which could be adopted in any combination the EPA chooses, include:[20]

- *Limiting the Scope of Chemicals Subject to the Rule to a Finite List of PFAS*. The proposed rule covered any PFAS that meet a structural formula. The EPA is considering limiting reporting to a discrete list of PFAS instead.

- *Exemptions for Research and Development Substances, Byproducts, Impurities, Recyclers, and Intermediates*. The EPA is considering whether to implement these exemptions from the regular Chemical Data Reporting process.
- *Exemption for Small Businesses*. The EPA is considering exemptions for businesses with less than $6 million or $12 million in sales.
- *Exemption for Article Importers*. The EPA is considering exemptions for article importers with less than $2 million or $6 million in sales.
- *Reporting Threshold*. The EPA is considering a reporting threshold of either 2,500 lbs. per year or 25,000 lbs. per year.
- *Longer Reporting Timeline for Small Businesses*. The EPA is considering extending the reporting deadline of 12 months post-final rule to 18 months for small businesses.
- *Simplified Reporting Forms*. The EPA is considering limiting required reporting for two subsets of businesses: those dealing in R&D substances manufactured in volumes of less than 10 kg per year and article importers.

The EPA also shed light on how it would implement the "known or reasonably ascertainable" reporting standard, though the exact bounds of the required inquiry remain quite vague. The EPA clarified that "[s]ubmitters need not conduct extensive supply chain surveys," but that some "inquiries outside the organization (e.g., contacting first tier/immediate suppliers, major suppliers, examining a supplier's public website)" could be necessary if the submitter's current knowledge is less than what a similarly situated reasonable submitter might be expected to have.[21] And submitters must conduct their inquiries "within the full scope of their organization," not simply within the ambit of "managerial or supervisory employees."[22] But submitters would not necessarily need to conduct an "exhaustive survey of all employees," and they need not contact former employees. Nor will submitters need to perform chemical analyses on articles or products for PFAS or generate new data not presently known to or reasonably ascertainable by the submitter.

## Notes

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1. Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33926 (proposed June 28, 2021) (to be codified at 40 C.F.R. pt. 705). The rule also covers manufacturers and importers of PFAS chemicals or chemical mixtures containing PFAS.

2. *See* U.S. EPA, Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances at 1 (2022) [hereinafter IRFA]. Although the rule is a "one-time" reporting of data since 2011, the data will influence EPA's future regulatory actions as part of the PFAS Strategic Roadmap. *See* IRFA 23 ("As EPA learns more about the family of PFAS, the Agency can do more to protect public health and the environment."); U.S. EPA, PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024 (2021), https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024.

3. National Defense Authorization Act for Fiscal Year 2020, Pub. L. 116-92, section 7351 (codified at 15 U.S.C. § 2607(a)(7)).

4. TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment, 87 Fed. Reg. 72439 (proposed Nov. 25, 2022).

5. 86 Fed. Reg. at 33926-27.

6. 86 Fed. Reg. at 33927, 33937.

7. 86 Fed. Reg. at 33927.

8. 15 U.S.C. § 2607(a).

9. National Defense Authorization Act for Fiscal Year 2020, Pub. L. 116-92, section 7351; 15 U.S.C. § 2607(a)(7).

10. 15 U.S.C. § 2607(a)(1).

11. 86 Fed. Reg. at 33931; *see also* 15 U.S.C. § 2607(b)(2).

12. 86 Fed. Reg. at 33931.

13. U.S. EPA, Instructions for Reporting 2020 TSCA Chemical Data Reporting at 4.2 (2020), https://www.epa.gov/sites/default/files/2020-12/documents/instructions_for_reporting_2020_tsca_cdr_2020-11-25.pdf; *see also* 40 C.F.R. § 704.3.

14. U.S. EPA, Instructions for Reporting 2020 TSCA Chemical Data Reporting at 4.2 (2020), https://www.epa.gov/sites/default/files/2020-12/documents/instructions_for_reporting_2020_tsca_cdr_2020-11-25.pdf.

15. *See supra* note 13.

16. *See* IRFA at 1.

17. 5 U.S.C. §§ 601 *et seq.* "Small business" is defined according to the Small Business Act. *See generally* 13 C.F.R. pt. 121; IRFA at 47-48.

18. 5 U.S.C. § 603.

19. 5 U.S.C. § 603(b), (c).

20. IRFA at 56-71.

21. IRFA at 7.

22. IRFA at 8.

# New Reimbursement Rules from Centers for Medicare & Medicaid Services Will Likely Impact Digital Health and Telemedicine

Jamie Ravitz, David Hoffmeister, Georgia Ravitz, Eva Yin, Paul Gadiock, Kathleen Snyder, and Jeff Weinstein*

*In this article, the authors discuss a final rule issued recently by the Centers for Medicare & Medicaid Services that contains significant changes for telehealth, digital remote therapeutic monitoring, and behavioral health providers.*

The Centers for Medicare & Medicaid Services (CMS) has issued the 2023 Physician Fee Schedule (PFS) Final Rule.[1] CMS publishes a PFS annually so as to make changes in federal healthcare reimbursement and policy. PFS changes often spill over into the private sector, as private payors typically consult the PFS when evaluating their own payment and policy arrangements. The new Final Rule, like its yearly predecessors, address widely varied issues across the Medicare program, including an overall provider fee cut and changed policies relating to Evaluation and Management Visits and in many other areas. The Final Rule includes several rules relating to coverage and payment for in three areas of particular interest to our clients: telehealth services, digital remote therapeutic monitoring (RTM), and behavioral health services. The Final Rule also addresses changes to expect after the COVID-19 public health emergency (PHE) expires. This article discusses a few notable developments in each of these areas.

## Telehealth Services

As part of the U.S. Department of Health and Human Services' strategy for addressing the PHE ongoing since 2020, CMS expanded use—and reimbursement—of Medicare telehealth services. CMS

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did so chiefly by means of "flexibilities": temporary waivers of narrow restrictions that otherwise apply to delivery of, and payment for, Medicare telehealth. Critical to the expansion of telehealth during the PHE have been flexibilities that allow telehealth services to be furnished in any geographic area and in any originating site setting (including the beneficiary's home); allow some services to be furnished via audio-only telecommunications systems; and allow physical therapists, occupational therapists, speech-language pathologists, and audiologists to furnish telehealth services.

Nearly three years into the PHE, the Final Rule sets out a path toward rescinding many current flexibilities in a manner that will provisionally confine and limit the scope of Medicare telehealth in the future. The Final Rule requires that patients again be physically present in an originating site—an office, clinic, or medical facility within a rural area—for most telehealth services. Medicare reimbursement for telehealth visits furnished by physical therapists, occupational therapists, speech language pathologies, and audiologists will no longer be allowed. The only Medicare services that will be permitted to be furnished audio-only will be mental health telehealth services. The Final Rule establishes a time frame for withdrawal of these flexibilities after 151 days following the declared end of the PHE. The Final Rule follows the schedule that Congress established for temporarily extending the telehealth flexibilities in March 2022 legislation.[2]

The Final Rule leaves open the possibility that some flexibilities may eventually be adopted permanently. Some important flexibilities under the PHE will be allowed to extend further past the end of the PHE in order to allow additional time for the collection of data that may support their inclusion as permanent additions to the Medicare telehealth services. For example, telehealth services requiring the "direct supervision" of a physician (i.e., physical presence in the same office suite as the auxiliary provider and the ability to immediately provide assistance and direction) are reimbursable under the PHE provided that the supervising professional has "virtual presence" via real-time interactive audio-video technology. CMS states that it will continue to permit direct supervision through virtual presence through at least the end of 2023, or any subsequent calendar year in which the PHE ends. CMS states that the information and evidence on virtual supervision, which it continues to gather, may guide future rulemaking in this area.

## Remote Therapeutic Monitoring

RTM is designed for remote patient treatment management using medical devices that collect non-physiological data. Data relating to key treatment-related criteria such as therapy/medication adherence, therapy/medication response, and pain level can be collected and billed remotely under RTM codes that CMS introduced into use at the start of 2022. (RTM must not be confused with similarly named remote patient monitoring—RPM—which collects physiological data.) The Final Rule establishes a new RTM device supply code for Cognitive Behavioral Therapy Monitoring, opening the door to additional RTM use cases. Most notable about the Final Rule's treatment of RTM may be the way that it broadly relaxes supervision requirements. Physicians are currently required to directly supervise "incident to" RTM billed under the physician's enrollment, in which clinical staff use data from medical devices to manage and monitor patient health. Starting in January 2023, physicians no longer need to be in the same building as clinical staff to satisfy the "general supervision" requirement and would be able to supervise virtually. The Final Rule declined to undertake some proposed changes that were expected to facilitate further Medicare expansion in this area. CMS opted neither to introduce a generic RTM device supply code that is condition/system agnostic nor to establish four new Healthcare Common Procedure Coding Systems (HCPCS) G-codes that providers could use when billing provision of RTM services by auxiliary staff.

## Behavioral Health Services

In its 2022 Behavioral Health Strategy,[3] CMS pledged to "improve access to high quality, affordable, person-centered behavioral health care, and ensure parity in access, coverage, and quality for physical and mental health services, including care enabled through telehealth and technology."

The Final Rule acts on the pledge by establishing multiple provisions expanding access to behavioral healthcare. Starting January 2023, marriage and family therapists, licensed professional counselors, and other types of auxiliary behavioral healthcare providers may provide "incident to" services to patients under general supervision of physician or non-physician practitioner, rather than

under direct supervision. As explained in the preceding section, this would allow auxiliary providers to furnish services to patients without the supervising practitioner being physically present to administer immediate assistance. However, the general supervision standard still requires that the services be performed under the supervisory practitioner's "overall direction and control."[4] Supervisory practitioners are still responsible for the training of the auxiliary providers performing the procedure and ensuring the quality and reliability of services performed.

