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September 2024

COVID-19

HHS Needs to Identify Duplicative Pandemic IT Systems and Implement Key Privacy Requirements

GAO-24-106638

GAO Highlights

Highlights of GAO-24-106638, a report to congressional committees

September 2024

COVID-19

HHS Needs to Identify Duplicative Pandemic IT Systems and Implement Key Privacy Requirements

Why GAO Did This Study

HHS and its component agencies are responsible for managing data collection activities to support public health preparedness and response during public health emergencies, such as the COVID-19 pandemic. The Consolidated Appropriations Act of 2023 reiterates the need for HHS to improve these data collection capabilities and includes provisions for GAO to review those capabilities. In addition, the CARES Act includes a provision for GAO to monitor and oversee the federal response to the COVID-19 pandemic.

This report addresses, among other things, the extent to which HHS has (1) identified and reduced unnecessary duplication, overlap, or fragmentation in its preparedness and response data capabilities; and (2) instituted privacy safeguards on selected systems when collecting public health preparedness and response data.

GAO identified lists of systems and compared HHS and component agency efforts to identify unnecessary duplication, overlap, and fragmentation to federal law and guidance. GAO also randomly selected nine systems for review of component agency implementation of privacy safeguards for systems that collect and store PII.

What GAO Recommends

GAO is making 14 recommendations to HHS, including establishing a systems inventory, addressing duplicative data, and fully implementing privacy safeguards. HHS generally agreed with the recommendations, although stating that two may not be feasible. GAO continues to believe they are valid.

View GAO-24-106638. For more information, contact Jennifer R. Franks at (404) 679-1831 or franksj@gao.gov.

What GAO Found

The Department of Health and Human Services (HHS) has not identified and reduced unnecessary duplication of data in its systems supporting pandemic public health preparedness and response. Because the department did not have a comprehensive list of these systems, GAO worked with key HHS component agencies and identified a total of 99 systems. HHS did not attempt to identify duplication or overlap for these systems. However, in its high-level review of the 99 systems, GAO identified instances of duplicative pandemic public health preparedness and response data in multiple systems. For example, two pandemic systems that collected similar COVID-19 data, such as cases, deaths, and hospitalization data are managed by the same program office.

Regarding privacy, according to the component agencies, 68 of the 99 identified systems collect and store personally identifiable information (PII). These agencies developed privacy impact assessments (PIA) for 53 of the 68; 15 did not have such assessments. Such assessments are essential to identifying and mitigating the privacy risks of systems containing PII. Until HHS ensures that PIAs are developed for all of its systems containing PII, it will have less assurance that privacy risks are assessed to prevent unauthorized disclosure.

Further, HHS and its component agencies did not implement all of the key privacy safeguards for the nine systems that GAO randomly selected for review (see figure). As a result, information collected and stored by some of these systems may be at higher risk for unauthorized disclosure.

HHS Component Agencies Implementation of Key Privacy Safeguards for Selected Pandemic Systems

	HHS Component Agencies and Selected Systems								
	ASPR		CDC			FDA		HRSA	NIH
Privacy requirements	ASPR Ready	Electronic Medical Records System	COVID-19 Clearing-house	Data Collation and Integration for Public Health Event Response	HHS Protect	Biologics Information Tracking System – Compliance	Human Cell and Tissue Establish-ment Registration System	Injury Compensa-tion System	National COVID Cohort Collabora-tive
System of Records Notice	●	●	●	●	●	○	N/A	●	N/A
System security categorizations	●	●	◐	●	◐	◐	●	●	●
Privacy plans	◐	●	●	●	●	●	●	●	●
Assessments of privacy controls	○	◐	●	●	●	○	●	●	●
System authorizations to operate	●	○	●	●	●	●	●	●	●
Monitor privacy controls	●	●	●	●	●	●	●	●	●

● Fully implemented ◐ Partially implemented ○ Not implemented **N/A**= this requirement is not applicable because the component provided evidence that a system of records notice was not required

ASPR = Administration for Strategic Preparedness and Response, CDC = Centers for Disease Control and Prevention, FDA = Food and Drug Administration, HHS = Department of Health and Human Services, HRSA = Health Resources and Services Administration, NIH = National Institutes of Health

Source: GAO analysis of agency information. | GAO-24-106638

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Abbreviations

ASPR	Administration for Strategic Preparedness and Response
ATO	authorization to operate
DCIPHER	Data Collation and Integration for Public Health Event Response
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CIO	Chief information officer
CIS	case isolate surveillance
COVID-NET	COVID-19 Associated Hospitalization Surveillance Network
CRRSA	Coronavirus Response and Relief Supplemental Appropriations Act
DMI	data modernization initiative
FDA	Food and Drug Administration
FITARA	Federal Information Technology Acquisition Reform Act
FTE	full-time equivalent
HHS	Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IT	information technology
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
OES	outbreak event surveillance
OMB	Office of Management and Budget
O&M	operations and maintenance
PDUFA	Prescription Drug User Fee Act
PIA	privacy impact assessment
PII	personally identifiable information
SAOP	senior agency official for privacy
SORN	system of records notice

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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September 18, 2024

The Honorable Bernard Sanders
Chair
The Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

Public health emergencies, such as the COVID-19 pandemic, can weaken our economy, threaten national security, cause hundreds of thousands of casualties, and damage public morale and confidence. COVID-19 drew attention to the urgent need for public health officials to access real-time information about emerging threats to enable them to make timely, responsive decisions.

Public health officials rely on information from a number of key sources to provide the situational awareness they need to prepare for and respond to a variety of public health emergencies, such as pandemics. This information includes critical response resources, medical care capacity, environmental threats, and the preparedness status of the many public health jurisdictions across the country. The Department of Health and Human Services (HHS) and its component agencies have developed and implemented systems to collect and analyze this information for public health preparedness and response during pandemics.[1]

The Consolidated Appropriations Act, 2023 highlights the need for HHS to improve its data capabilities for public health preparedness and response

[1]HHS operating divisions include Centers for Disease Control and Prevention, the Administration for Strategic Preparedness and Response, Food and Drug Administration, Indian Health Service, National Institutes of Health, and Health Resources and Services Administration, among others. For the purpose of this report, they are hereinafter collectively referred to as component agencies.

during pandemics.[2] The act includes provisions for us to report on HHS and its component agencies' efforts to identify and reduce duplication, overlap, or fragmentation for pandemic public health preparedness and response data capabilities, and to protect personally identifiable information (PII).[3]

In addition, the CARES Act includes a provision for us to report regularly on the federal response to the pandemic. Specifically, the act calls for us to conduct monitoring and oversight of the federal government's efforts to prepare for, respond to, and recover from the COVID-19 pandemic.[4]

Our specific objectives for this review were to determine the extent to which HHS has (1) identified and reduced unnecessary duplication, overlap, or fragmentation in its pandemic public health preparedness and response data capabilities; (2) identified funding and other resources for the operation of its pandemic public health preparedness and response data capabilities; and (3) instituted privacy safeguards when collecting pandemic public health preparedness and response data.

For all three objectives, we focused on HHS and its component agencies that maintain systems supporting pandemic public health preparedness and response. These component agencies are the Administration for Strategic Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), and National Institutes of Health (NIH).

To address the first objective, we identified requirements in the Consolidated Appropriations Act, 2023 aimed at identifying and reducing duplication, overlap, or fragmentation in pandemic public health

[2]Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 2216, 136 Stat. 5740 (2022). The data capabilities include the collection of public health preparedness, response, and recovery data regarding disease tracking, hospitalizations, critical care capacity, and testing programs for diseases, such as COVID-19. For the purposes of this report, the systems we discuss are those that assist HHS in pandemic preparedness and response, however, these systems could also have other functions related to public health.

[3]Personally identifiable information is any information that can be used to distinguish or trace an individual's identity, such as name, date or place of birth, and Social Security number; or that otherwise can be linked to an individual.

[4]Pub. L. No. 116-136, § 19010(c), 134 Stat. 579 (2020). We regularly issue government-wide reports on the federal response to COVID-19. These reports are available on GAO's website at https://www.gao.gov/coronavirus.

preparedness and response data capabilities. We asked HHS and its component agencies to provide a list of systems that support pandemic public health preparedness and response, and the data collected by each system. We then compared the lists of systems provided by the component agencies to systems identified as supporting pandemic public health preparedness and response in previously issued GAO reports.[5] We analyzed the lists of systems to identify areas where programs may request or collect the same data.

We also compared HHS and its component agencies' efforts to identify and reduce duplication, overlap, or fragmentation among its systems to federal requirements. These requirements included the Consolidated Appropriations Act, 2023 and the Federal Information Technology Acquisition Reform Act (FITARA) of 2014.[6] We also compared HHS and its component agencies' efforts to identify, reduce, or better manage duplication among their systems to key practices identified in a prior GAO report.[7]

We supplemented our analysis with interviews of relevant HHS officials in ASPR, CDC, FDA, HRSA, IHS, and NIH. We discussed their efforts to identify systems involving pandemic public health preparedness and response data and their efforts to reduce unnecessary duplication when collecting this data. In addition, we interviewed representatives from selected national public health organizations representing state, territorial, and local public health officials, including the Association of State and Territorial Health Officials, Council of State and Territorial Epidemiologists, and National Association of County and City Health Officials. We discussed the actions the organizations have taken to collaborate with the department regarding the use of systems that support pandemic public health preparedness and response, and efforts to identify duplicative systems.

[5]GAO, *COVID-19: Pandemic Lessons Highlight Need for Public Health Situational Awareness Network*, GAO-22-104600 (Washington, D.C.: June 23, 2022) and *Public Health Information Technology, HHS Has Made Little Progress Toward Implementing Enhanced Situational Awareness Network Capabilities*, GAO-17-377 (Washington, D.C.: Sep 6, 2017).

[6]Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, 136 Stat. 5740 (2022). Carl Levin and Howard P. 'Buck' McKeon National Defense Authorization Act for Fiscal Year 2015, Pub. L. No. 113-291, div. A, title VIII, subtitle D, 128 Stat. 3438 (2014).

[7]GAO, *Fragmentation, Overlap, and Duplication: An Evaluation and Management Guide,* GAO-15-49SP (Washington, D.C.: Apr. 14, 2015).

To address the second objective, we identified federal budgetary requirements and best practices identified in a prior GAO report on developing and managing program costs.[8] We then analyzed the HHS component agencies' lists for the reported fiscal year 2023 funding sources and costs for the systems that support pandemic public health preparedness and response activities. We also analyzed system funding documentation, such as budget requests and contracts. We compared the system funding information to the federal budgetary requirements and best practices. In addition, we identified best practices in GAO's IT workforce planning framework. [9] We analyzed the HHS component agencies' lists for staffing information, including the number of full-time, full-time equivalent, and part-time staff dedicated to the management of the pandemic public health preparedness and response systems.[10] We also analyzed system staffing documentation, such as staffing plans, organization charts, and contracts. We then compared the staffing information and documentation to the best practices for workforce planning. Additionally, we supplemented our analysis with interviews with relevant HHS officials in ASPR, CDC, FDA, HRSA, IHS, and NIH.

To address the third objective, we identified federal requirements aimed at establishing safeguards for systems that store and process PII.[11] We then compared HHS privacy policies, memorandums, and privacy impact

[8]The White House, *National Security Memorandum on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security*, NSM-15 (Washington, D.C.: Oct. 18, 2022); GAO, *Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Program Costs*, GAO-20-195G (Washington, D.C.: Mar. 12, 2020).

[9]GAO, *IT Workforce: Key Practices Help Ensure Strong Integrated Program Teams; Selected Departments Need to Assess Skill Gaps*, GAO-17-8 (Washington, D.C.: Nov. 30, 2016).

[10]A full-time equivalent is a standard measure of labor that reflects the total number of regular straight-time hours (i.e., not including overtime or holiday hours) worked by employees divided by the number of compensable hours applicable to each fiscal year. See the Office of Management and Budget Circular No. A-11, Preparation, Submission, and Execution of the Budget (Washington, D.C.: Aug. 11, 2023).

[11]E-Government Act of 2002, Pub. L. No. 107-347, § 208, 116 Stat. 2899, 2921 (Dec. 17, 2002) (44 U.S.C. § 3501 note); Privacy Act of 1974, Pub. L. No. 93-579, 88 Stat. 1896 (Dec. 31, 1974) (codified as amended at 5 U.S.C. § 552a); Office of Management and Budget, *Managing Information as a Strategic Resource*, Circular A-130 (Washington, D.C.: July 28, 2016); *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*, M-03-22 (Washington, D.C.: Sept. 26, 2003); and National Institute of Standards and Technology SP 800-37, Revision 2: *Risk Management Framework for Information Systems and Organizations: A System Life Cycle Approach for Security and Privacy* (Gaithersburg, Md.: December 2018).

assessments (PIAs) to the federal requirements.[12] We randomly selected a sample of nine systems from the components' lists of systems compiled from objective one that store and process PII.[13] For the selected systems, we then collected and analyzed security documentation, such as privacy plans and controls, and compared the documentation to the federal requirements. Additionally, we supplemented our analysis with interviews with relevant HHS officials in ASPR, CDC, FDA, HRSA, IHS, and NIH. A full description of our objectives, scope, and methodology can be found in appendix I.

We conducted this performance audit from February 2023 to September 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

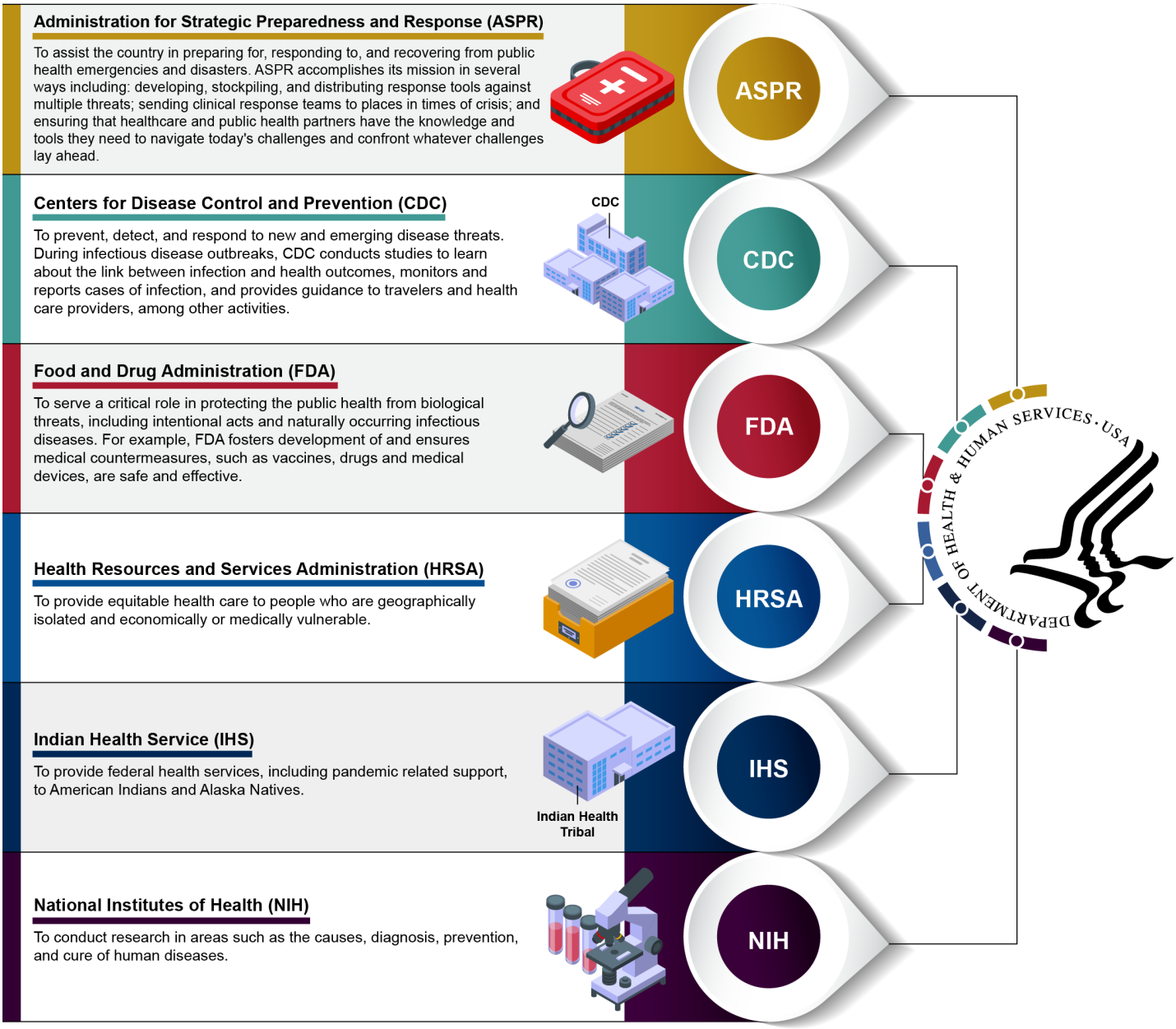
Background

The mission of HHS is to enhance the health and well-being of Americans by providing effective public health and human services. To support this mission, HHS designates its component agencies with responsibilities for managing public health preparedness and response activities during public health emergencies, such as pandemics. Figure 1 describes the key missions of the HHS component agencies related to public health preparedness and response.

[12]A privacy impact assessment (PIA) analyzes agency information systems containing personally identifiable information (PII) to ensure that the PII is handled according to applicable privacy requirements. A PIA also determines the privacy risks associated with an information system and evaluates ways to mitigate privacy risks.

[13]Our initial selection was of 10 systems and included FDA's Event-based Text-mining for Health Electronic Records system. FDA had initially included the system as one that included PII. After our selection, FDA analyzed the information stored by the system and determined that it did not include PII. Therefore, this system was removed from our final evaluation of privacy requirements, resulting in nine systems. The findings from these systems for each component, while randomly selected, are not generalizable to all systems in that component. However, for the selected systems, we were able to assess whether there were instances of the agencies not meeting all of the privacy requirements.

Figure 1: Department of Health and Human Services (HHS) Component Agencies that Support Public Health Preparedness and Response and Their Key Missions



Sources: GAO analysis of HHS data; HHS (logo), ylivdesign/stock.adobe.com (illustrations); Rasarin/stock.adobe.com (pointed circle icons). | GAO-24-106638

These component agencies collaborate with various entities to collect and share important health information related to preparing for or responding to pandemics. These entities include state, local, and territorial public health agencies, health care providers, laboratories, and other federal departments, such as the Department of Homeland Security.

HHS and its component agencies use a number of information systems to carry out their mission. For example, ASPR used the Health Partner Order Portal system to manage and report key data related to the ordering and distribution of COVID-19 vaccines. Additionally, HHS developed HHS Protect in April 2020 to help integrate COVID-19 data and other types of health information collected by various federal, state, and local public health and commercial entities.[14] Further, FDA used the Adverse Event Reporting System to collect and maintain adverse event reports submitted by health care professionals and consumers regarding adverse events, such as side effects and injuries associated with drugs and vaccines.

Federal Laws and Guidance Advise Agencies on Identification of Duplication, Overlap, or Fragmentation

In December 2014, Congress enacted FITARA, which requires agencies to ensure that their chief information officers (CIO) have a significant role in the decision process for budgeting, governance, and oversight processes related to IT.[15] The law requires agency CIOs to conduct an annual review of the agency's portfolio of IT investments. During these reviews, agency CIOs are to identify ways to increase the efficiency of IT investments by identifying potential duplication and opportunities to consolidate the management of IT services when making annual and multi-year IT planning, programming, and budgeting decisions. Also, agency CIOs are to identify potential cost savings from consolidating IT investments and services.

We previously reported in 2018 that HHS had not developed IT management policies that address the role of the agency CIO to improve the management of the agency's IT through portfolio reviews to identify duplication.[16] We recommended that the Secretary of HHS ensure that

[14]According to CDC officials, HHS Protect management and ownership was later transitioned to CDC.

[15]Carl Levin and Howard P. 'Buck' McKeon National Defense Authorization Act for Fiscal Year 2015, Pub. L. No. 113-291, div. A, title VIII, subtitle D, 128 Stat. 3438 (2014).

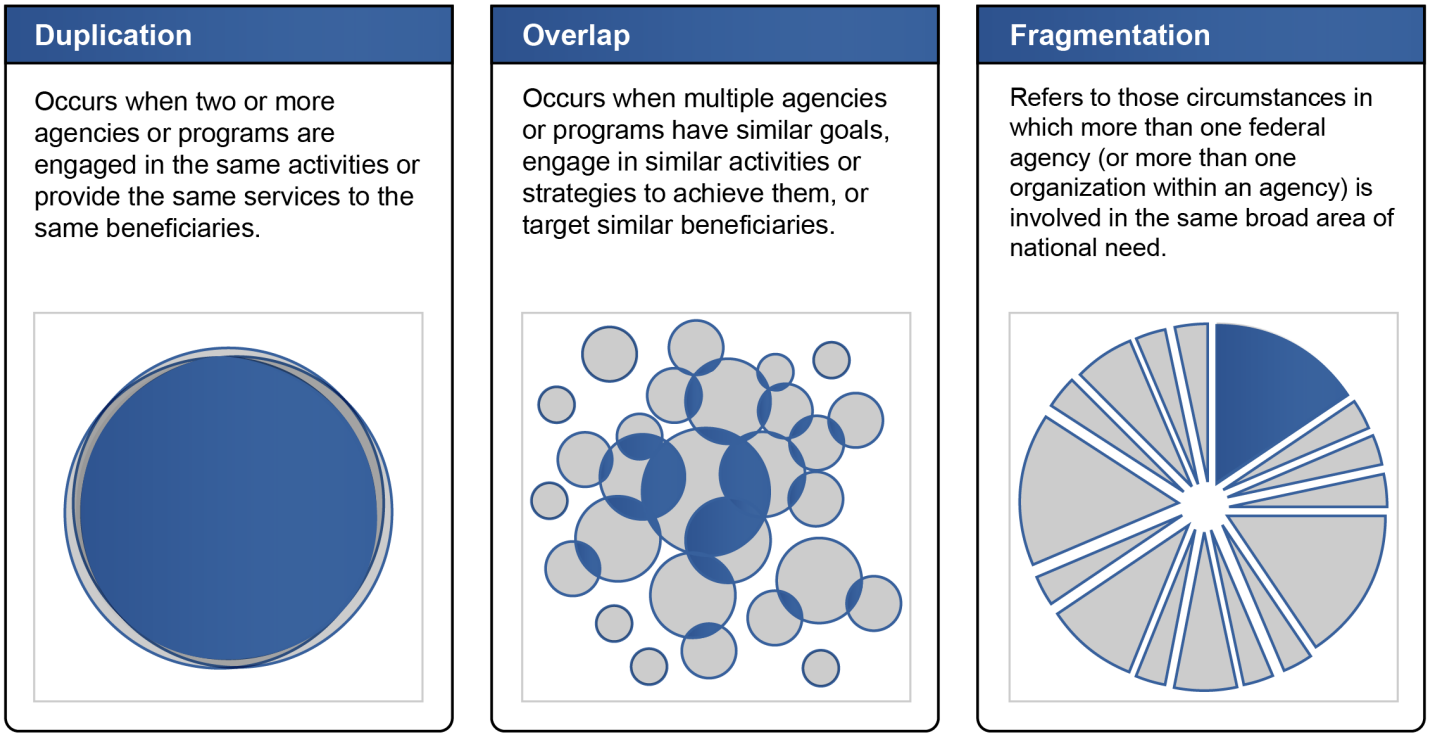
[16]GAO, *Federal Chief Information Officers: Critical Actions Needed to Address Shortcomings and Challenges in Implementing Responsibilities*, GAO-18-93 (Washington D.C.: Aug 2, 2018).

the department's IT management policies address the role of the CIO for key responsibilities, including conducting portfolio reviews. HHS agreed with the recommendation. However, as of June 2024, HHS has yet to fully implement it.

GAO's *Fragmentation, Overlap, and Duplication Guide* also defines guidance for agencies to identify, evaluate, and reduce, or better manage instances of duplication, overlap, and fragmentation across their programs and systems, and to avoid negative consequences, such as wasting resources (e.g. time, money, and appropriate staff).[17] For the purpose of this report, unnecessary duplication refers to an instance where data capabilities are already being performed by another group in a more efficient manner. Therefore, when an agency develops and implements additional systems performing a similar task, this results in redundancy. Figure 2 defines duplication, overlap, and fragmentation across agency programs and systems.

[17]GAO-15-49SP.

Figure 2: GAO Definitions of Duplication, Overlap, and Fragmentation



Source: GAO, GAO icons. | GAO-24-106638

Consistent with the guide, steps for addressing duplication, overlap, and fragmentation across agency programs and systems include:

1. identifying an approach, or process, for selecting programs, including supporting systems to be reviewed;
2. once those programs have been selected, gathering relevant background information, such as the relationships between the supporting systems and the data collected to understand if the data are being duplicated across multiple systems;
3. identifying the potential positive or negative effects of any fragmentation, overlap, or duplication; and
4. identifying options to increase efficiency and reduce or better manage any fragmentation, overlap, or duplication and communicating findings with the appropriate agency officials to determine mitigation efforts, such as eliminating or consolidating systems.