CMS also finalized reimbursement of clinical psychologists and licensed clinical social workers as part of an integrated care team under code G0323. The new code requires "at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems. . . ." Requirements stipulate that, to be reimbursed, services must involve treatment coordination with and/or referral to physicians and practitioners authorized by law to prescribe medications, provide emergency services, and counseling and/or psychiatric consultation.

## Conclusion

The Final Rule contains significant changes for telehealth, RTM, and behavioral health providers. These include new codes that will afford additional use cases, and loosened supervision requirements that, in the case of RTM and behavioral health, should broaden opportunities for furnishing of incident to services by clinical staff and auxiliary providers. The Final Rule seems to anticipate further growth in these areas and aims to facilitate it. Concerning telehealth, the Final Rule largely provides for phased retrenchment following the end of the PHE. The Final Rule also leaves open the possibility that some aspects of the temporary expansion of telehealth under the PHE, such as virtual supervision may be permanently established by future rulemaking. Prospects for telehealth, RTM, and behavioral health companies in the context of the Medicare program and beyond will be greatly affected by the provisions of the Final Rule.

## Update

On December 29, 2022, President Biden signed into law omnibus legislation that extends the telehealth flexibilities through December 31, 2024.[5] Among the flexibilities extended for two years will be Medicare reimbursement for telehealth services furnished in any area and at any originating site; telehealth services through audio-only telecommunications; and the expanded list of telehealth practitioners, including therapists, speech-language pathologists, and audiologists. CMS is expected to undertake new rule-making in the coming months that will conform agency policy concerning telehealth flexibilities to the extended timeframe set out in the recent law. The extension of flexibilities under statute will afford CMS time for further consultation with legislators and stakeholders about the potential for basic changes in Medicare telehealth.

## Notes

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1. https://www.federalregister.gov/documents/2022/11/18/2022-23873/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other. CMS prepared a helpful summary of highlights from the Final Rule, available at https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2023-medicare-physician-fee-schedule-final-rule.
2. Consolidated Appropriations Act of 2022 § 301.
3. https://www.cms.gov/cms-behavioral-health-strategy.
4. *See, e.g.*, 42 C.F.R. § 410.32(b)(3)(i).
5. Consolidated Appropriations Act of 2023 § 4113.

# Department of Health and Human Services Offers HIPAA Guidance on Online Tracking Technologies

Paul Bond, Shannon Britton Hartsfield, Ilenna J. Stein, and Mark S. Melodia*

*In this article, the authors discuss the steps that healthcare companies can take both to comply with new guidance issued by the U.S. Department of Health and Human Services' Office of Civil Rights and to mitigate litigation and regulatory risk.*

For years, patients and healthcare companies have been wrestling with privacy issues relating to cookies, pixels, and other tracking technologies. The U.S. Department of Health and Human Services' (HHS) Office of Civil Rights (OCR), which enforces the Health Insurance Portability and Accountability Act (HIPAA), has not substantially involved itself in this prolonged and public debate until now. As described below, the OCR has now spoken loudly. Without public comment, the OCR has issued a bulletin (the Bulletin) that may profoundly impact this debate.

More specifically, since at least the turn of the millennium, plaintiffs and their class action lawyers have alleged that tracking tools on websites and apps infringe on consumer privacy by allowing third parties to snoop without ordinary people understanding what information about them is being shared with others. Over at least the past several years, the focus has shifted to claims that healthcare companies specifically are improperly disclosing patient confidences by integrating into the code on their public websites digital advertising, analytics, and even security tools provided by Meta (formerly Facebook), Google, and lesser-known third parties not operating under Business Associate Agreements (BAAs). Healthcare companies have pushed back, stating that these tools are ubiquitous on the internet and serve legitimate business purposes, including security, improving website function and design, and guiding targeted outreach to the public, particularly during public

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health crises like a pandemic. Further, healthcare companies have argued that unless a patient actually logs into a patient portal, the healthcare company has no way of knowing if the person is a patient versus, for example, a family member or caretaker of a patient, a job applicant, a researcher, or even a bot. A wave of class actions have been filed in 2022, typically seeking many millions in statutory damages under state wiretap act laws, and each potentially turning on how much privacy is expected when a member of the general public uses a website provided by a healthcare company. From a regulatory perspective, some companies have concluded that device identifiers and internet protocol (IP) addresses of website visitors are not protected under HIPAA, while others have limited or even removed third-party trackers from their websites.

## The Bulletin on Tracking Technology

The Bulletin indicates that websites and mobile applications that use tracking technology could put healthcare companies at risk of privacy violations, even those websites and mobile apps for which no login is required (unauthenticated). The Bulletin applies to a broad range of healthcare companies—not just providers but also health plans, app developers working with them and others. The Bulletin uses a similarly broad brush to define the information with which it is concerned, emphasizing that all data elements that could be protected health information (PHI)—particularly identifiers listed in the so-called de-identification safe harbor—must be protected in the digital environment. If those identifiers, no matter how innocuous they seem, are going to third parties via tracking technology, covered entities and business associates need to ensure that the PHI is protected with appropriate BAAs or patient authorizations.

The Bulletin addresses tracking technologies in detail, and discusses how the HIPAA rules apply to the use of such technologies in connection with user-authenticated web pages, unauthenticated web pages, and mobile apps. HIPAA protects any unique identifying code relating to an individual if it relates to their healthcare. An individual's IP address, geographic location, dates of appointments, and a number of other data elements are PHI under HIPAA if they relate to the individual's condition, care, or payment. Information

is not considered to be completely de-identified unless a qualified expert documents that it is or all identifiers are completely removed.

The Bulletin presumes that when a regulated entity collects individually identifiable health information (IIHI) through a website or mobile app, the individual is automatically connected to that entity, and that connection "is indicative that the individual has received or will receive healthcare services or benefits from the covered entity." The Bulletin assumes that any website or app visitor who is tracked is or will be a patient, even though there are many reasons why a member of the public might visit a particular website, such as to apply for a job or locate a friend who works at the facility. This assumption, which runs contrary to fact and everyday experience, is exactly the same overgeneralization that plaintiffs and class action counsel are urging courts across the country to accept as true.

## Technology Risks

According to the Bulletin, tracking on user-authenticated websites carries significant risk, since the tracking technologies within such pages may have access to detailed treatment information. Even tracking tools on unauthenticated websites can involve disclosure of PHI, according to the OCR's new guidance. The Bulletin provides, as an example, a visitor on an unauthenticated web page. This person has not logged in or identified themself in any way, but the web page includes third-party tracking technology that captures clickstream data and the IP address. If this visitor seeks out information related to specific health conditions (the Bulletin mentions pregnancy and miscarriage) or uses website functionality to search for doctors or schedule appointments, the tracking technology may have access to PHI in the OCR's view. The Bulletin indicates that a regulated entity's mobile app that collects network location, geolocation, device IDs, or advertising IDs would be collecting PHI.

If HIPAA covered entities and business associates use tracking technology, the Bulletin indicates that they must do the following:

- Make sure that all disclosures of PHI are permitted by the Privacy Rule and, unless an exception applies, are the minimum necessary;

- Ensure that they have applicable permission prior to any disclosure of PHI and that the tracking vendor has signed a HIPAA BAA or that the patient signs a HIPAA-compliant authorization prior to the disclosure;
- Even if the vendor does not save the PHI or removes PHI before saving data, the disclosure still requires a signed BAA and permissible purpose; and
- Analyze the tracking technologies in the entity's HIPAA Risk Analysis and Risk Management process and ensure that transmitted PHI is properly secured.

## Breach Risk Assessments

The Bulletin indicates that, unless there is a BAA with the vendor or some other HIPAA-compliant pathway, disclosure of PHI to a tracking technology vendor "that compromises the security or privacy of PHI" is a breach. Additionally, the vendor must actually meet the definition of a business associate for the healthcare company to avail itself of the BAA exception. For example, signing a BAA with a third party that plans to use the PHI for its own marketing purposes will not prevent a PHI disclosure from constituting a breach. A breach requires notice to affected individuals, HHS and, in certain cases, the media. The HIPAA rules provide that most impermissible uses or disclosure of PHI are "presumed to be a breach" unless the covered entity or business associate demonstrates, based on a risk assessment, "that there is a low probability that the protected health information has been compromised." The regulations require an assessment of at least four specific factors.[1] A risk assessment based on tracking technology should consider the following.

### The Nature and Extent of the PHI Involved, Including the Types of Identifiers and the Likelihood of Reidentification

Tracking technologies could capture a number of data elements that could constitute IIHI, including device IDs, advertising IDs, geographic location, and IP address. These could constitute PHI, so the risk assessment would need to determine the likelihood that these identifiers could identify an individual or the individual's household member. For example, an IP address associated with a

public computer in a library might not be PHI, but an IP address associated with a particular private device would be. To the extent the tracking device collected direct identifiers—including names, medical record numbers, home addresses, and email addresses—that factor would be more likely to suggest a compromise of PHI. Additionally, the fact that a person with a particular device clicked on a hospital's home page might not suggest more than a low probability of compromise, but if that individual clicked on a website of a psychiatric facility or a specialty medical center, it could suggest compromise.