Federal Agencies, Including HHS, Face Privacy Challenges

The protection of personal privacy has become a more significant issue in recent years with the advent of new technologies and the proliferation of personal information. The increasingly sophisticated ways in which the federal government obtains and uses PII have the potential to assist in performing critical functions, such as helping to detect and prevent cyber threats and enhancing online interactions with the public. However, these technological developments can also pose challenges in ensuring the protection of privacy. Recognizing these challenges, we expanded our existing information security high-risk area to include protecting the privacy of PII as a high-risk area in 2015.[18] Since then, we have made 186 recommendations in public reports for protecting privacy and sensitive data across the federal government. As of June 2024, 100 of these recommendations—two of which were made to HHS—had not been fully implemented.

We previously reported in September 2022 that HHS did not fully define or document processes for privacy workforce management.[19] We recommended that the department fully define and document a process for ensuring that the senior agency official for privacy (SAOP) or other designated privacy official is involved in addressing the hiring, training, and professional development needs of the agency with respect to privacy. In May 2023, we designated this recommendation as a priority recommendation.[20] HHS concurred with the recommendation, but as of June 2024, had not yet implemented it.

Additionally, in December 2022, we reported that HHS's privacy program did not have the capability to digitally accept access and consent forms from individuals that were properly identity proofed and authenticated.[21] We recommended that the department establish a reasonable time frame for when it will be able to digitally accept these forms from individuals who were properly identity proofed and authenticated, and post the forms on

[18]See most recent high-risk list at www.gao.gov/high-risk-list.

[19]GAO, *Privacy: Dedicated Leadership Can Improve Programs and Address Challenges*, GAO-22-105065 (Washington, D.C.: Sept. 22, 2022).

[20]GAO, *Priority Open Recommendations: Department of Health and Human Services*, GAO-23-106467 (Washington, D.C.: May 10, 2023).

[21]Individuals use access and consent forms to establish their identity and request access to or provide written consent for the disclosure of their records. GAO, *Information Management: Agencies Need to Streamline Electronic Services*, GAO-23-105562 (Washington, D.C.: Dec. 20, 2022).

the department's privacy program website. HHS concurred with the recommendation, but as of June 2024, had not yet implemented it.

HHS Has Not Identified and Reduced Unnecessary Duplication, Overlap, or Fragmentation of Data in Its Pandemic Systems

HHS has not developed a comprehensive list of systems supporting pandemic public health preparedness and response, which is a precursor to being able to effectively identify unnecessary duplication, overlap, or fragmentation. Additionally, HHS has not identified and reduced unnecessary duplication, overlap, or fragmentation among systems supporting pandemic public health preparedness and response. Nonetheless, we and others identified examples of duplicative data on these systems. The shortfalls in HHS's efforts to identify unnecessary duplication among its systems is due, in part, to a lack of prioritization.

HHS Has Not Developed a Comprehensive List of Systems Supporting Pandemic Public Health Preparedness and Response

The Paperwork Reduction Act in 1995 and the Office of Management and Budget (OMB) Circular A-130 requires agencies' CIOs to manage and inventory information systems that collect data associated with the agency's mission, including pandemic systems.[22] Further, the Consolidated Appropriations Act, 2023 requires HHS and its component agencies to identify and develop a comprehensive list of pandemic public health preparedness and response data capabilities.[23]

However, HHS's CIO had not developed a department-wide comprehensive list of pandemic systems that would include component agencies' systems to support pandemic public health preparedness and response. Since a comprehensive list of pandemic systems did not exist, at our request, HHS's relevant component agencies (ASPR, CDC, FDA, HRSA, IHS, and NIH) identified a total of 99 data collection systems that support pandemic public health preparedness and response.

However, the lists of systems provided by the component agencies were inconsistent in nature. For example, system lists for many of the component agencies did not include relevant pandemic systems, which raised questions about the comprehensiveness of the lists. For example,

[22]Paperwork Reduction Act of 1995, Pub. L. No. 104-13, 109 Stat. 172 (44 U.S.C. § 3501 et seq.). Office of Management and Budget, Revised *Circular A-130, Managing Information as a Strategic Resource* (Washington, D.C.: July 28, 2016). OMB defines a major information system as a system that is crucial to an agency's mission.

[23]Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, 136 Stat. 5740 (2022).

CDC's initial list of systems that support pandemic public health preparedness and response did not include previously reported key pandemic systems:[24]

- COVID-19 Associated Hospitalization Surveillance Network (commonly referred to as COVID-NET)—used for conducting surveillance for laboratory confirmed COVID-19-associated hospitalizations in children and adults;
- Flu Effectiveness Network—used for estimating the effectiveness of the vaccines;
- Epidemic Information Exchange—used for supporting the sharing of indicator and public health data, such as COVID-19 cases among CDC, state, territorial, local, and tribal public health departments.

CDC officials stated that these systems were missing from the list due to an oversight. Subsequently, they updated the list with the missing systems.

In another example, the IHS system list did not include the Influenza-like Illness Awareness System. This system collects electronic health record data from IHS and various tribal sites to detect an increase of influenza-like illness cases in tribal and urban facilities. IHS officials stated that the system was not initially included because it functions as a syndromic surveillance system for disease tracking and not as a public health response and recovery tool.[25] IHS officials subsequently updated their system list to include the Influenza-like Illness Awareness System because it supports public health pandemic preparedness and response through national disease surveillance activities.

Although component agencies updated their systems lists to include pandemic systems after we identified them, without a department-wide list, it is uncertain whether all key pandemic systems have been included. Appendix II includes the list of data collection systems HHS's component agencies identified as supporting pandemic public health preparedness and response.

[24]GAO-22-104600.

[25]Syndromic surveillance serves as an early warning system by tracking, in near real-time, symptoms of patients in emergency departments and other settings before and after a diagnosis is confirmed. This provides public health officials with a timely system for detecting unusual levels of illness and understanding and monitoring health events.

HHS Has Not Identified and Reduced Unnecessary Duplication, Overlap, or Fragmentation

As previously mentioned, FITARA requires agency CIOs to conduct an annual review of the agency's portfolio of IT investments.[26] The review is to include identifying ways to increase the efficiency of IT investments by identifying potential duplication, waste, and opportunities to consolidate the management of IT services. Also, agency CIOs are to identify potential cost savings from consolidating IT investments and services.

In addition, the Consolidated Appropriations Act, 2023 requires HHS and its component agencies to identify and reduce unnecessary duplication among its data capabilities.[27] Further, GAO's Fragmentation, Overlap, and Duplication Guide assists agencies with identifying and evaluating duplication, overlap, and fragmentation to reduce, eliminate, or better manage negative consequences, such as wasting resources (e.g. time, money, and appropriate staff).[28] Specifically, the guide recommends that agency systems are to be reviewed to identify any positive or negative effects of any duplication, overlap, or fragmentation. Further, any findings should be developed and communicated with the appropriate agency officials to determine mitigation efforts, such as eliminating or consolidating systems.

HHS's CIO had not conducted department-wide reviews of its various systems, including those that support pandemic public health preparedness and response, to identify and reduce any unnecessary duplication, overlap, or fragmentation.[29] The Office of the CIO and ASPR officials stated that the HHS IT governance process did not include a formal process to review its systems to identify and reduce duplication, overlap, or fragmentation. These officials explained that there were opportunities in the review process, such as gate and portfolio reviews, where management officials could ask questions regarding systems' functions to determine potential duplication. While opportunities might exist, the departments' efforts to identify potential duplication, overlap, and fragmentation were not part of the review process.

[26]Federal information technology acquisition reform provisions of the Carl Levin and Howard P. 'Buck' McKeon National Defense Authorization Act for Fiscal Year 2015, Pub. L. No. 113-291, §833, 128 Stat. 3442 (2014).

[27]Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 2216(a), 136 Stat. 5740 (2022).

[28]GAO-15-49SP.

[29]GAO has ongoing work assessing federal agencies', including HHS, adherence to FITARA portfolio reviews of IT investments.

Instead, HHS relied on its component agencies to perform a review of their IT systems, including pandemic systems, to identify potential duplication, overlap, or fragmentation. Two of the six HHS component agencies that have systems that collect pandemic-related data reported that they performed reviews to identify unnecessary duplication, overlap, or fragmentation among their systems. However, these component agencies did not provide evidence of a review process for identifying instances of unnecessary duplication, overlap, or fragmentation.

Specifically, CDC officials reported that their systems are reviewed by its IT and data governance architecture review team. The officials stated that the team's review process focuses on standardizing and reducing duplication among its public health data systems. In addition, according to CDC officials, the agency's governance processes conform to the HHS Policy for Information Technology Acquisition Review under the requirements of FITARA. However, the documented IT and data governance architecture review and governance processes did not include the steps that should be taken, such as identifying the similar types of data collected, to identify instances of unnecessary duplication, overlap, or fragmentation. In addition, CDC officials did not provide evidence that they conducted such a review of their systems.

Further, HRSA officials stated that their systems undergo an annual review through their resource planning and management process. These officials stated that the review is to identify duplication among systems and prevent fragmentation and overlap with existing HRSA systems. These officials also explained that systems go through an approval process that involves critical stakeholders, including the HRSA CIO. However, these processes did not outline the steps for identifying and reducing unnecessary duplication, overlap, or fragmentation during these system reviews.

The remaining four component agencies did not provide evidence that they had established a process to conduct reviews of their systems to identify duplication, overlap, or fragmentation. Specifically, NIH and IHS officials stated that a system review was unnecessary because their systems were unique and only processed pandemic-related data internally. NIH officials stated that they were part of several meetings with other agency counterparts and were able to determine that no other system was similar. Nonetheless, neither NIH nor IHS provided evidence of an established process to conduct system reviews to identify unnecessary duplication, overlap, or fragmentation.

Additionally, ASPR and FDA did not conduct reviews to identify instances of duplication, overlap, or fragmentation among its pandemic systems. Specifically, ASPR officials stated they relied on the HHS IT governance process for their reviews. However, as noted above, the governance process did not include a formal review of systems to identify and reduce duplication, overlap, or fragmentation. Also, according to FDA officials, as part of their modernization reviews, they identified duplicative data in one pandemic system. However, they did not have a formal process for conducting duplication reviews for all of their pandemic systems.

Although HHS relied on component agencies to review their pandemic systems to identify potential duplication, overlap, and fragmentation, the component agencies were only able to review duplication within their systems and not across the department. It is important that the HHS CIO conducts reviews to ensure that duplication, overlap, and fragmentation are identified and reduced across various components throughout the department.

We and Others Identified Examples of HHS Component Agency Systems Collecting Duplicative Data

We and others found instances of HHS component agencies collecting duplicative data. Specifically, we found duplication among four systems that collect pandemic public health preparedness and response data. For example, two systems—Case Isolate Surveillance (CIS) and Outbreak Event Surveillance (OES)—function as surveillance systems to track foodborne outbreaks and provide this information to state health officials.[30] According to CDC officials, CIS collects individual case information, while OES collects outbreak, or event-based, aggregate information. However, both systems collect similar data, such as hospitalizations and deaths related to foodborne outbreaks. Further, these data are collected from similar sources, such as state public health laboratories and epidemiology centers.

In another example, two systems function as a common operating platform and work together to collect and share data relating to various disease outbreaks, including COVID-19. Those systems were the Data Collation and Integration for Public Health Event Response (DCIPHER) and HHS Protect. Both systems collect similar data, such as COVID-19

[30]According to CDC officials, the Case Isolate Surveillance system is responsible for monitoring all national surveillance efforts for the National Center for Emerging and Zoonotic Infectious Diseases division. Additionally, these officials stated the Division of Foodborne, Waterborne, and Environmental Diseases Outbreak Event Surveillance within National Center for Emerging and Zoonotic Infectious Diseases division provides reporting partners with the ability to enter data about enteric disease outbreaks caused by food, water, and person-to-person contact, among other things.

cases, deaths, laboratory results, and hospitalization data. Further, both systems are managed by the same CDC program office and utilize the same cloud-based technology to share information between the systems.[31]

CDC officials acknowledged the similar data collected between the CIS and OES systems. These officials stated they are developing a modernization plan to consolidate these systems into DCIPHER. Officials estimated that the consolidation of CIS would potentially save $75,000 per year in operations and management costs. The officials also estimated that the consolidation of OES would potentially save $150,000 per year in operations and maintenance costs.[32] This consolidation effort, according to CDC officials, should be completed by August 2025. However, CDC has not finalized plans for the consolidation of the systems into DCIPHER that would describe the costs, data, functions, and technical resources to be consolidated.

CDC officials also acknowledged the similar functions and the sharing of data collected between DCIPHER and HHS Protect. According to a plan dated April 2024, CDC is to consolidate these two systems into a single common operating platform called CDC Response Ready Enterprise Data Integration. One of the goals of this consolidation, according to the plan, is to reduce duplication in the resources for these systems. According to CDC officials, this consolidation is slated to be complete by August 2025, but they had not yet identified potential cost savings for completing this consolidation.[33]

In addition to the duplication that we found, representatives from state, territorial, and local public health organizations also identified an instance of duplication during the response to the COVID-19 pandemic. These

[31]Cloud-based technology is based on the concept of cloud computing, which enables on-demand access to shared computing resources that provide services more quickly and at a lower cost than if agencies maintained these resources independently.

[32]According to CDC officials, they provided a notional, predicted potential estimate of operations and management cost savings for migrating OES into DCIPHER and not the total cost savings because it would take significant effort to determine the total cost savings of the migration. They further stated that they do not know the number of years the potential cost savings would cover for both OES and CIS after the migration.

[33]CDC officials stated the consolidation of the Data Collation and Integration for Public Health Event Response into Response Ready Enterprise Data Integration platform has not begun. CDC officials could not identify a time frame for when the consolidation would begin. These officials stated that, as a result, it is too early to provide potential cost savings related to this consolidation.

representatives described a situation where state health departments and hospitals reported COVID-19 data to HHS Protect to track and monitor COVID-19 cases. They expressed how this led to duplication of COVID-19 data because in many cases, the hospitals were already reporting this data to their respective state health departments, which subsequently reported this information to CDC.

These representatives stated that the new process placed a burden on hospital staff because they had to report COVID-19 data to CDC twice through HHS Protect and their respective state health department and hospital systems. Further, these representatives stated that HHS Protect was not interoperable with state health department and hospital systems which resulted in hospital staff having to, in some cases, manually report COVID-19 case data to HHS Protect.[34]

Shortfalls in Comprehensive List and Review Process Are Due, in Part, to Lack of Prioritization

HHS's lack of a department-wide, comprehensive list and review process for identifying duplicative pandemic systems were due, in part, to the department not prioritizing these activities. HHS and component agency officials reported that they had to devote resources to addressing other priorities, including the COVID-19 pandemic. Since HHS's CIO did not assume the responsibility of developing a department-wide, comprehensive list, there was no foundation for identifying, reducing, or mitigating the negative effects of duplication across component agency systems at the department-level.

However, the requirements to develop a comprehensive list of pandemic systems and conduct reviews to identify duplication are longstanding. As previously noted, the Paperwork Reduction Act of 1995 requires agency CIOs to identify and inventory mission-related systems, including pandemic systems. Further, since 2014, FITARA requires CIOs to review IT investments to identify duplication and opportunities to consolidate IT services.

[34]In August 2021, we reported on HHS Protect hospital capacity reporting requirements and the challenges experienced by reporting entities, among other things. GAO, *COVID-19: HHS's Collection of Hospital Capacity Data*, GAO-21-600 (Washington, D.C.: Aug. 5, 2021). In June 2022, we reported that state public health officials most often identified gaps in interoperability among systems, such as health department systems, as one of their top challenges related to the management of public health information during the public health emergency, GAO-22-104600. In September 2020, we reported on challenges related to sharing data among public health entities, including the lack of an overall strategy to guide the establishment of interoperability among systems. GAO, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions,* GAO-20-701 (Washington, D.C.: September. 21, 2020).

Until HHS's CIO develops and maintains a department-wide, comprehensive list of pandemic systems, HHS will miss opportunities to more efficiently deliver information systems and non-duplicative pandemic data to users. Further, until the HHS CIO conducts required reviews of their pandemic systems to identify and reduce unnecessary duplication, overlap, or fragmentation, HHS and its component agencies may waste funding and conduct overlapping duties among its systems. This could delay the department's response to public health emergencies.

HHS Had Not Proactively Identified Funding and Staffing Resources for Its Pandemic Systems

HHS and its component agencies had not taken steps to proactively identify funding sources and costs for all of their pandemic public health preparedness and response systems. Similarly, HHS and its component agencies had not taken steps to proactively identify staffing resources for all of these systems.

HHS and Its Component Agencies Had Not Identified Funding Sources and Costs for Pandemic Systems

The President's *National Security Memorandum on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* requires agencies, including HHS, to identify funding resources in their budget requests allocated to biodefense and pandemic preparedness.[35] In addition, GAO's *Cost Estimating and Assessment Guide* states that agencies should identify and track costs to ensure that they are accurate, including funding sources to manage a program. Further, the guide states that agencies should identify development, operation, and maintenance costs for its systems.[36]

HHS receives funding from a variety of sources to support activities related to pandemic public health preparedness and response. In 2023, $81.7 billion was allocated to pandemic preparedness activities. Figure 3 shows examples of the funding sources that the HHS component

[35]The White House, *National Security Memorandum on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security, NSM-15* (Washington, D.C.: Oct. 18, 2022). Biodefense includes actions to counter biological threats, reduce biological risks, and prepare for, respond to, and recover from biological incidents.

[36]GAO-20-195G.

agencies identified for the pandemic public health preparedness and response systems.

Figure 3: Examples of Funding Sources for the Department of Health and Human Services (HHS) Pandemic Public Health Preparedness and Response Systems

Funding Source	Description
Laws that provide supplemental funding	
Prescription Drug User Fee Act *(October 29, 1992)*	Provides the Food and Drug Administration (FDA) with the authorization to assess and collect fees on certain human drug applications to support the human drug application review processes.
21st Century Cures Act *(December 13, 2016)*	Provides a total of $4.8 billion in funding to the National Institutes of Health (NIH) for innovative scientific initiatives and provides additional hiring and pay flexibilities to HHS to facilitate FDA's recruitment and retention of scientific and technical personnel.
CARES Act *(March 27, 2020)*	Provides $4.3 billion in funding to the Centers for Disease Control and Prevention (CDC) to remain available until September 30, 2024, to prevent, prepare for, and respond to the coronavirus.
Coronavirus Response and Relief Supplemental Appropriations Act *(December 27, 2020)*	Provides $55 million in funding to FDA and $1.25 billion to NIH to prevent, prepare for, and respond to the coronavirus; and $8.75 billion to CDC for coronavirus vaccination efforts.
American Rescue Plan Act of 2021 *(March 11, 2021)*	Provides $500 million in funding to CDC to support modernizing the nation's public health surveillance infrastructure in response to COVID-19 and emerging biological threats.
Programs that provide funding	
Advanced Molecular Detection	Provides laboratory, bioinformatics, and epidemiology technologies across CDC and nationwide in order to build the capacity necessary for modernized public health detection and surveillance to protect the nation from disease threats.
Data Modernization Initiative	Provides modernized core data and surveillance infrastructure across the federal and state public health landscape.
Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases	Provides financial support and technical assistance to the nation's health departments to detect, prevent, and respond to emerging infectious diseases.

Sources: GAO (analysis, heart and folder icons) of Department of Health and Human Services data; narathip/stock.adobe.com (icons). | GAO-24-106638

Prior to this review, HHS had not taken steps to proactively identify and track the specific funding sources and costs for each of the systems supporting pandemic public health preparedness and response. At our request, the HHS component agencies identified fiscal year 2023 funding sources and costs for 95 of the 99 (96 percent) data collection systems that support pandemic public health preparedness and response.

However, not all HHS components track funding sources and costs per system. Instead, funding is tracked by program. For example, FDA officials stated that the operation and maintenance costs for 27 of its pandemic systems are tracked at the program level, which can include numerous systems, rather than at the system level. So, while FDA could not identify costs for these 27 systems separately, they were able to identify total costs for all of the systems under the program they support. Similarly, CDC officials stated that it could not identify fiscal year 2023 funding sources and costs for one system, CDC Red Sky, because it shared costs with the Emergency Operations Management System, and that it would not be feasible to identify the costs between both systems.[37]

Nonetheless, of the reported $81.7 billion allocated to pandemic preparedness activities for fiscal year 2023, the HHS component agencies reported that approximately $623.4 million was used to operate and maintain 95 out of 99 (96 percent) of their pandemic systems.[38] Table 1 includes the reported fiscal year 2023 funding sources and total costs for the five systems with the highest reported costs in fiscal year 2023. Appendix II includes a list of the HHS data collection systems identified by component agencies that support pandemic public health preparedness and response and their reported fiscal year 2023 funding sources and total costs.

[37]The CDC Red Sky system gathers data and information about public health events and displays the data in a real-time dashboard and global map that is intended to track active health events and improve situational awareness. According to CDC officials, the Emergency Operations Management System supports CDC's Emergency Operations Center, which monitors public health threats. Officials also stated that CDC Red Sky and the Emergency Operations Management System share costs because they share the same database.

[38]The costs provided by the component agencies consisted of both appropriated funds and obligated funds and varied by component agency.

Table 1: Department of Health and Human Services (HHS) Pandemic Public Health Preparedness and Response Systems with the Greatest Reported Costs in Fiscal Year 2023

HHS component agencies	System name and description	Fiscal Year 2023 funding source	Total Fiscal Year 2023 costs (in millions)
Centers for Disease Control and Prevention (CDC)	Tiberius Platform – provides supply chain insight to guide medical countermeasures for COVID-19 and Mpox.	Administration for Strategic Preparedness and Response funds, CDC COVID-19 funds, and program funds.	$84.3
CDC	National Healthcare Safety Network – provides tracking and response capabilities to identify emerging and enduring threats across health care (e.g., COVID-19, health care-associated infections, and antimicrobial-resistant infections).	Appropriated funds, supplemental funds, and interagency agreements from the Centers for Medicare & Medicaid Services, the Department of Veteran Affairs, and the Food and Drug Administration.	$63.4
National Institutes of Health	National COVID Cohort Collaborative – collects deidentified clinical data for COVID-19 research. According to NIH, this system represents a shared vision for turning real-world data into the knowledge needed to address COVID-19 as the pandemic evolves.	National Institutes of Health Office of the Director, Advanced Research Projects Agency for Health, and National Center for Advancing Translational Sciences appropriated funds and Office of the Assistant Secretary for Planning and Evaluation funds.	$50.1
CDC	National Syndromic Surveillance Program – provides a public health situational awareness network for outbreaks, disasters, injuries, and other responses.	Appropriated funds including Surveillance, Epidemiology, and Public Health Informatics and Data Modernization Initiative funds, American Rescue Plan Act funds, and CDC Centers, Institutes, and Offices allocated funds.	$39.3
CDC	U.S. Influenza Vaccine Effectiveness Networks – estimates the effectiveness of influenza vaccines in preventing illness, severe outcomes, and transmission of illness.	Program funds, COVID-19 funds, and Prevention and Public Health funds	$36.3

Source: GAO analysis of HHS data. | GAO-24-106638

Note: We identified these systems as the five systems with the highest costs, based on the total costs reported by HHS. The costs provided by the component agencies consisted of both appropriated funds and obligated funds and varied by component agency.

Although the component agencies identified funding information for most of their pandemic public health preparedness and response systems at our request, they did not identify funding sources and costs for all of them. Specifically, HHS could not provide complete funding information

for 4 of the 99 (4 percent) pandemic public health preparedness and response systems.

As we previously discussed, CDC could not identify funding information for Red Sky because it shares costs with another system. CDC and IHS did not provide rationale for why they could not identify complete funding information for the remaining three systems.

HHS and Its Component Agencies Had Not Identified Staffing Resources

GAO's IT workforce planning framework indicates agencies should identify and track staffing resources as well as the amount and type of staff (i.e., full-time, full-time equivalents (FTEs), contractor, or part-time staff) dedicated to a system.[39] According to the framework, in order to have effective team composition, agencies should determine the necessary skills, team size, and availability of staff. In addition, key workforce planning activities include developing staffing requirements and assessing staffing needs regularly.

Prior to this review, HHS had not taken steps to proactively identify and track staffing resources for its systems, including those supporting pandemic public health preparedness and response. At our request, the component agencies identified staffing information for 96 of 99 (97 percent) systems, including the type of staff and number of staff necessary to operate and maintain them. In some instances, staffing was identified by program and not by individual system. Therefore, the staffing levels for these systems varied widely in 2023. For example:

- IHS officials stated that staffing for the Influenza-like Illness Awareness System consisted of one FTE and one contractor dedicated to system maintenance.
- ASPR officials stated that staffing for the ASPR Ready system consisted of one FTE and eight contractor staff members.[40]
- CDC officials identified that staffing for the National Healthcare Safety Network consisted of 34 FTEs and 296 contractor staff members.[41]

However, HHS component agencies could not identify complete staffing information for the remaining three systems (three percent). Officials at

[39]GAO-17-8.

[40]According to ASPR officials, ASPR Ready supports agency collaboration and information and data management for the agency's preparedness and response missions.