Not all improper disclosures of PHI are automatically a breach. For example, in the preamble to the 2013 HITECH Act omnibus rule, the OCR indicated that an impermissible disclosure of a list of patient names, addresses, and hospital identification numbers is likely to result in a determination that PHI has been compromised, depending on an assessment of the additional factors below. On the other hand, if the only PHI disclosed was "a list of patient discharge dates and diagnoses, the entity would need to consider whether any of the individuals could be identified based on the specificity of the diagnosis, the size of the community served by the covered entity, or whether the unauthorized recipient of the information may have the ability to combine the information with other available information to re-identify the affected individuals."[2] Even if this factor suggests a low probability of compromise due to the limited nature of the PHI, the regulated entity must still consider the factors below before deciding whether to provide breach notification.

### The Unauthorized Person Who Used the PHI or to Whom the Disclosure Was Made

If the tracking vendor is a HIPAA business associate that, through a simple mistake, did not sign the BAA or is an entity that otherwise has obligations to protect the privacy and security of the information, such factors could indicate a low probability of compromise. If the vendor is a social media company or search giant that is able to easily combine the PHI with other data it holds to identify an individual, however, then the PHI may be compromised. If the recipient used the PHI for marketing or other impermissible purposes, that would be further evidence of potential compromise.

### Whether the PHI Was Actually Acquired or Viewed

If the tracking is accomplished through software that does not result in a transfer of PHI to a third party, there may not be a breach. If the tracking vendor receives the PHI, however, there could be a compromise.

### The Extent to Which the Risk to the PHI Has Been Mitigated

There could be circumstances where PHI is disclosed to a tracking vendor, but the situation is mitigated sufficiently so as not to constitute a compromise of the PHI, potentially. For example, if the tracking vendor receives PHI for the regulated entity's healthcare operations purpose, but no signed BAA is in place, a risk assessment may be able to determine a low probability of compromise if the recipient has only further used and disclosed the PHI for a HIPAA-permissible purpose and is otherwise in compliance with HIPAA's requirements for business associates. The OCR has indicated that an entity is a business associate if it meets the definition, even if it fails to enter into a BAA.[3] Therefore, it is conceivable that entering into a BAA and obtaining written assurances from the vendor that it has only used and disclosed PHI in accordance with HIPAA could potentially assist with a conclusion of a low probability of compromise.

## If the Tracking Technology Is a "Breach," What Then?

If the tracking technology involves a disclosure of PHI in a manner that does not comply with HIPAA and the regulated entity is unable to demonstrate a low probability of compromise, the regulated entity, if it is a business associate, must notify the relevant covered entity. Covered entities must notify the affected individuals no later than 60 calendar days after discovery of the breach.[4] A breach is considered to be "discovered" on the first day on which it is known to the covered entity or, by exercising reasonable diligence, would have been known. Arguably, for a number of covered entities using these tracking technologies, December 1, 2022, probably starts the clock ticking. It may have started much

earlier, as the potential risks of these technologies has been widely reported and have also been the subject of litigation, even though the OCR has chosen until now not to share its views on this contentious topic. The notices must include certain provisions required by the HIPAA rules and must be sent by first-class mail to the individual's last known address, or it could be sent by electronic mail if the individual agrees to electronic notice and such agreement has not been withdrawn.

Regulated entities may be collecting IIHI from individuals who have not yet received healthcare services or benefits from the covered entity. The Bulletin suggests that the fact that an individual merely connects to the website indicates that the individual may have or will receive services or benefits "and thus relates to the individual's past, present, or future healthcare or payment for care." It is likely that an entity's website could have thousands or millions of visits from individuals who do not, in fact, have a relationship with the entity and for whom the entity has no contact information. In situations where a covered entity has insufficient or out-of-date contact information but still concludes following the risk analysis that notice is required, the covered entity must provide substitute notice combined with actual mailed notice for any persons for whom adequate contact information exists. If 10 or more individuals have insufficient contact information, the entity can provide substitute notice either by (1) conspicuously posting a notice on the home page of its website for 90 days or (2) providing conspicuous notice in major print or broadcast media in geographic areas where the affected individuals likely reside.

Breaches also require notices to the HHS secretary. Media notice is mandated for breaches involving PHI of more than 500 residents of a state or jurisdiction. Depending on the nature of the information breached, there may be additional notice requirements under state law.

## Likely Litigation Results

While the Bulletin's content, by its own terms, "do not have the force and effect of law and are not meant to bind the public in any way," it will likely be cut and pasted into hundreds of class action lawsuits in 2023, and cut and pasted again in as many briefs by class action counsel fending off motions to dismiss. The Bulletin

reflects the (counterfactual) view that use by the general public of healthcare company websites and apps is tantamount to evidence of a patient relationship, and that even without the user logging in or identifying themselves, PHI may be created. Further, the Bulletin provides *dicta* without any factual findings or chance for public comment that disclosure of such information "may result in identity theft, financial loss, discrimination, stigma, mental anguish, or other serious negative consequences to the reputation, health, or physical safety of the individual or to others identified in the individual's PHI."

Between the Bulletin and the avalanche of breach notices it seems likely to set off, the existing litigation on these issues seems likely to grow in the near term. In addition, while HIPAA has no private right of action, the OCR's new guidance creates additional risk for healthcare companies by inviting individuals who believe their health privacy rights have been violated to file a complaint with the OCR.

## Compliance and Strategy Implications

In addition to making any required breach notifications, healthcare companies should also work with their privacy and security departments as well as counsel to assess and mitigate ongoing risk. Indeed, per the Bulletin, healthcare companies must now take steps "addressing the use of tracking technologies in the regulated entity's Risk Analysis and Risk Management processes."

Healthcare companies must know and reassess their strategy with respect to third-party tracking. This should include:

- Inventory of current third-party tracking activity on websites and apps;
- Assessment of tracking against the Bulletin's guidance;
- Considering removing tracking technologies or limiting their placement on certain sensitive pages;
- Considering changes to technology used or configuration to reduce information provided to third-party trackers;
- Executing compliant BAAs and/or obtaining specific HIPAA-valid patient authorizations in advance of individuals engaging with a website; and

- Evaluating and improving governance over new websites and mobile apps for compliance purposes, including hardening of procurement and vendor oversight programs and the development of rules of the road for healthcare information technology, marketing and digital teams.

Healthcare companies can take these reasonable steps to both comply with this new guidance and mitigate litigation and regulatory risk.

## Notes

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1. 45 C.F.R. § 164.402.
2. Final Rule, OCR, HHS, "Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5566, 5642-43 (Jan. 25, 2013).
3. *Id.* at 5574.
4. 45 C.F.R. § 164.404.

# Federal Acquisition Regulatory Council's Proposed Rule on Greenhouse Gas Emissions Would Impose Significant Compliance Obligations on Federal Contractors

Richard B. Oliver, Matt Carter, Alex D. Tomaszczuk, Michael S. McDonough, and Jeffrey A. Knight*

*In this article, the authors explain that the Federal Acquisition Regulatory Council recently issued a far-reaching proposed rule that includes significant compliance obligations for contractors related to their greenhouse gas emissions.*

The Federal Acquisition Regulatory Council (FAR Council) recently issued a proposed rule,[1] implementing Section 5(b)(i) of Executive Order 14030 (Climate-Related Financial Risk), that would require most federal contractors to make disclosures and representations regarding their greenhouse gas (GHG) emissions and certain contractors to also set science-based targets to reduce those emissions. The proposed rule adopts the definition of GHG from Federal Acquisition Regulation (FAR) 23.001, which defines GHG as carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, nitrogen trifluoride, and sulfur hexafluoride.

The proposed rule would apply to "major" and "significant" contractors. A "major contractor" is defined as any entity that received more than $50 million in federal contract obligations in the prior fiscal year. A "significant contractor" is defined as any entity that has received $7.5 million or more (but less than $50 million) in federal contract obligations in the prior fiscal year. Accordingly, small businesses receiving as little as $7.5 million in awards are covered by the proposed rule. All small businesses that meet the $7.5 million threshold are to be treated as "significant contractors," so the additional obligations that apply to "major contractors"

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(discussed below) would not apply to small businesses. Further, all contractors would have to certify on SAM.gov whether they are or are not a major or significant contractor and, if so, represent their compliance with the three obligations discussed below.

## Obligations

The proposed rule includes three main obligations. First, the proposed rule would require both major and significant contractors to prepare an annual GHG inventory of their "Scope 1" and "Scope 2" GHG emissions. Scope 1 emissions include GHG emissions from sources that are owned or controlled by the contractor. Scope 2 emissions are those GHGs "associated with the generation of electricity, heating and cooling, or steam, when these are purchased or acquired for the reporting company's own consumption but occur at sources owned or controlled by another entity." Major and significant contractors must also disclose their GHG inventory on SAM.gov. In terms of calculating GHG emissions, the proposed rule provides that contractors "may calculate emissions using the calculation tool of their choice, as long as it is in alignment with the GHG Protocol Corporate Accounting and Reporting Standard" and directs contractors to the Environmental Protection Agency's simplified GHG emissions calculator.[2]

The second obligation, which applies only to major contractors, is a requirement to complete an annual climate disclosure and make the disclosure available on a publicly accessible website (e.g., the contractor's own website). The disclosure must include the contractor's GHG inventory of Scope 1 and Scope 2 emissions, and any "relevant Scope 3 emissions, which are [GHG] emissions that are a consequence of the operations of the reporting entity but occur at sources other than those owned or controlled by the entity," such as the sources in its supply chain. The disclosure also must describe the contractor's climate risk assessment process and any risks that it has identified. The proposed rule provides that the disclosure obligation may be fulfilled by completing a questionnaire through the Carbon Disclosure Project or CDP,[3] a nonprofit entity that runs a global environmental disclosure system.

The third obligation, which also applies only to major contractors, is a requirement to develop science-based targets and have the targets validated by the Science-Based Targets initiative (SBTi).[4]

The proposed rule defines a "science-based target" as "a target for reducing GHG emissions that is in line with reductions that the latest climate science deems necessary to meet the goals of the Paris Agreement to limit global warming to well below 2°C above pre-industrial levels and pursue efforts to limit warming to 1.5°C." The contractor's targets must be validated by the SBTi within the previous five calendar years and must also be made available on a publicly accessible website.