[41]According to CDC officials, the reported staffing for the National Healthcare Safety Network includes the staffing for a larger program for which the network supports.

the component agencies operating and maintaining the remaining three systems—one CDC system and two IHS systems—did not provide rationale for why they could not provide the information.

HHS and the component agencies' not proactively or consistently identifying and tracking funding and staffing information for all of their pandemic systems was due to HHS not prioritizing it. HHS and component agency officials reported that they had to devote resources to addressing other priorities, including the COVID-19 pandemic. This issue is compounded by the fact that the department does not have a comprehensive list of pandemic systems. Therefore, the department does not have the foundation necessary for identifying and tracking the funding and staffing resources for pandemic systems across the department. Despite the federal government's response to pandemics, such as COVID-19, the nation continues to face public health risks for the foreseeable future. Not being sufficiently prepared for these risks can negatively affect the time and resources needed to achieve recovery from future pandemics.

Until HHS is able to proactively and consistently identify and track the funding resources dedicated to all of its pandemic public health preparedness and response systems, the department lacks assurance that it has the funding information needed to effectively manage its systems at all times in preparation for, during, and after pandemics. This is critical because many of the funding resources provided for these systems come from funding provided during the COVID-19 pandemic, and the future of these funding resources remains uncertain. For example, all of the component agencies identified instances where future funding levels may be affected by the loss of pandemic-related funding, such as funding supplemented by the CARES Act.[42] See appendix III for a summary of HHS component agencies' comments on the impact of pandemic-related funding on their systems.

Further, until HHS proactively and consistently identifies and tracks the staffing resources dedicated to managing all of its pandemic systems, the department lacks assurance that it is effectively managing the staffing resources necessary for preparing for and responding to pandemics. It is important to determine staffing resources to address pandemic needs during and outside of pandemic time frames. HHS component agency officials stated that staff may manage multiple systems and have

[42]Pub. L. No. 116-136, § 19010, 134 Stat. 579 (2020).

additional duties during pandemic response, so it is important that HHS identifies staffing needs prior to and during pandemics to ensure that the systems are operating as intended.

HHS Partially Implemented Key Privacy Safeguards for Collecting PII in Systems Supporting Pandemic Response

HHS and its component agencies have established officials that are responsible for privacy activities. However, HHS and its component agencies have not fully addressed key federal privacy requirements, such as developing PIAs and privacy plans, for all of their pandemic systems that include PII.[43]

HHS and Its Component Agencies Established Officials Responsible for Privacy

OMB Circular A-130 requires agencies to designate a SAOP responsible for establishing and maintaining an agency-wide privacy program to ensure compliance with policies involving protection of PII.[44] Although the SAOP is responsible for the agency's privacy program, OMB guidance provides for the delegation of privacy functions to other qualified agency personnel, such as senior officials for privacy.

According to the HHS *Policy for Information Security and Privacy Protection*, the Chief Information Officer serves as the department's SAOP.[45] According to the policy, the SAOP is responsible for ensuring compliance with privacy requirements, developing and evaluating privacy policy, and managing privacy risks. In addition, according to HHS policy, each component agency is to have a senior official for privacy that supports the HHS SAOP and manages the implementation of privacy requirements within their component agency. These officials vary for each component agency; some component agencies have established privacy positions. For example:

[43]Personally identifiable information (PII) is any information that can be used to distinguish or trace an individual's identity, such as name, date or place of birth, and Social Security number; or that otherwise can be linked to an individual. A privacy impact assessment (PIA) analyzes how PII is handled in information systems to ensure that handling conforms to applicable privacy requirements. A PIA also determines the privacy risks associated with an information system and evaluates ways to mitigate privacy risks.

[44]Office of Management and Budget Circular A-130*, Managing Information as a Strategic Resource* (Washington, D.C.: July 28, 2016).

[45]Department of Health and Human Services, *HHS Policy for Information Security and Privacy Protection* (Washington, D.C.: Nov. 18, 2021).

- CDC's senior official for privacy is the Chief Privacy Officer who is to, among other things, review and approve privacy plans for CDC information systems before the systems are approved to operate on the agency's network.
- HRSA's Chief Information Security Officer serves as its senior official for privacy that oversees privacy compliance activities and leads a team of privacy officers. According to HRSA officials, these officers are responsible for conducting PIAs and responding to PII incidents.
- FDA's senior official for privacy is responsible for overseeing and coordinating the component agencies' privacy compliance efforts, including approving PIAs before they are sent to the HHS SAOP for approval.

HHS Component Agencies Did Not Develop Privacy Impact Assessments for Many Pandemic Systems

According to the E-Government Act of 2002 and OMB Memorandum M-03-22, *Guidance for Implementing the Privacy Provisions of the E-Government Act*, agencies are required to develop a PIA before developing or procuring IT that store and process PII. In addition, according to HHS policy, the SAOP requires PIAs to be developed for the department's systems that collect and store PII.

However, HHS's component agencies had not developed PIAs for all of their pandemic public health preparedness and response systems that collect and store PII. According to the component agencies, 68 of the 99 (69 percent) systems identified as supporting pandemic public health preparedness and response collected and stored PII. PIAs were developed for 53 (78 percent) of these systems, leaving 15 (22 percent) systems without an assessment of privacy risks.

Seven of the 15 (47 percent) systems that had no PIAs were CDC systems. CDC stated that PIAs were not required for these systems for various reasons. For example, CDC officials stated that three of the seven systems were covered by other systems' PIAs. However, these systems were not mentioned in other PIAs as being included in the assessment. Nonetheless, in May 2024, CDC officials stated that they had initiated but not yet finalized a separate PIA for one of the three systems—the Surveillance of Emerging Threats to Pregnant People and Infants Network.[46]

[46]The Surveillance of Emerging Threats to Pregnant People and Infants Network identifies the impact of emerging and reemerging health threats, such as COVID-19 on pregnant people and their infants.

For three additional systems, CDC stated that a PIA was not required because they had either a cooperative agreement or data use agreement for the information collected and stored by the system. However, CDC identified these systems as collecting and storing PII. Therefore, a PIA should have been performed for these systems.

For the last CDC system that lacked a PIA, officials stated that the system supports various programs across CDC and the programs are to manage the PIAs for the data they store in the system. However, CDC did not provide evidence that the programs maintained a PIA for this system.

Seven of the 15 (47 percent) systems that had no PIAs were FDA systems. In commenting on a draft of this report, FDA officials stated that these systems were included as part of the PIAs of other systems.[47] However, these seven systems were not mentioned in other PIAs as being included in the assessment. The officials stated that developing separate PIAs for every piece of technology used in a system and naming every piece of technology associated with a system within the applicable PIA would be unfeasible. However, by not identifying the specific systems that are to be covered by a privacy assessment, it is unclear whether the agency has adequately performed assessments on every system that collects or stores PII.

Regarding the final system, ASPR had completed a PIA for the Cooperative Agreement Accountability and Management Platform, but it expired during our audit.[48] According to ASPR officials, a new PIA was submitted in February 2024 to authorizing officials for review and approval, but as of July 2024 it had not yet been approved.

Until HHS's component agencies ensure that privacy risks are assessed and privacy impact assessments are developed for all of their information systems containing PII, including those that support pandemic public health preparedness and response, HHS will have less assurance that it fully understands the risks and the privacy protections necessary for these systems.

[47]One PIA can cover multiple systems that may have common privacy controls. In addition, some systems can include a variety of sub-systems and may inherit privacy controls from the larger system.

[48]According to ASPR officials, the Cooperative Agreement Accountability and Management Platform supports the management of certain Office of Health Care Readiness cooperative agreements and supplemental funding.

HHS Partially Implemented Key Privacy Requirements for Selected Pandemic Systems That Include Personal Information

Federal requirements include several key privacy safeguards for information systems that include PII. According to the Privacy Act of 1974, agencies are required to have documented system of records notices (SORN) that notify the public when the agency establishes or makes changes to a system of records.[49] According to OMB Circular A-130, agencies should be transparent about practices in regard to PII and provide accessible notice to the public regarding the collection, storage, and disclosure of PII.[50]

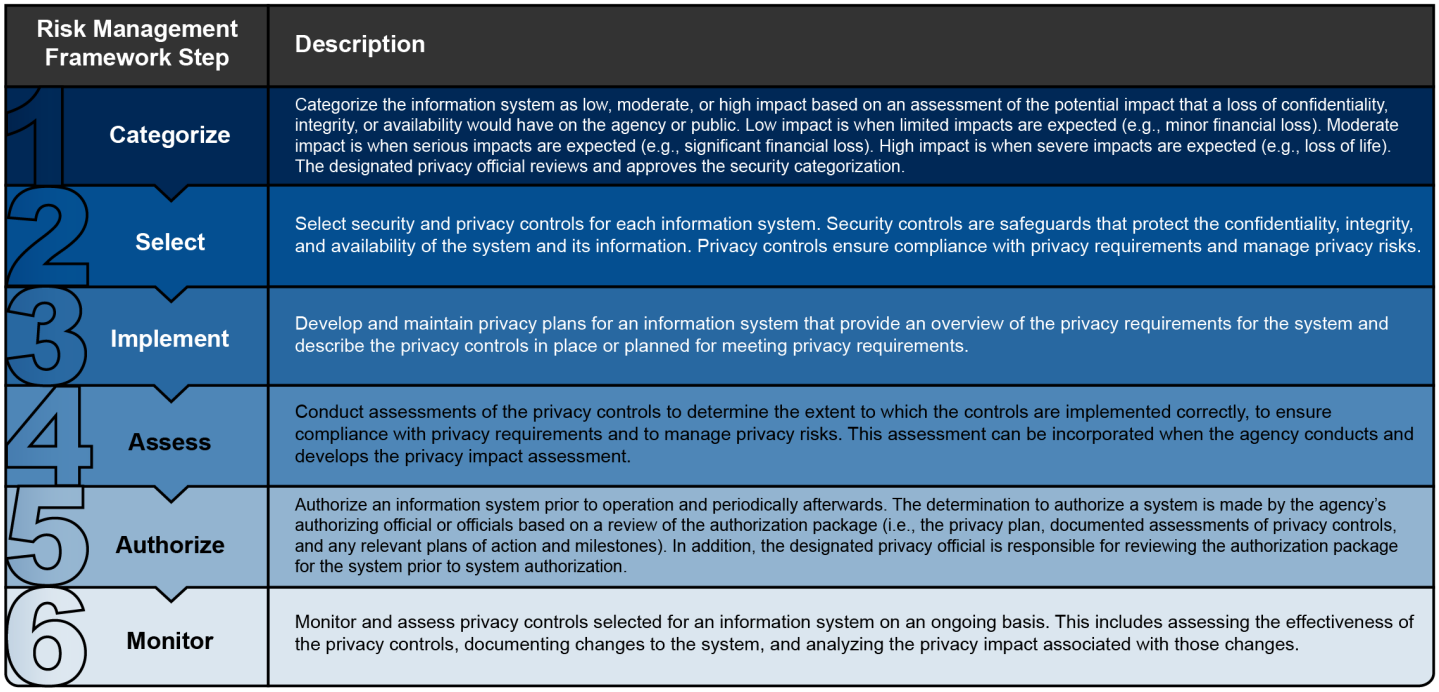
In addition, according to OMB Circular A-130, agencies should implement the National Institute of Standards and Technology (NIST) Risk Management Framework to manage privacy risks related to systems that include PII.[51] Figure 4 below summarizes the steps for implementing the NIST Risk Management Framework.

[49]Privacy Act of 1974, Pub. L. No. 93-579, 88 Stat. 1896 (Dec. 31, 1974) (codified as amended at 5 U.S.C. § 552a). A system of records is a group of records containing personal information under the control of any agency from which information is retrieved by the name of an individual or an individual identifier. SORNs are to identify, among other things, the types of data collected, the types of individuals about whom information is collected, the intended routine uses of the data, and procedures that individuals can use to review and correct personal information. The Privacy Act applies to systems of records, specifically, not all systems containing personally identifiable information.

[50]Office of Management and Budget Circular A-130*, Managing Information as a Strategic Resource* (Washington, D.C.: July 28, 2016).

[51]National Institute of Standards and Technology SP 800-37, Revision 2: *Risk Management Framework for Information Systems and Organizations: A System Life Cycle Approach for Security and Privacy* (Gaithersburg, Md.: December 2018).

Figure 4: Steps for Implementing the Risk Management Framework



Source: GAO analysis of Office of Management and Budget and National Institute of Standards and Technology requirements. | GAO-24-106638

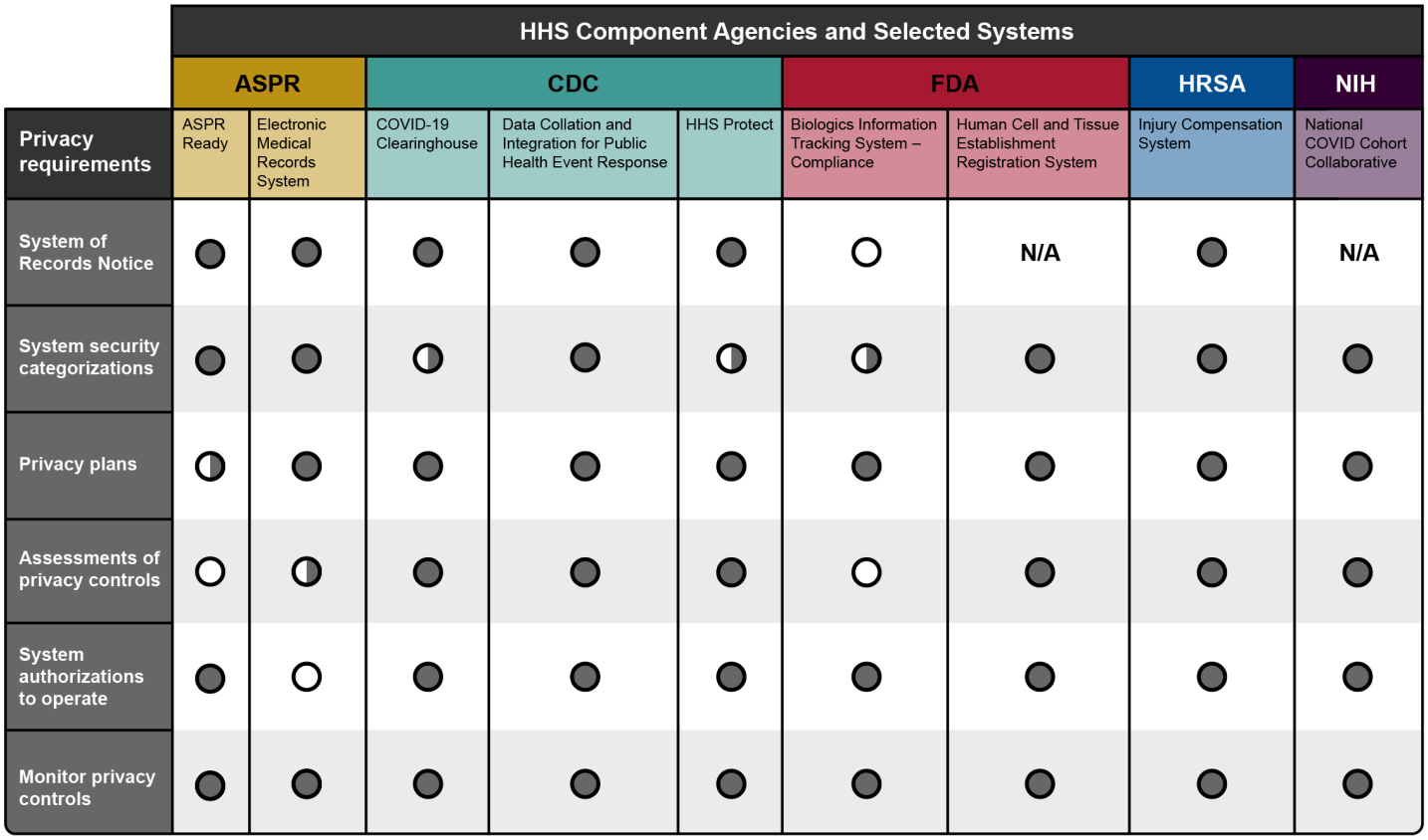
HHS partially implemented selected key privacy requirements identified in the Privacy Act of 1974 and OMB Circular A-130 for the selected pandemic public health preparedness and response systems that include

PII.[52] Figure 5 below summarizes the extent to which HHS's component agencies implemented the requirements for nine selected systems.[53]

[52]Privacy Act of 1974, Pub. L. No. 93-579, 88 Stat. 1896 (Dec. 31, 1974) (codified as amended at 5 U.S.C. § 552a). For our review, the key privacy requirements identified in the Privacy Act of 1974 address implementing systems of records notices. Office of Management and Budget Circular A-130*, Managing Information as a Strategic Resource* (Washington, D.C.: July 28, 2016).

[53]Our selection of 10 systems included FDA's Event-based Text-mining for Health Electronic Records system. FDA had initially stated that the system included PII. After our review began, FDA analyzed the information stored by the system and determined that it did not include PII. Therefore, this system was removed from our final evaluation of privacy requirements, resulting in nine systems. The nine systems were ASPR Ready, the Electronic Medical Records System, COVID-19 Clearinghouse, DCIPHER, HHS Protect, Biologics Information Tracking System—Compliance, Human Cell and Tissue Establishment Registration System, Injury Compensation System, and the National COVID Cohort Collaborative.

Figure 5: The Extent to Which HHS Component Agencies Implemented Key Privacy Requirements for Selected Systems



ASPR = Administration for Strategic Preparedness and Response, CDC = Centers for Disease Control and Prevention, FDA = Food and Drug Administration, HHS = Department of Health and Human Services, HRSA = Health Resources and Services Administration, NIH = National Institutes of Health

Source: GAO analysis of agency information. | GAO-24-106638

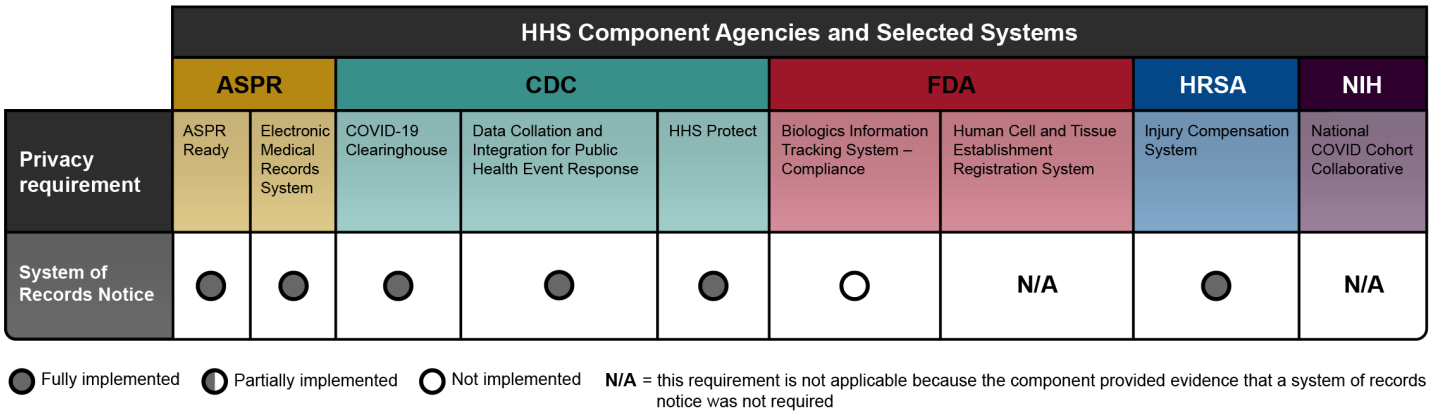
Note: The systems for each component agency were randomly selected from the agency's systems that include personally identifiable information, as identified by the component agencies and are not generalizable to all of the agencies' systems.

Develop SORNs. According to the Privacy Act of 1974, agencies are required to have documented SORNs that notify the public when the agency establishes or makes changes to a system of records.[54] Figure 6

[54]Privacy Act of 1974, Pub. L. No. 93-579, 88 Stat. 1896 (Dec. 31, 1974) (codified as amended at 5 U.S.C. § 552a).

below summarizes the extent to which the component agencies developed SORNs for the selected pandemic systems that collect and store PII.

Figure 6: The Extent to Which HHS Component Agencies Implemented System of Record Notices for Selected Systems



ASPR = Administration for Strategic Preparedness and Response, CDC = Centers for Disease Control and Prevention, FDA = Food and Drug Administration, HHS = Department of Health and Human Services, HRSA = Health Resources and Services Administration, NIH = National Institutes of Health

Source: GAO analysis of agency information. | GAO-24-106638

SORNs were developed or the agencies determined they were not needed for eight of the nine selected pandemic public health preparedness and response systems collecting and storing PII. For example:

- ASPR developed a SORN for ASPR Ready, which includes records that contain PII, such as home addresses, social security numbers, and telephone numbers.
- CDC has an existing SORN that covers the COVID-19 Clearinghouse, which includes PII from individuals with diseases and other preventable conditions of public health significance.[55] Records in the system also include case reports, medical records, and questionnaires.
- HRSA developed a SORN for the Injury Compensation System, which includes medical, medical expense, and employment records used to

[55]According to CDC officials, the COVID-19 Clearinghouse is a cloud repository for state, tribal, local, territorial, or national organizations to upload and store COVID-19 vaccination data.

support claims alleging injury or death and to make program recommendations and decisions.[56]

FDA did not develop a SORN for one of the nine systems. Specifically, FDA did not provide evidence that an assessment was conducted to determine that a SORN was not required for the Biologics Information Tracking System – Compliance system.[57] Until FDA conducts an assessment to determine if SORNs are required for their pandemic systems that include PII, they lack assurance that they are effectively informing the public about the department's use of PII.

SORNs were not applicable for two of the nine systems—the National COVID Cohort Collaborative and the Human Cell and Tissue Establishment Registration System.[58] According to FDA and NIH officials, the Privacy Act did not apply to the selected systems.

Specifically, one selected system, the National COVID Cohort Collaborative, has a PIA that noted that the system does not contain personal information for the research data it collects and, therefore, would not require a SORN. The system's PIA noted that the system only collects PII from the users that access the system (e.g., email addresses) and deidentifies datasets for research. Further, according to the Human Cell and Tissue Establishment Registration System's PIA, although the system contains PII, it does not use names or other personal identifiers (e.g., an individual's name, date of birth, and social security number) to retrieve records.

Develop security categorizations. According to the NIST Risk Management Framework, agencies should develop security categorizations for the systems that collect and store PII. Figure 7 below

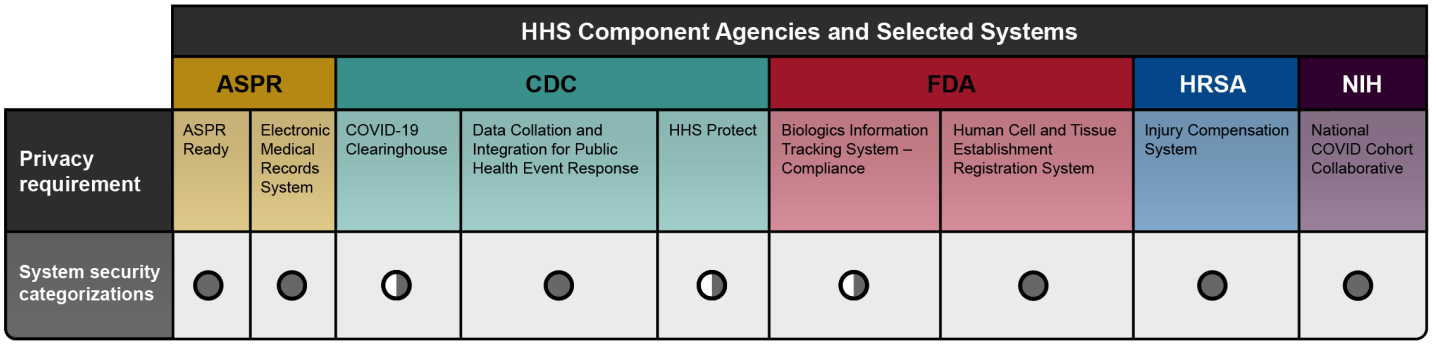
[56]According to HRSA officials, the Injury Compensation System collects data from claims that allege injuries or deaths from certain countermeasures, such as COVID-19 vaccine and ventilators. Further, its purpose is to provide compensation to individuals for covered serious injuries or deaths that occur as the direct result of the administration or use of countermeasures covered by a federal declaration under the Public Readiness and Emergency Preparedness Act.

[57]According to FDA officials, the Biologics Information Tracking System – Compliance system tracks inspections and complaints for biological products.

[58]According to NIH officials, the National COVID Cohort Collaborative collects deidentified clinical data for COVID-19 research. According to FDA officials, the Human Cell and Tissue Establishment Registration System reports on facilities that manage human cells and tissues.

summarizes the extent to which the component agencies developed security categorizations for the selected systems.