A contractor's obligation to prepare its GHG inventory will begin one year after the publication of the final rule. The obligations specific to major contractors will begin two years after the publication of the final rule.

## Exceptions

With respect to exceptions, a significant or major contractor is not required to prepare a GHG inventory of its Scope 1 or Scope 2 emissions and a major contractor is not required to complete an annual climate disclosure or set science-based targets for GHG reduction, if the contractor is a(n):

1. Alaska Native Corporation, Community Development Corporation, Indian tribe, Native Hawaiian Organization, or Tribally owned concern;
2. Higher education institution;
3. Nonprofit research entity;
4. State or local government; or
5. Entity deriving 80 percent or more of its annual revenue from federal management and operating contracts that are subject to agency annual site sustainability reporting requirements.

Finally, the proposed rule includes new procedures for determining responsibility under FAR 9.104-3. If a contractor's SAM representations indicate that it is a significant or major contractor and that it is not in compliance with its obligations under the proposed rule, then the contracting officer is directed to follow new procedures set forth at FAR 9.104-3(e). In that regard, under these new procedures, contracting officers must *presume* that the contractor is nonresponsible, unless the contracting officer can establish the following:

1. The contractor's noncompliance resulted from circumstances properly beyond its control;
2. The contractor has provided sufficient documentation that demonstrates substantial efforts to comply; and
3. The contractor has made a public commitment to comply as soon as possible on a publicly accessible website (within one year).

## Notes

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1. https://www.federalregister.gov/documents/2022/11/14/2022-24569/federal-acquisition-regulation-disclosure-of-greenhouse-gas-emissions-and-climate-related-financial.
2. https://www.epa.gov/climateleadership/simplified-ghg-emissions-calculator.
3. https://www.cdp.net/en/guidance.
4. https://sciencebasedtargets.org/faqs#what-are-science-based-targets.

# Department of Labor's Office of Federal Contract Compliance Programs Proposes Significant Changes to Compliance Review Scheduling Letter and Itemized Listing

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*In this article, the authors summarize key proposed changes requested by the Department of Labor for documents that initiate audits by the Office of Federal Contract Compliance Programs.*

The U.S. Department of Labor's Office of Federal Contract Compliance Programs (OFCCPs) has submitted a request[1] to the Office of Management and Budget (OMB) for reauthorization of its compliance review scheduling letter and accompanying itemized listing,[2] that is, the documents that initiate OFCCP audits. The proposed changes, which OFCCP maintains will better facilitate its review of contractor establishments, would substantially increase the initial response burden on contractors selected for audit in a number of areas. The changes also reflect OFCCP's continued heightened focus on enforcement nearly two years into the Biden administration, particularly with respect to contractor compensation, personnel selection decisions, and outreach and recruitment. This article summarizes the key proposed changes and the impact on contractors.

## Expanded Compensation Submission

The proposed revisions to the itemized listing substantially expand the compensation-related data and information that contractors would be required to provide at the outset of an audit, as discussed below.

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## Prior Year Compensation Data

Currently, contractors are required only to provide current year compensation data. The revised itemized listing would also require submission of prior year compensation data. In its justification[3] for the changes, OFCCP notes that while the agency has the authority to review employment activity data covering the two years preceding the initiation of the compliance review, its existing practice is to request this data only after a desk audit reveals a potential disparity. The agency perceives the current practice as an "inefficient" approach and asserts that "reviewing more data during the desk audit will allow OFCCP to better identify whether there is systemic pay discrimination happening at a contractor's workforce and whether the potential discrimination was ongoing prior to the first snapshot."

## Compensation Data for Staffing Agency Employees

The proposed revisions would require contractors to provide two years of compensation data for "temporary employees, *including those provided by staffing agencies*" (emphasis added). This would also include data regarding factors that impact compensation of such employees. This expansion should be of concern to contractors who use temporary staffing agencies to augment their workforce, particularly because in many (if not most) cases, contractors do not determine compensation for staffing agency employees and may not even know the wage rates for such employees.

## Expanded Compensation Factor Data and Supporting Documentation

The itemized listing would be expanded to identify additional compensation factors and supporting documentation for contractors to produce with their initial submission. Among the items that contractors would now be expected to provide the agency are expanded factors used to determine employee compensation (such as education, experience, location, and time in current position) as well as policies that outline and explain compensation practices, listing as examples "policies, guidance, or trainings regarding initial compensation decisions, compensation adjustments, the use

of salary history in setting pay, job architecture, salary calibration, salary benchmarking, compensation review and approval."

### Proof of Compliance with Obligation to Analyze Compensation

OFCCP's revised Directive 2022-01,[4] which addressed contractors' obligation to comply with 41 CFR 60-2.17(b)(3) and its requirement that contractors perform an annual in-depth analysis of their compensation systems, included a list of the minimum documentation the agency would require from contractors to demonstrate compliance. The revised itemized listing would require contractors to produce that documentation at the outset of an OFCCP audit.

## Augmented Personnel Activity Data Requests

OFCCP also proposes to collect expanded data from contractors relating to personnel activity, in particular promotions and terminations. This indicates a clear shift from the agency using high-level data at the outset of the audit to identify potential areas for follow-up relating to personnel activity, to conducting a "deep dive" analysis from the start. If OMB approves this expansion, contractors would be required to, among other things:

1. Break out competitive and noncompetitive promotions (whose definitions OFCCP invites the public to comment on);
2. Provide employee-level promotion data, including race/ethnicity, gender, previous and current supervisors, previous and current compensation, department, and job title; and
3. Employee-level termination data, including race/ethnicity, gender, and termination reason.

## Enhanced Documentation of Outreach and Recruitment Efforts

If adopted, the updated itemized listing also would require contractors to provide extensive documentation regarding their

outreach and recruitment efforts to individuals with disabilities and protected veterans, as well as documentation of actions to address any determination that those outreach and recruitment efforts were not effective. These requirements would be in addition to the current itemized listing requirement to submit the contractor's required assessment of the effectiveness of these efforts.

## New Requests for Employment Policies

OFCCP also is asking OMB to approve its new requests for employment documents, most notably to include:

- Policies regarding recruiting, screening, and hiring, "including the use of artificial intelligence (AI), algorithms, automated systems or other technology-based selection procedures";
- Employment policies concerning Equal Employment Opportunity, anti-harassment, and complaint procedures; and
- Agreements (e.g., arbitration agreements) that "impact employees' equal opportunity rights and complaint processes."

The request for policies relating to the use of AI and other technology-based selection procedures is particularly noteworthy, though not surprising given OFCCP Director Jenny R. Yang's previous statements making clear that contractors' use of AI would be a focus for the agency moving forward.

## Multiple AAP Submission for Contractors with Multiple AAPS in Campus-Like Settings

The proposed revised scheduling letter would require contractors, including post-secondary institutions, with a "campus-like" setting to submit the information for all affirmative action plans (AAPs) maintained by the contractor for establishments located in the city and state identified in the scheduling letter. Capturing multiple establishments in campus settings in one audit has long been an OFCCP objective, but current OFCCP regulations arguably do not support such an expansion of audit scope.

## What This Means for Contractors

Overall, OFCCP's substantial overhaul of its scheduling letter and itemized listing for the first time in years highlights the agency's increasingly aggressive enforcement posture and signals a return (which many contractors already have experienced) to a more granular/deep dive approach to most OFCCP audits that was common in the Obama administration but had abated somewhat during the Trump administration.

If approved, the new scheduling letter and itemized listing will represent a substantial increase in the initial response burden on contractors selected by OFCCP for audit. Contractors have only 30 days to submit documents and information responsive to the scheduling letter and itemized listing, and the agency no longer is providing deadline extensions, absent "extraordinary circumstances." Accordingly, it will be even more important for contractors to ensure that they keep up-to-date with their affirmative action compliance obligations, including the maintenance and preparation of any required documentation that will need to be submitted to OFCCP at the outset of an audit.

## Notes

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1. https://www.regulations.gov/document/OFCCP-2022-0004-0001.
2. https://www.regulations.gov/document/OFCCP-2022-0004-0003.
3. https://www.regulations.gov/document/OFCCP-2022-0004-0002.
4. https://www.dol.gov/agencies/ofccp/directives/2022-01-Revision1.

# Treasury Department Issues Final Rule on Beneficial Ownership Reporting Requirements Under the Corporate Transparency Act

Jeff C. Dodd, Kevin E. Gaunt, Carleton Goss, Eric R. Markus, and Elizabeth P. White*

*In this article, the authors examine new regulations implementing beneficial ownership reporting requirements under a critical part of the Anti–Money Laundering Act of 2020.*

The Financial Crimes Enforcement Network (FinCEN) issued final regulations (the Final Rule)[1] implementing the comprehensive beneficial ownership reporting requirements of the Corporate Transparency Act (CTA),[2] a critical part of the Anti–Money Laundering Act of 2020 (the AMLA).

The AMLA and CTA provisions are intended to prevent bad actors from using shell companies and complex corporate structures to facilitate and disguise their illicit activity. The Final Rule seeks to achieve the CTA's goal of addressing weaknesses in the existing patchwork of state laws regarding the collection and maintenance of beneficial ownership information by establishing a clear federal standard for the collection of this information, and by requiring FinCEN to create and maintain a nonpublic registry to store that information. The Biden administration has recently emphasized efforts to combat global corruption; that new focus goes hand-in-hand with the U.S. Treasury Department's acknowledgment for the need to limit the misuse of legal entities by building a beneficial ownership registry, consistent with efforts of the Financial Action Task Force[3] and G7 and G20 leaders to curb the ability of criminal enterprises to hide behind anonymous shell companies.