Figure 7: The Extent to Which HHS Component Agencies Developed Security Categorizations for the Selected Systems



Fully implemented | Partially implemented | Not implemented | **N/A** = this requirement is not applicable because the component provided evidence that a system of records notice was not required

ASPR = Administration for Strategic Preparedness and Response, CDC = Centers for Disease Control and Prevention, FDA = Food and Drug Administration, HHS = Department of Health and Human Services, HRSA = Health Resources and Services Administration, NIH = National Institutes of Health

Source: GAO analysis of agency information. | GAO-24-106638

System security categorizations were established for six of the nine selected systems supporting pandemic public health preparedness and response. The system security categorizations were based on an assessment of the potential impact that a loss of confidentiality, integrity, or availability would have on the agency and the public. In addition, the HHS SAOP reviewed and approved the security categorizations. These categorizations were documented in the systems' PIA. Five of the six systems were categorized as moderate impact systems. The remaining system, the Electronic Medical Records System, was categorized as a high impact system.[59]

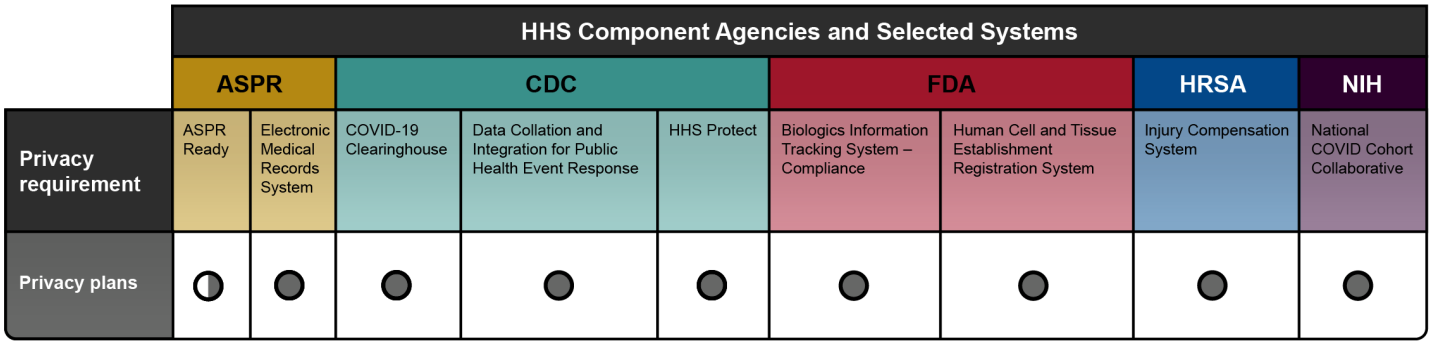
[59]According to ASPR officials, the Electronic Medical Record System supports the documentation of all medical care provided during National Disaster Medical System deployments and enables medical personnel to automate data processes (e.g., data entry and data reporting). According to these officials, ASPR's National Disaster Medical System provides personnel, equipment, and supplies in response to public health emergencies, including pandemic diseases. In addition, according to these officials, the Electronic Medical Record System is an application part of the Disaster Medical Information Suite, a suite of applications used to track National Disaster Medical System responses.

CDC partially developed the system security categorization for two systems. While CDC developed system security categorizations for its HHS Protect system and the COVID-19 Clearinghouse, the senior official for privacy had not reviewed and approved the categorizations. According to CDC officials, the component agency is currently discussing process improvement steps for documenting the senior official for privacy's review of system security categorizations by September 2024.

FDA partially developed the system security categorization for one system. While FDA developed the system security categorization for the Biologics Information Tracking System-Compliance system, the senior official for privacy had not reviewed and approved the categorization. According to FDA officials, the senior official for privacy reviews and approves system security categorizations when they review system PIAs. However, the component agency had not developed a PIA for this system. Until CDC and FDA develop security categorizations for the systems that include PII and document the review and approval of them, the component agencies have less assurance that they are appropriately considering the potential impact that a security breach of PII would have on them and the public.

Develop privacy plans. According to the NIST Risk Management Framework, agencies should develop privacy plans for the systems that collect and store PII. Figure 8 below summarizes the extent to which the component agencies developed privacy plans for the selected systems.

Figure 8: The Extent to Which HHS Component Agencies Developed Privacy Plans for the Selected Systems



Fully implemented | Partially implemented | Not implemented | **N/A** = this requirement is not applicable because the component provided evidence that a system of records notice was not required

ASPR = Administration for Strategic Preparedness and Response, CDC = Centers for Disease Control and Prevention, FDA = Food and Drug Administration, HHS = Department of Health and Human Services, HRSA = Health Resources and Services Administration, NIH = National Institutes of Health

Source: GAO analysis of agency information. | GAO-24-106638

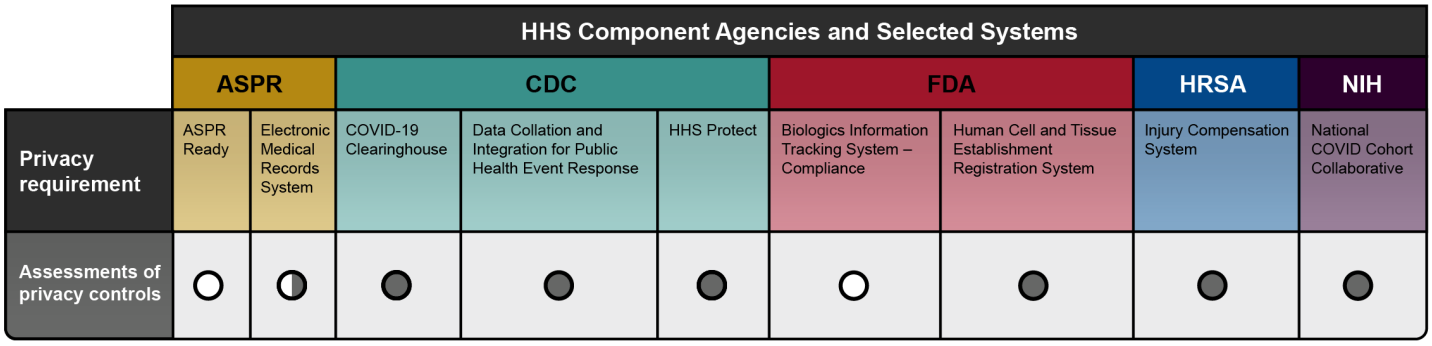
Privacy plans were developed for eight of the nine selected pandemic public health preparedness and response systems. These plans documented the privacy controls in place or planned for the systems.[60]

ASPR partially implemented the requirement to develop a privacy plan for one of the systems we selected from the component agency. Specifically, ASPR developed a privacy plan for ASPR Ready that included an overview of privacy requirements. However, the plan did not include the privacy controls in place or planned for meeting the privacy requirements. Until ASPR fully develops privacy plans, the component agency is at increased risk that privacy requirements have not been established, and therefore, adequate privacy controls may not be place.

Assess privacy controls. According to the NIST Risk Management Framework, agencies should conduct assessments of privacy controls for the systems that collect and store PII. Figure 9 below summarizes the extent to which the component agencies conducted assessments of privacy controls for the selected systems.

[60]According to NIH officials, the National COVID Cohort Collaborative is a subsystem under the National Center for Advancing Translational Sciences General Support System, which has a privacy plan that includes privacy controls and requirements.

Figure 9: The Extent to Which HHS Component Agencies Assessed Privacy Controls for the Selected Systems



Fully implemented | Partially implemented | Not implemented | **N/A** = this requirement is not applicable because the component provided evidence that a system of records notice was not required

ASPR = Administration for Strategic Preparedness and Response, CDC = Centers for Disease Control and Prevention, FDA = Food and Drug Administration, HHS = Department of Health and Human Services, HRSA = Health Resources and Services Administration, NIH = National Institutes of Health

Source: GAO analysis of agency information. | GAO-24-106638

Privacy controls were assessed for six of the nine selected pandemic public health preparedness and response systems. ASPR did not assess privacy controls for two systems, ASPR Ready and the Electronic Medical Records System. One reason for this is that, as previously discussed, the ASRP Ready privacy plan did not include the privacy controls for the system. Therefore, they did not have information necessary to conduct the privacy assessment. Since the component agency did not identify the privacy controls needed for the system, it cannot ensure that it is effectively assessing the controls. In addition, although ASPR had documented the privacy controls in the Electronic Medical Records System's PIA, it had not yet assessed them. ASPR officials stated that the privacy assessment for the Electronic Medical Records System is planned and would be completed by the end of fiscal year 2024.

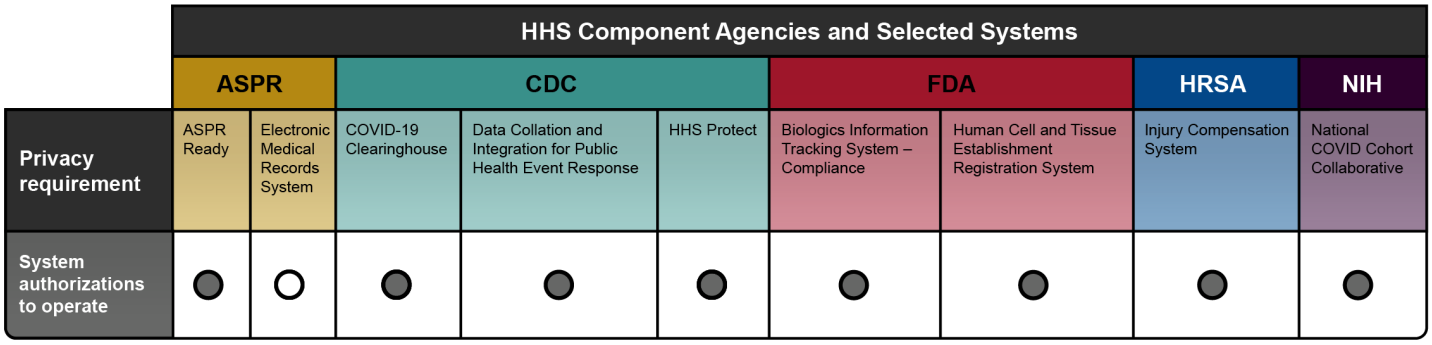
In addition, we could not find evidence that FDA assessed privacy controls for one system, the Biologics Information Tracking System-Compliance. According to FDA officials, the privacy controls were inherited from another system.[61] However, there was no mention of

[61]According to NIST, an inherited security control is a situation in which an information system or application receives protection from security controls (or portions of security controls) that are developed, implemented, assessed, authorized, and monitored by entities other than those responsible for the system or application; entities either internal or external to the organization where the system or application resides.

Biologics Information Tracking System-Compliance or its larger program—the FDA Center for Biologics Evaluation and Research—in that system's security assessment report. Until ASPR and FDA fully assess privacy controls for their systems that collect PII, the component agencies are at risk of exposing PII collected and stored by these systems, such as patient medical data.

Develop authorizations to operate. According to the NIST Risk Management Framework, agencies should develop authorizations to operate (ATOs) for the systems that collect and store PII. Figure 10 below summarizes the extent to which the component agencies developed ATOs for the selected systems.

Figure 10: The Extent to Which HHS Component Agencies Developed Authorizations to Operate for the Selected Systems



ASPR = Administration for Strategic Preparedness and Response, CDC = Centers for Disease Control and Prevention, FDA = Food and Drug Administration, HHS = Department of Health and Human Services, HRSA = Health Resources and Services Administration, NIH = National Institutes of Health

Source: GAO analysis of agency information. | GAO-24-106638

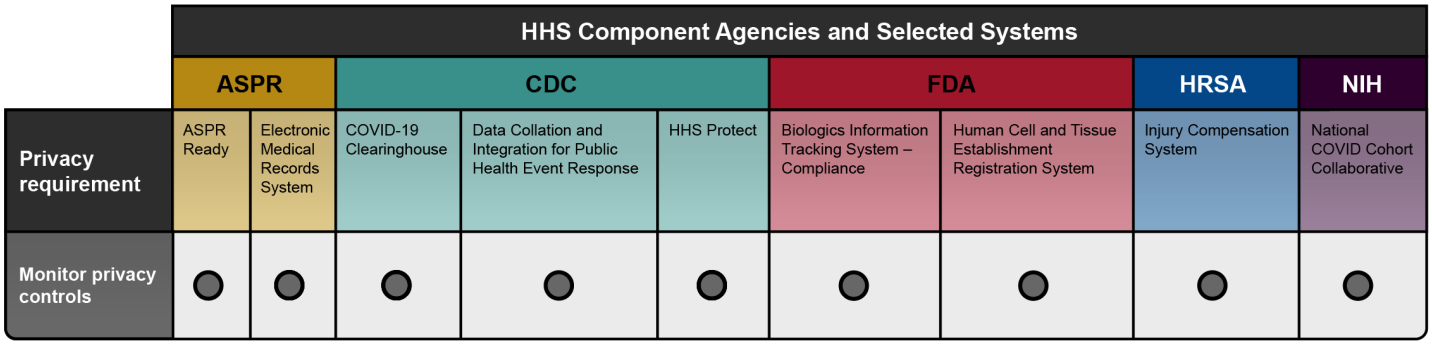
ATOs were developed for eight of the nine selected systems. These ATOs included the approval of their authorizing officials.