While the Final Rule tweaked some of the proposed rules outlined in FinCEN's December 7, 2021, Notice of Proposed Rulemaking (NPRM) (such as by extending reporting deadlines and

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reducing the reporting requirements for "company applicants"), the Final Rule largely retains the overall framework and requirements proposed in the NPRM. Among other provisions, as discussed below in more detail, the Final Rule defines who qualifies as a beneficial owner—those exercising "substantial control" and those with a 25% "ownership interest"—and amends the existing Customer Due Diligence (CDD) Rule.

The Final Rule specifies a January 1, 2024, implementation date, but even it notes that it will need to perform substantial implementation work (including a secure database for collecting beneficial ownership information) and that the effective date will depend on that implementation and Congressional funding. Nonetheless, the Final Rule will have a major impact on businesses and their advisors, so planning for the Final Rule is advisable. FinCEN estimates that once the regulations go into effect on January 1, 2024, tens of millions of existing companies will have to make a report under the CTA[4] and approximately two million new entities created each year (and individuals and businesses that routinely facilitate the creation of these entities) will potentially be subject to the regulations. Failure to comply with the new reporting regime could result in civil and criminal penalties.

## The Backstory

Enacted on January 1, 2021, as part of the AMLA, the CTA introduced sweeping reforms to U.S. anti–money laundering and counter-terrorist financing laws. The AMLA and CTA were intended to modernize the Bank Secrecy Act, thwart the use of shell companies by criminals, address emerging financial threats, reform whistle-blower incentives, and improve coordination and information sharing between regulators, law enforcement, and financial institutions. Before the CTA and the Final Rule, entities were not required to report beneficial ownership information (BOI) to federal and state governments. That said, financial institutions are required to collect certain BOI when accounts are opened under existing FinCEN regulations.

The CTA and the Final Rule impose reporting requirements[5] for BOI and describe who must file a BOI report, what information must be reported, and when such a report is due. FinCEN also notes in the comments to the Final Rule that it has been developing

the Beneficial Ownership Secure System (BOSS) to receive, store, and maintain BOI.

## The Full Story

Each state has its own processes and requirements for the formation of corporations and other legal entities. The CTA is intended to close this gap in U.S. anti–money laundering laws by requiring FinCEN to collect the names of beneficial owners at the time of entity formation. Critical to understanding who needs to file—and when—are several key defined terms in the Final Rule, discussed further below.

### Reporting Companies

The Final Rule takes an expansive view of the CTA's definition of "reporting companies" that must report information regarding their beneficial ownership to FinCEN. Under the regulations, a "domestic reporting company" is any entity that is created by the filing of a document with a secretary of state or similar office of a jurisdiction within the United States.[6] A "foreign reporting company" is any entity formed under the law of a foreign jurisdiction that is registered to do business within the United States.

### Exempt Companies

Because the CTA is focused on shell companies and other entities that are lightly regulated and are not required otherwise to report beneficial ownership information, the Final Rule traces the CTA statute and exempts 23 categories of entities from the reporting requirement, including publicly traded companies; banks, federal, or state credit unions; registered money transmitter businesses; brokers or dealers registered with the Securities and Exchange Commission (SEC); insurance companies; investment companies and advisers registered with the SEC; and qualifying larger businesses. FinCEN is authorized to expand the list from the statutory list of exempt entities, but it declined to do so.

The Final Rule clarifies the "large operating companies" exemption for entities that have a physical U.S. office, more than 20

"full-time" employees, and which reported more than $5 million in gross receipts or sales on its last U.S. federal tax return. Importantly, the adopting release for the Final Rule notes that companies are not allowed to consolidate head count across affiliated entities even though the revenue test is on a consolidated basis.[7] So, even though wholly owned subsidiaries of exempt companies would be themselves exempt, the parent cannot count the subsidiary's employees for the purposes of determining whether it is a large operating company, which could mean that both would end up reporting if the parent itself did not have 20 full-time employees.

## Beneficial Owner

A "beneficial owner" is defined as someone who directly or indirectly "exercises substantial control over the entity," or who owns or controls at least 25% of the reporting entity's ownership interests:

### *The "Substantial Control" Prong*

The Final Rule requires a reporting company to identify any and all individuals who satisfy the "substantial control" prong. This is more expansive than the existing CDD Rule that requires a covered entity to report only one beneficial owner under the substantial control prong. Moreover, the Final Rule defines three indicators or badges of substantial control:

1. Service as a senior officer of a reporting company;
2. Authority over the appointment or removal of any senior officer or dominant majority of the board of directors (or similar body) of a reporting company; and
3. Direction, determination, decision-making functions, or substantial influence over important matters of a reporting company.

Importantly, FinCEN noted that it found the definition of "control" used by the SEC to be "too narrowly focused" for purposes of the CTA. In the Final Rule and its comments, FinCEN broadly defines the last prong so that an individual who has "substantial influence" over "important decisions" will be deemed to be a beneficial owner. It provides a nonexhaustive list of the types of

"important decisions," including compensation, approval of equity issuances or operating budgets, changes to governing documents, among others. Control can be found not only through board representation and ownership but also through, among other things, "rights associated with any financing arrangement or interest." As the adopting release notes, FinCEN is quite aware that this definition will require disclosure of the identities of more individuals than is currently the case under the existing CDD Rule. Notably, under the CDD Rule, only one beneficial owner need be identified under its control test.

### *The "Ownership" Prong*

The Final Rule also expands the "25% of ownership interest" rule beyond that of the CDD Rule for financial institutions.

It expansively includes in "ownership interests" not only traditional equity interests but also profits interests, convertible instruments, options, warrants, and arrangements relating to voting. The Final Rule describes multiple types of ownership interests that vary in terms of ease of definition. At one end of the spectrum, equity and stock interests, capital or profits interest, and proprietorship interests can be, under the right circumstances, straightforward. However, the Final Rule also defines the term "ownership interest" to include a host of future conversions of ownership interests that are not easily defined and will likely depend on retrospective analysis that will provide no comfort when reporting companies are making difficult judgments. The Final Rule also adds a catch-all provision to the definition of ownership to include "[a]ny other instrument, contract, arrangement, understanding, relationship, or other mechanism used to establish ownership."

We also note that the Final Rule also includes a discussion of how ownership interests should be calculated in determining whether an individual owns or controls—directly or indirectly—25% or more of the ownership interests of a reporting company.

### *Company Applicant*

In the case of a domestic reporting company, the "company applicant" is the individual who files the document that forms the entity; for foreign reporting companies, the company applicant is the individual who files the document that registers the entity to do business in the United States.

The Final Rule tracks the CTA's definition of "company applicant" of a reporting company. The Final Rule, however, does add that in addition to the person filing the entity formation or registration document, a reporting company must also report "any individual who directs or controls the filing of such document by another person." This requirement is designed to ensure that the reporting company provides information on individuals who are responsible for the decision to form a reporting company. FinCEN believes that this information will be useful to investigate the submission of inaccurate information if it is able to identify both the individual who submitted the report and the person who directed or controlled that activity.

The Final Rule differs from the NPRM, however, in that:

- Domestic reporting companies created prior to the effective date, or foreign reporting companies registered prior to the effective date, are not required to submit company applicant information (rather, they will only need to report their creation or registration and BOI information); and
- "Company applicants" are limited to only one or more individuals.

## What Information Must Be Reported and When Must the Report Be Filed

A reporting company must timely submit a report to FinCEN. The required reports must include each beneficial owner and each company applicant's full legal name, date of birth, current residential or business address,[8] and a unique identifier from either an acceptable identification document or a previously assigned FinCEN identifier. The filing must also contain an image of the identification document.

For reporting companies formed or registered after the effective date, the regulations provide that the initial report must be submitted within 30 calendar days of the date the entity was formed or first registered (this is one change from the NPRM, which initially set a 14-day period for the initial filing). Reporting companies in existence prior to the effective date will have one year (until January 1, 2025) to file their initial reports. The Final Rule also states that if an exempt entity becomes subject to the CTA reporting requirements, it is required to file a report with FinCEN within 30 calendar days

after the date on which it no longer meets the exemption criteria (or within the remaining days left in the one-year filing period if it ceases to be exempt during the first year after the effective date, whichever period is longer).

The Final Rule also outlines timeframes for companies that need to file updated and corrected reports. Reporting companies must file updated reports within 30 days "after the date on which there is any change with respect to any information previously submitted to FinCEN." Unfortunately, this 30-day deadline appears to start on the day the change occurred regardless of whether the reporting company has actual or constructive knowledge of the change.

The Final Rule also extends the 14-day deadline initially proposed in the NPRM for filing corrected reports to now allow 30 days from the date that the reporting company "becomes aware or has reason to know that any required information contained in any report . . . was inaccurate when filed and remains inaccurate." FinCEN's comments to the Final Rule note that the changes to align updated and corrected report deadlines with the initial report deadline of 30 days was intended to "harmonize the reporting timelines, provide substantial time to obtain required information, and minimize potential confusion."

## Odds and Ends

Notably, given the sensitivity of the reportable information, the BOSS beneficial ownership registry will not be public. The law authorizes FinCEN to disclose the beneficial ownership information it collects for only two purposes: (1) to facilitate important national security, intelligence, and law enforcement activities, and (2) to confirm beneficial ownership information provided to financial institutions to facilitate their compliance with applicable anti–money laundering and customer due diligence requirements. FinCEN may also disclose beneficial ownership information to financial institutions to facilitate compliance with the CDD Rule so long as it has the reporting company's consent.

The CTA provides that any willful violation of beneficial ownership reporting requirements can lead to penalties, including (1) civil penalties of up to $500 per day that a violation has not been remedied, and (2) criminal penalties of up to $10,000 and imprisonment of up to two years. The Final Rule adopts this penalty

framework, clarifying that liability can be for direct or indirect violations, and for acts (i.e., reporting of inaccurate information) or omissions (i.e., failure to provide or update any required information). Accordingly, any person who willfully fails to file complete beneficial ownership information, who files false or fraudulent information, or who knowingly makes an unauthorized disclosure or use of beneficial ownership information obtained from FinCEN is subject to civil and criminal liability.

In addition to the CTA and its beneficial ownership disclosure requirements, the AMLA also provides for expanded whistle-blower incentives and protections, additional (and stronger) Bank Secrecy Act violations and penalties, and expanded subpoena power for the government, along with numerous other changes that will warrant watching as they are implemented.

## Notes

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1. https://www.federalregister.gov/documents/2022/09/30/2022-21020/beneficial-ownership-information-reporting-requirements.

2. The CTA is found at 31 U.S.C. § 5336; the Final Rule will be at 31 C.F.R. § 1010.380 once effective.

3. Notably, Financial Action Task Force has specifically identified the United States' lack of beneficial ownership reporting requirements as a critical shortcoming of the U.S. anti–money laundering regime.

4. Entities formed or registered before the effective date have one year to file reports.

5. The Final Rule is the first of three required rulemakings related to the CTA. FinCEN will ultimately issue two additional rulemakings for the purposes of (1) creating a secure central database and establishing the rules for which individuals and entities may access BOI, for what purposes, and what safeguards will be required to protect this information, and (2) revising and conforming FinCEN's existing CDD Rule for financial institutions.

6. Accordingly, as the adopting release relating to the Final Rule notes, sole proprietorships, trusts, and general partnerships would not usually be reporting companies because a filing is not required to create them.

7. 87 FR 59498, 59543 ("FinCEN declines to permit companies to consolidate employee headcount across affiliated entities. Although the CTA specifies that gross receipts or sales are to be consolidated, the CTA contains no similar specification for employee headcount.").

8. The Final Rule clarifies that company applicants that provide a business service as a corporate or formation agent may report their business address rather than a residential address.

# Consumer Financial Protection Bureau Signals Stricter Enforcement of "Unfair" Banking Fees

Clifford S. Stanford, Brendan Clegg, and Caroline K. Eisner*

*In this article, the authors explain how the Consumer Financial Protection Bureau plans on regulating bank fees and outline what banks can do to prepare for agency scrutiny.*

Building on a current governmental focus on banking overdraft practices, the Consumer Financial Protection Bureau (CFPB) has issued compliance Bulletin 2022-06,[1] regarding unfair returned deposited item fee assessment practices, and Circular 2022-06,[2] regarding unanticipated overdraft fee assessment practices. Together, the bulletin and circular provide a view of the CFPB's theory behind the recent increased regulatory scrutiny of deposit account–related fees.

## CFPB Reproach of APSN Overdraft and Deposit Item Fees

The specific guidance in the bulletin and circular addresses two categories of fees that the CFPB claims come as surprises to consumers: returned item fees and authorize positive, settle negative (APSN) fees. Such fees, says the CFPB, may well be unavoidable to a customer and not outweighed by countervailing benefits or business considerations. Accordingly, the bulletin and circular state that these fees are "unfair" under the Consumer Financial Protection Act (CFPA).

### Returned Item Fees

The bulletin addresses fees incurred when checks are deposited but do not clear, either in the form of a returned item fee

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on a depositor customer or a nonsufficient funds (NSF) fee on an originator customer. Specifically, the bulletin targets the fees that depositor customers incur if they attempt to deposit checks that cannot clear, either because there are insufficient funds to clear, because a stop payment order was issued by the originator's depository institution, or because the originating account has been closed. The CFPB points out that depositor customers are unlikely to know that a check they attempt to deposit will not clear and also cannot verify with the originator's depository institution whether the check will clear. In some factual scenarios, a returned item fee could be imposed more reasonably, such as when a depositor customer repeatedly deposits bad checks from the same originator or attempts to deposit unsigned checks. But according to the CFPB, "[b]lanket policies of charging Returned Deposited Item fees to consumers for all returned transactions irrespective of the circumstances of the transaction or patterns of behavior on the account are likely unfair."

## APSN Fees

The circular cherry-picks the APSN-specific overdraft fees for critique among all the overdraft-related fees. APSN fees occur when a bank authorizes a transaction at the time a customer's account balance is positive but the transaction settles at a later time when the account's balance is negative, triggering an overdraft fee. These situations arise based on the intertwined timing between customer transactions and a bank's posting order for processing and settling deposits, credits, checks, and other items in a customer's account. This leads to different available balances and ledger balances for an account. The CFPB's position in the circular is that overdraft fees should be assessed based on an account's available balance because doing otherwise is not reasonably calculable or foreseeable to a customer.

All overdraft fees have been lumped together in recent public discussions criticizing so-called "junk fees" that are charged by banks. The fees targeted by the bulletin and circular have already been under close scrutiny in compliance exams in recent years, as have other deposit-related fees such as NSF and non-APSN overdraft fees. Many banks have eliminated all their overdraft fees, while others have adopted more consumer-friendly overdraft practices

that recognize the value to the customer of providing overdraft coverage and minimize unanticipated fees. As the circular notes, overdraft services were born out of the banking industry's ability to help depositors through courtesy programs, paying certain transactions despite a lack of funds. Other facets of overdraft programs that are growing in adoption—such as grace periods to bring account balances positive, caps on the number of fees charged per day, and covering de minimis transactions without triggering fees—are ignored by the circular but are still very much discussed by regulators during bank supervisory examinations.

This leaves banks wondering whether there is a spectrum of overdraft fees that are legal under the Truth in Lending Act and Regulation Z and the Electronic Fund Transfer Act and Regulation E but disfavored by the CFPB and other supervisory agencies. Banks are left to question whether their fee structure overall will be found to be too consumer-unfriendly, potentially constituting an unfair, deceptive, or abusive act or practice (UDAAP), or permissibly justified by countervailing benefits and business considerations.

Banks should prepare to discuss their fee structures and associated disclosures with their supervising regulators if they have not already. And beyond supervision, the enforcement divisions of federal and state banking agencies are also waiting in the wings.

## Potential Agency Enforcement Paths

The bulletin and the circular together effectively put banks over the $10 billion asset threshold on notice that their returned deposited item and overdraft fee practices will come under supervisory scrutiny from the CFPB and could land banks in hot water. Banks should expect the CFPB to request policy and procedure documents, copies of consumer complaints, and financial details on these fees as soon as their next exam cycle. Given the recent prominence of the fee issue—marked by a recent appearance by Director Rohit Chopra with President Biden announcing initiatives to address "junk fees"—and the publication of these issuances, the CFPB may be planning for a horizontal-style review of large and regional banks' fee practices. The CFPB may rely on its consumer complaint data to select individual banks for further scrutiny. Depending on what examiners learn during the exam process, the CFPB may tee up a more formal investigation that could lead to

an enforcement action against a bank. Under the agency's UDAAP authority, the CFPB has already issued consent orders against banks related to their overdraft practices that impose significant compliance requirements, assess civil money penalties, and require restitution to affected customers.

The bulletin and circular lay out the CFPB's legal analysis, leading to its conclusion that practices related to returned deposited item fees and certain overdraft fees are "likely unfair" under the CFPA. Both the bulletin and circular reinforce the CFPB's view that monetary harm—even from small-dollar fee assessments—can constitute "substantial injury," a view based in part on the CFPB's assumption that such fees would affect a "large number" of customers. Both the bulletin and circular should be read holistically as an articulation of the CFPB's theory for finding violations of the CFPA, applicable to any bank when the facts fit the elements that make up the theory.

Interestingly, the bulletin notes that the CFPB does not intend to seek monetary relief for returned deposited item fees assessed before November 1, 2023, as a "matter of prosecutorial discretion." While this gives banks some measure of relief for their past practices, it can and should be read as a warning to eliminate the practices described in the bulletin as soon as possible.

The decision by the CFPB to discuss overdraft fee practices in a circular, rather than a bulletin, also has interesting enforcement implications. As described in the circular, the CFPB's position on this issue is intentionally being communicated to "all parties" with authority to enforce federal consumer financial law; as the CFPB enumerates, this includes state attorneys general, state regulators, the federal banking agencies, and other federal agencies, including the Federal Trade Commission and Department of Justice. Thus, on the topic of overdraft fees, the CFPB has intentionally signaled that banks that may be outside its statutory reach, including banks with less than $10 billion in assets, are not entirely off the regulatory hook. In particular, the CFPB expressly signaled that the circular reflected the CFPB's "intended approach when cooperating in enforcement actions" with other state and federal agencies. This follows the CFPB's encouragement from earlier this year to state regulatory authorities to pursue companies and individuals for violations of federal consumer financial protection law.

## Conclusion

How the CFPB's desire to pursue enforcement actions against banks will play out against the backdrop of the recent *Community Financial* decision by the U.S. Court of Appeals for the Fifth Circuit,[3] holding its funding structure unconstitutional remains to be seen. Assuming that courts outside the Fifth Circuit do not stay, block, or dismiss CFPB enforcement actions until the U.S. Supreme Court has weighed in on the questions raised in the *Community Financial* decision, banks should prioritize a review of their policies and procedures around returned deposited item fees and overdraft fees to determine their potential exposure to the CFPB (or other regulators).

## Notes

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1. https://files.consumerfinance.gov/f/documents/cfpb_returned-deposited-item-fee-assessment-practice_compliance-bulletin_2022-10.pdf.

2. https://files.consumerfinance.gov/f/documents/cfpb_unanticipated-overdraft-fee-assessment-practices_circular_2022-10.pdf.

3. Cmty. Fin.l Servs. Ass'n of Am., Ltd. v. Consumer Fin. Prot. Bureau, No. 21-50826 (5th Cir. Oct. 19, 2022).

# Robust Financial Guidelines on Tap for Fannie Mae and Freddie Mac Seller/Servicers and Ginnie Mae Issuers

Amy McDaniel Williams, Edward L. Douma, Brit Mohler Dufilho, William J. Van Thunen, and Claudia H. Fendian*

*In this article, the authors explain the new financial eligibility requirements for Fannie Mae and Freddie Mac seller/servicers and Ginnie Mae issuers.*

Regulation is like a knife: used as a scalpel, regulation can provide protections for vulnerable Americans; used as a machete, regulation can convince businesses to withdraw from sectors providing services to Americans, thus unintentionally harming people. Similar to the sharpening of a good knife, good regulation becomes scalpel-sharp by being scraped over hard questions; shedding imperfections where necessary and honing in where essential. Are recently promulgated rules governing mortgage servicers, which will not take effect until late-2023, scalpels or machetes? Agency action suggests the Federal Housing Finance Agency (FHFA) and the Government National Mortgage Association (Ginnie Mae) are committed to honing the minimum financial eligibility requirements governing mortgage servicers and creating a more secure environment for consumers and investors.

Over the past decade, regulated banks have exited the mortgage servicing business, selling their mortgage servicing rights (MSRs) to nonbank servicers, including hedge funds, who are not regulated as banks. For instance, at Ginnie Mae, nonbank servicers now handle 64% of the servicing for new loans, whereas in 2011 nonbank servicers handled only 6% of Ginnie Mae servicing. Regulators have expressed concern about the role of nonbank mortgage servicers. Will they have access to credit in times of stress? Will their drive to increase returns to investors lead them to cut corners and violate the law or consumers' rights?

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With these concerns in mind, the FHFA and Ginnie Mae worked together to update financial eligibility requirements for Fannie Mae and Freddie Mac seller/servicers and Ginnie Mae issuers. On August 17, 2022, they jointly announced[1] more robust minimum financial eligibility requirements for seller/servicers and issuers, which will first take effect on September 30, 2023. While these updated requirements were adopted with the goals of maintaining the safety and soundness of Ginnie Mae and the Government-Sponsored Enterprises (GSEs) and improving alignment among Fannie Mae, Freddie Mac and Ginnie Mae participants, they diverge as noted in the tables below.

These heightened requirements and this divergence have already caused some seller/servicers and issuers to question their ability to continue to service Ginnie Mae MSRs at current levels, particularly in light of the new Risk-Based Capital requirements discussed below. A product of Ginnie Mae's engagement with its issuer community, the recently released Frequently Asked Questions about Ginnie Mae's Amended Eligibility Requirement[2] sheds additional light on Ginnie Mae's rationale for the amended eligibility requirements and foreshadows how the requirements may impact issuer's financing of MSRs after the effectiveness of the amended eligibility requirements.

The year leading up to the effective date for these new guidelines gives servicers time to plan and execute strategies for coming into compliance. Ginnie Mae has expressed that, while it believes that this time is sufficient time to bring affected issuers into compliance, it needs to understand issuers' strategies to ensure that compliance efforts do not cause dislocations in the MSR market. Lack of transparency in the MSR market adds to uncertainty about true value and may serve to increase price volatility.

## Key Differences from Current Requirements

### FHFA Requirements

The tables that follow demonstrate the changes to the definitions and various requirements with respect to the FHFA guidelines.

| Definitions | Fannie Mae and Freddie Mac Servicer Eligibility Guidelines 1.0 | Fannie Mae and Freddie Mac Servicer Eligibility Guidelines 2.0 | Who the Requirement Applies to |
|---|---|---|---|
| Tangible Net Worth | Total Equity<br>• Less Goodwill and Other Intangible Assets<br>• Less "Affiliated Receivables" and "Pledged Assets net of associated Liabilities" | Total Equity<br>• Less Goodwill and Other Intangible Assets<br>• Less "Affiliated Receivables" and "Pledged Assets net of associated Liabilities"<br>• Less Deferred Tax Assets net of associated Deferred Tax Liabilities | All Seller/ Servicers |
| Eligible Liquidity | • Unrestricted Cash and Cash Equivalents<br>• The following unpledged, Available-for-Sale or Held-for-Trading securities:<br>  • Agency MBS<br>  • Obligations of GSEs<br>  • U.S. Treasury Obligations | • Unrestricted Cash and Cash Equivalents<br>• The following unpledged, Available-for-Sale or Held-for-Trading securities:<br>  • Agency MBS<br>  • Obligations of GSEs<br>  • U.S. Treasury Obligations<br>• 50% of the unused portion of committed Agency servicing advance lines of credit | All Non-Depositories |

| Requirements | Fannie Mae and Freddie Mac Servicer Eligibility Guidelines 1.0 | Fannie Mae and Freddie Mac Servicer Eligibility Guidelines 2.0 | Who the Requirement Applies to |
|---|---|---|---|
| Minimum Tangible Net Worth | Base: $2.5 million<br>Plus<br>• 25 bps of UPB for total 1-4 unit residential mortgage loans serviced | Base: $2.5 million<br>Plus<br>• Enterprise Servicing: 25 bps<br>• Ginnie Mae Servicing: 35 bps<br>• PLS & Other Servicing: 25 bps | All Seller/ Servicers |
| Capital Ratio | Tangible Net Worth/Total Assets greater than or equal to 6% | Tangible Net Worth/Total Assets greater than or equal to 6% | All Non-Depositories |
| Base Liquidity | 3.5 bps of Agency Servicing UPB | **Enterprise Servicing**<br>• Scheduled/ Scheduled: 7 bps<br>• Scheduled/ Actual: 7 bps<br>• Actual/Actual: 3.5 bps<br>**Ginnie Mae Servicing**: 10 bps<br>**PLS & Other Servicing**: 3.5 bps | All Non-Depositories |
| NPL* Threshold | Agency NPL greater than 6% requires an incremental NPL charge | No NPL threshold | |
| Incremental NPL Charge | Plus an incremental 200 bps charge on Agency NPL for the portion of Agency NPL greater than 6% of Agency servicing | No incremental NPL charge | |

| **Requirements** | **Fannie Mae and Freddie Mac Servicer Eligibility Guidelines 1.0** | **Fannie Mae and Freddie Mac Servicer Eligibility Guidelines 2.0** | **Who the Requirement Applies to** |
|---|---|---|---|
| Origination Liquidity | No origination liquidity requirement | 50 bps times (Loans Held for Sale + Pipeline loans with Interest Rate Lock Commitments after Fallout Adjustments) | All Non-Depositories excluding Small Sellers |
| Liquidity Buffer | No liquidity buffer requirement | Enterprise Servicing: 2 bps<br>Ginnie Mae Servicing: 5 bps | Large Non-Depositories |
| Capital and Liquidity Plans | No requirement to submit capital and liquidity plans | Require annual capital and liquidity plans that include MSR stress tests as part of the plan | Large Non-Depositories |
| Third-Party Ratings | No third-party ratings requirement | Require third-party servicer and credit ratings as follows:<br>• ≥$50 billion in Servicing UPB must have one primary servicer or master servicer rating, as applicable<br>• >$100 billion in Servicing UPB must have a primary servicing rating or master servicer rating, as applicable, and one third-party long-term | Large Non-Depositories |

| Requirements | Fannie Mae and Freddie Mac Servicer Eligibility Guidelines 1.0 | Fannie Mae and Freddie Mac Servicer Eligibility Guidelines 2.0 | Who the Requirement Applies to |
|---|---|---|---|
| | | senior unsecured debt rating or long-term corporate family rating<br>• > $150 billion in Servicing UPB must have a primary servicer rating or master servicer rating, as applicable, and two third-party long-term senior unsecured debt ratings or long-term corporate family ratings | |

* NPL is defined as nonperforming loans.

## Ginnie Mae Requirements

The table that follows demonstrates the changes to the various requirements with respect to the GNMA guidelines.

| Requirements | Ginnie Mae Issuer Eligibility Guidelines 1.0 | Ginnie Mae Issuer Eligibility Guidelines 2.0 | Who the Requirement Applies to |
|---|---|---|---|
| Minimum Tangible Net Worth | Base: $2.5 million<br>Plus<br>• 35 bps of UPB for outstanding Ginnie Mae obligations | Base: $2.5 million<br>Plus<br>• Enterprise Servicing: 25 bps<br>• Ginnie Mae Servicing: 35 bps | All Issuers |
| | | • PLS & Other Servicing: 25 bps | |

| Requirements | Ginnie Mae Issuer Eligibility Guidelines 1.0 | Ginnie Mae Issuer Eligibility Guidelines 2.0 | Who the Requirement Applies to |
|---|---|---|---|
| Base Liquidity | 3.5 bps of Agency Servicing UPB | **Enterprise Servicing**<br>• Scheduled/ Scheduled: 7 bps<br>• Scheduled/ Actual: 7 bps<br>• Actual/Actual: 3.5 bps<br>**Ginnie Mae Servicing**: 10 bps<br>**PLS & Other Servicing**: 3.5 bps | All Single-Family Issuer Applicants |
| Eligible Liquidity | • At least $1 in liquid assets, including cash, cash equivalents and AAA-rated government securities | • At least $1 in liquid assets, including cash, cash equivalents and AAA-rated government securities<br>• Plus includes: Agency MBS, obligations of GSE and principal and interest advances, taxes and insurance advances, and foreclosure advances | All Single-Family Issuer Applicants |
| Origination Liquidity | No origination liquidity requirement | The greater of (i) $1 million and (ii) 50 bps times (Loans Held for Sale + Pipeline loans with Interest Rate Lock Commitments after Fallout Adjustments) | Originators of more than $1 billion in UPB of any residential first mortgages |

| Requirements | Ginnie Mae Issuer Eligibility Guidelines 1.0 | Ginnie Mae Issuer Eligibility Guidelines 2.0 | Who the Requirement Applies to |
|---|---|---|---|
| Risk-Based Capital Requirement | No RBCR requirement | At least 6% as calculated by: (Adjusted Net Worth less Excess MSRs) divided by the Risk Weighted Assets | All Single-Family Issuer Applicants |

## Key Differences Between FHFA and Ginnie Mae

The FHFA will be requiring liquidity buffers equal to 2 basis points for GSE unpaid principal balance (UPB) and 5 basis points for Ginnie Mae UPB. These requirements will apply to seller/servicers classified as "large" (as defined by UPB issuance). Ginnie Mae has not announced a liquidity buffer requirement.

Allowable liquid assets under Ginnie Mae and the FHFA are different as well. The FHFA allows for 50% of an unused portion of a committed agency servicing advance line of credit to count toward a seller/servicer's liquid assets. By contrast, Ginnie Mae allows servicing advance receivables to count toward liquid assets but does not permit inclusion of a line of credit.

Lastly, the FHFA has not imposed a RBCR, while Ginnie Mae is doing so. As mentioned above, Ginnie Mae is requiring a RBCR of at least 6%, using the formula of (1) Adjusted Net Worth less Excess MSR, divided by (2) the Risk Weighted Assets. Unlike the majority of the revised guidelines, which become effective late 2023, the RBCR requirement implementation has been extended to December 31, 2024.

## Key Takeaways

Some speculated at the announcement of the revised guidelines that nonbank interests in the single-family sector would cool in response. As of the end of September 2022, nonbanks serviced $5.276 trillion on the outstanding single-family mortgage-backed securities (MBS) issued by Fannie Mae, Freddie Mac and Ginnie

Mae, which was a 2.1% increase from June 2022, and raised the overall nonbank share of the Ginnie Mae MSR market to just shy of 80%, at 78.9%. So far, nonbank interest in the market remains high, particularly in the Ginnie Mae market; however, it is uncertain how the revised requirements might affect nonbank interest between now and the effective date of the changes.

While Ginnie Mae's President Alanna McCargo has said "the overwhelming majority of Ginnie Mae issuers are compliant with these requirements today," Ginnie Mae issuers and GSE seller/servicers should continue to engage with Ginnie Mae and the FHFA on these amended eligibility requirements during the implementation period. Notably, as a result of stakeholder feedback and evolving market dynamics, on October 21, 2022, Ginnie Mae extended the original compliance date for the RBC portion of the new requirements by one year, from December 31, 2023, to December 31, 2024. In particular, issuers and seller/servicers should continue to evaluate how their current and future MSR financing arrangements will impact their ability to comply with the eligibility requirements generally and Ginnie Mae's risk-based capital requirement specifically. After all, handling a scalpel with continued attention and care is the surest way to avoid unintended cuts.

## Notes

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1. https://www.fhfa.gov/Media/PublicAffairs/Pages/FHFA-and-Ginnie-Mae-Announce-Updated-Min-Financial-Eligibility-Reqs-for-Enterprise-Seller-Servicers-and-Ginnie-Mae-Issuers.aspx.

2. https://www.ginniemae.gov/newsroom/Documents/issuer_eligibility_faq_09_20_2022.pdf.

# Securities and Exchange Commission Alleges That Investment Adviser Failed to Adequately Disclose ESG Investment Policies and Procedures

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*In this article, the authors discuss an enforcement action brought recently by the Securities and Exchange Commission that highlights the agency's growing interest in environmental, social, and governance-related disclosures and alleged "greenwashing" by asset managers.*

The Securities and Exchange Commission (SEC) has charged an investment adviser subsidiary of a major U.S. financial institution with violations of Section 206(4) of the Investment Advisers Act of 1940 (Advisers Act) and Rule 206(4)-7 thereunder relating to environmental, social, and governance (ESG) investments. The SEC alleged that the adviser's statements labeling certain investments as having been screened pursuant to its policies and procedures for ESG criteria were inaccurate because the policies and procedures the adviser used in selecting ESG-related investments were either nonexistent or ignored by employees. The adviser agreed to pay a $4 million penalty, to enter into a cease-and-desist order, and censure to resolve the charges.

This enforcement action, which follows similar recent actions by the SEC, highlights the SEC's growing interest in ESG-related disclosures and alleged "greenwashing" by asset managers. The SEC's focus on ESG disclosures underscores the need for issuers that market ESG products to accurately disclose their written policies and procedures when making investment decisions. Issuers should also be aware of the SEC's proposed rule regarding the naming,

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investment content and disclosure requirements for ESG-related funds.

## The SEC's Enforcement of ESG Disclosures

ESG investing integrates ESG factors into investment decisions. To meet growing demand among investors for these products, asset managers have developed and marketed certain funds and strategies as ESG products. In March 2021, the SEC formed the Climate and ESG Task Force within the SEC's Division of Enforcement to "identify any material gaps or misstatements in issuers' disclosure of climate risks under existing rules" and "analyze disclosure and compliance issues relating to investment advisers' and funds' ESG strategies."[1]

Since forming the Climate and ESG Task Force, the SEC has charged both issuers and investment advisers with violations related to their ESG disclosures. For instance, in April 2022, the SEC's Climate and ESG Task Force alleged that a Brazilian mining company, Vale S.A., misrepresented in SEC filings and other company documents that a failed tailings dam at its Brumadinho facility complied with international standards when the company had documented evidence that it did not. And in May 2022, the Climate and ESG Task Force brought and settled charges that an investment adviser subsidiary of Bank of New York Mellon falsely represented that investments in certain financial products had undergone an ESG quality review prior to their selection, when allegedly a significant percentage of those investments had not.

## The SEC's Most Recent ESG Enforcement Action

The recent action marks the latest installment in the SEC's enforcement of ESG disclosures. The SEC alleged that, from 2017 through February 2020, the investment adviser at issue here—Goldman Sachs Asset Management L.P.—failed to implement adequate written policies and procedures governing the selection of ESG investments. Specifically, the SEC stated that the adviser made misrepresentations concerning the policies and procedures governing the selection of ESG-related investments in a separately managed account and two mutual funds. After incorporating "ESG" into the names of these products, the adviser represented in prospectuses

and other materials that each security would be subject to a two-step review that would screen certain industries and then apply proprietary research to eliminate investments that failed to meet ESG standards before making investment decisions.

When the adviser began marketing the separately managed account as ESG, however, the adviser allegedly had no written policies or procedures governing the selection of ESG investments. According to the SEC, only months later did the adviser implement a written framework to govern the second step of the ESG selection process—namely, the elimination based on proprietary research of investments that passed initial screening. Those written policies and procedures—which the adviser allegedly shared with third parties in pitch books, requests for proposals, and other materials—required the relevant investment teams to complete a proprietary questionnaire measuring specified ESG factors before making any investments. The results of that questionnaire would then be fed through a proprietary matrix to yield a numerical score determining the suitability of the investment for inclusion in the relevant financial product.

Despite the presence of these written policies and procedures, which existed for much of the life of the separately managed account and from the inception of the two mutual funds, the SEC alleged that the investment team routinely failed to complete the proprietary questionnaire before selecting investments. In many cases, the SEC alleged, the investment team instead relied on pre-existing research conducted pursuant to different processes and completed the proprietary questionnaires only after making the relevant investment.

Accordingly, the SEC alleged that the adviser violated the Advisers Act and related rule by failing to implement written policies and procedures governing the selection of securities when first marketing the separately managed account as ESG. It also failed to provide employees with adequate guidance, in both the separately managed account and the subsequent mutual funds, upon implementing the relevant written policies and procedures and thus failed to accurately characterize the implementation of its program in its public disclosures. In settling the action, the adviser agreed to a penalty of $4 million, to enter into a cease-and-desist order, and censure.

## The SEC's Proposed "Names Rule"

On May 25, 2022, the SEC proposed an amendment to Rule 35d-1 under the Investment Company Act of 1940 that would expand the types of names subject to naming requirements. This new "Names Rule" would require any fund whose name suggests the fund focuses its investments on particular characteristics—including ESG—to invest at least 80% of the fund's value in those investments. The proposed rule would also classify fund names as materially misleading if, for instance, the fund's name suggests it invests in ESG but the ESG factors the fund uses are no more significant than other factors in the investment selection process. As proposed, the rule would be subject to only a few narrow exceptions, including when the valuation of a fund's assets changes due to sudden market fluctuations. The final version of the new Names Rule is expected to be issued in the first quarter of 2023.

## Conclusion

The SEC Order is yet another example of the SEC's growing scrutiny of ESG-related disclosures and alleged "greenwashing" in the marketplace. Issuers that market ESG financial products should appropriately disclose criteria, policies, and procedures they employ in determining an investment as ESG favorable. Once they adopt such procedures, they need to take steps to ensure they consistently follow their policies and monitor such compliance. Furthermore, in developing such policies and procedures, issuers and advisers should consider how, along with fund names and investment strategies, they are consistent with the proposed Names Rule.

## Notes

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1. Press Release, SEC Announces Enforcement Task Force Focused on Climate and ESG Issues, SEC (Mar. 4, 2021), https://www.sec.gov/news/press-release/2021-42.