However, ASPR did not have evidence of an ATO for the remaining selected system, the Electronic Medical Record System. According to ASPR officials, the ATO expired in May 2024. Prior to the expiration, in February 2024, the component agency submitted a request to the authorizing official to extend the system's ATO. However, as of July 2024, an extension to the ATO had not been approved. Until ASPR develops

the authorization to operate, the component agency is operating a system that contains privacy information without an authorization to do so.

Conduct privacy continuous monitoring. According to the NIST Risk Management Framework, agencies should regularly monitor privacy controls for the systems that collect and store PII. The component agencies conducted privacy continuous monitoring for all nine of the selected systems. Figure 11 below summarizes the extent to which the components conducted privacy continuous monitoring for the selected systems.

Figure 11: The Extent to Which HHS Component Agencies Conducted Monitoring for Privacy Controls for the Selected Systems



ASPR = Administration for Strategic Preparedness and Response, CDC = Centers for Disease Control and Prevention, FDA = Food and Drug Administration, HHS = Department of Health and Human Services, HRSA = Health Resources and Services Administration, NIH = National Institutes of Health

Source: GAO analysis of agency information. | GAO-24-106638

Implementation of most of the six key privacy requirements across the nine selected systems is a positive step. Nonetheless, until HHS fully implements key privacy safeguards for protecting PII within pandemic systems, this information may be at higher risk for unauthorized disclosure.

Conclusions

Over the last 29 years, HHS's CIO had the responsibility of developing a department-wide comprehensive list of systems that collect data associated with its mission, including those that support pandemic preparedness and response, and has yet to develop it. Without a comprehensive list, there was no foundation for conducting reviews to identify and reduce the negative effects of unnecessary duplication, overlap, and fragmentation across component agency systems at the

department level. Also, without the comprehensive list of these systems, HHS does not have the foundation for identifying the necessary funding and staffing resources to manage systems supporting pandemic preparedness and response. Until HHS conducts required reviews of these systems to identify duplication, overlap, and fragmentation, the department may waste resources and unnecessarily perform overlapping duties among its systems. This could delay the department's response to public health emergencies. Further, until HHS proactively and consistently identifies and tracks funding and staffing resources for these systems, the department lacks assurance that it has the critical resources needed to effectively manage its systems in preparation for, during, and after pandemics.

Longstanding privacy laws and guidance required HHS and its component agencies to implement privacy safeguards to protect PII, such as developing PIAs, SORNs, and privacy plans. While HHS and its component agencies developed PIAs for most of the systems supporting pandemic preparedness and response that include PII some systems were left without this assessment. Further, since HHS and its component agencies have either partially or did not implement key privacy safeguards for some selected systems that collect PII during pandemics, the department lacks assurance that its pandemic systems are adequately protected. Until HHS and the component agencies fully implement key privacy safeguards for protecting PII within their pandemic systems, this information may be at higher risk for unauthorized disclosure.

Recommendations for Executive Action

We are making a total of 14 recommendations to HHS and the component agencies:

- The Secretary of HHS should ensure that the HHS CIO develops and maintains a department-wide comprehensive list of systems, including component systems, that support pandemic public health preparedness and response. (Recommendation 1)
- The Secretary of HHS should ensure that the HHS CIO conducts reviews of systems that support pandemic public health preparedness and response across the department to identify and reduce any unnecessary duplication, overlap, or fragmentation and identify mitigation options, such as consolidation or elimination of systems. The HHS CIO should share the results of its reviews with components when identifying any instances of unnecessary duplication, overlap, or fragmentation. (Recommendation 2)

- The Secretary of HHS should ensure that component agencies proactively and consistently identify and track the funding sources and costs dedicated to operating and maintaining all of their systems supporting pandemic public health preparedness and response. (Recommendation 3)
- The Secretary of HHS should ensure that component agencies proactively and consistently identify and track staffing resources, including the type and number of staff dedicated to managing all of their systems supporting pandemic public health preparedness and response. (Recommendation 4)
- The Secretary of HHS should ensure that the Administration for Strategic Preparedness and Response has an updated privacy impact assessment for the Cooperative Agreement Accountability and Management Platform. (Recommendation 5)
- The Secretary of HHS should ensure that the Administration of Strategic Preparedness and Response revises the system privacy plan for ASPR Ready to include the privacy controls in place or planned for meeting the privacy requirements. (Recommendation 6)
- The Secretary of HHS should ensure that the Administration for Strategic Preparedness and Response develops assessments of privacy controls for ASPR Ready and the Electronic Medical Records System. (Recommendation 7)
- The Secretary of HHS should ensure that the Administration for Strategic Preparedness and Response develops the authorization to operate for the Electronic Medical Records System. (Recommendation 8)
- The Secretary of HHS should ensure that the Director of the Centers for Disease Control and Prevention conducts and develops privacy impact assessments for all pandemic public health preparedness and response systems that include personally identifiable information. (Recommendation 9)
- The Secretary of HHS should ensure that the Director of the Centers for Disease Control and Prevention ensures that the senior official for privacy reviews and approves the system security categorizations for the COVID-19 Clearinghouse and HHS Protect. (Recommendation 10)
- The Secretary of HHS should ensure that the Commissioner of the Food and Drug Administration conducts and develops privacy impact assessments for all pandemic public health preparedness and

response systems that include personally identifiable information. (Recommendation 11)

- The Secretary of HHS should ensure that the Commissioner of the Food and Drug Administration conducts an assessment to determine if a system of records notice is required for the Biologics Information Tracking System – Compliance. (Recommendation 12)
- The Secretary of HHS should ensure that the Commissioner of the Food and Drug Administration ensures that the senior official for privacy reviews and approves the system security categorization for the Biologics Information Tracking System – Compliance. (Recommendation 13)
- The Secretary of HHS should ensure that the Commissioner of the Food and Drug Administration develops an assessment of privacy controls for the Biologics Information Tracking System – Compliance. (Recommendation 14)

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review and comment. The Assistant Secretary for Legislation provided written comments that are reprinted in appendix IV and summarized below. HHS and its component agencies also provided technical comments, which we incorporated as appropriate.

In its written comments, HHS generally agreed with most of our recommendations, stating that it would continue to develop required privacy and security compliance materials for all information systems, including those noted in our recommendations. It added that going forward, they would continue to seek opportunities to strengthen their procedures and compliance with them.

In addition, the department fully concurred with the goal of identifying duplication, overlap and fragmentation of data systems that support pandemic response. HHS stated that it would analyze the costs and benefits for the best way to reduce unnecessary duplication and enhance efficiencies in public health data systems that support its pandemic preparedness and response efforts.

HHS did not generally agree with two recommendations (3 and 4). Specifically, HHS stated that attempting to isolate funding and staffing information may not be feasible. However, by proactively and consistently identifying and tracking the resources needed to operate and maintain HHS's pandemic public health preparedness and response systems, the

department would have increased assurance that it can effectively manage its systems in preparation for future public health emergencies. Given the uncertainty of many of the funding sources for these vital systems, information on the funding and staffing needed to operate and maintain them will be critical for future success. Accordingly, we continue to believe our recommendations related to funding and staffing information are warranted.

The department added that it believed that we may not have fully considered that the selected HHS systems that we reviewed had public health data, but that not all of that data is related to pandemic preparedness and response. Therefore, the department noted, the purpose of those systems is not solely related to pandemic public health preparedness and response efforts. We understand that the systems we reviewed may also be used for other public health efforts and not solely dedicated to pandemic preparedness and response and noted that in the report. Nonetheless, HHS would benefit from studying these systems to determine where duplicative information is being collected or overlapping activities are being performed by multiple systems. Without such a review, HHS is limited in their ability to determine where unnecessary duplication, fragmentation, and overlap may be occurring.

After the completion of our review, several HHS components provided us with additional information and documentation intended to demonstrate they had implemented our recommendations related to key privacy safeguards for protecting PII. This documentation related to recommendations 6, 12, 13, and 14. We will follow up to confirm that the actions taken on our recommendations are, to the extent possible, achieving the desired results. If confirmed, we plan to consider the recommendations as implemented.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

If you or your staff have any questions about this report, please contact Jennifer R. Franks at (404) 679-1831 or franksj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.

Jennifer R. Franks, Director
Center for Enhanced Cybersecurity
Information Technology and Cybersecurity

Appendix I: Objectives, Scope, and Methodology

Our objectives were to determine to what extent has the Department of Health and Human Services (HHS) (1) identified and reduced unnecessary duplication, overlap, or fragmentation in its pandemic public health preparedness and response data capabilities; (2) identified funding and other resources for the operation of the pandemic public health preparedness and response data capabilities; and (3) instituted privacy safeguards when collecting pandemic public health preparedness and response data.

For all three objectives, we focused on HHS and its component agencies that maintain systems supporting pandemic public health preparedness and response. These component agencies include the Administration for Strategic Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), and National Institutes of Health (NIH).

For the first objective, we identified Consolidated Appropriations Act, 2023 requirements aimed at identifying and reducing duplication, overlap, or fragmentation in pandemic public health preparedness and response data capabilities.[1] HHS and component agency officials reported that selected agencies maintain systems that support pandemic public health preparedness and response.

We requested HHS and these component agencies to provide a department-wide and individual lists of systems that support pandemic public health preparedness and response, and the data collected by each system.[2] For each identified system, we requested the data collected by each system, such as system descriptions, types of data collected, and data sources. We then compared the lists of systems provided by the component agencies to systems that support pandemic public health preparedness and response identified in previously issued GAO reports.[3]

[1]Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, 136 Stat. 5740 (2022).

[2]For the purposes of this report, the systems we discuss are those that assist HHS in pandemic preparedness and response, however, these systems could also have other functions related to public health.

[3]GAO, *COVID-19: Pandemic Lessons Highlight Need for Public Health Situational Awareness Network*, GAO-22-104600 (Washington, D.C.: June 23, 2022) and *Public Health Information Technology, HHS Has Made Little Progress Toward Implementing Enhanced Situational Awareness Network Capabilities*, GAO-17-377 (Washington, D.C.: Sep 6, 2017).

We also identified federal requirements regarding identifying duplication, overlap, and fragmentation during IT investment portfolio reviews in the Federal Information Technology Acquisition Reform Act (FITARA) of 2014 and the Consolidated Appropriations Act, 2023.[4] We analyzed the lists of systems identified by the component agencies to identify areas where programs may request or collect the same data. We also reviewed HHS documentation, such as systems IT investment portfolio review plans and results, and plans to consolidate and retire systems. We then compared HHS and its components' efforts to federal requirements on duplication, overlap, and fragmentation identified in FITARA and the Consolidated Appropriations Act. We also compared HHS and its component agencies' efforts to identify and reduce duplication among their systems to key practices identified in a prior GAO report.[5]

We supplemented our analysis with interviews of relevant HHS officials in ASPR, CDC, FDA, HRSA, IHS, and NIH. We discussed efforts to identify systems involving pandemic public health preparedness and response data and their efforts to reduce unnecessary duplication when collecting these data. In addition, we interviewed representatives from selected national public health organizations representing state, territorial, and local public health officials, including the Association of State and Territorial Health Officials, Council of State and Territorial Epidemiologists, and National Association of County and City Health Officials. We discussed the actions the organizations have taken to collaborate with the department regarding the use of systems that support pandemic public health preparedness and response and to identify duplicative systems.

To address the second objective, we identified federal budgetary requirements and best practices on managing program costs identified in the *National Security Memorandum on Countering Biological Threats,*

[4]Federal information technology acquisition reform provisions of the Carl Levin and Howard P. 'Buck' McKeon National Defense Authorization Act for Fiscal Year 2015, Pub. L. No. 113-291, 128 Stat. 3442 (2014); Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, 136 Stat. 5740 (2022).

[5]GAO, *Fragmentation, Overlap, and Duplication: An Evaluation and Management Guide,* GAO-15-49SP (Washington, D.C.: Apr. 14, 2015).

Enhancing Pandemic Preparedness, and Achieving Global Health Security and GAO's Cost Estimating and Assessment Guide.[6]

We analyzed the HHS component agencies' lists for the reported fiscal year 2023 funding sources and costs for the 99 systems that support pandemic public health preparedness and response activities.[7] We also analyzed system funding documentation, such as budget requests and contracts. We then compared the reported system funding information and funding documentation to federal requirements for identifying funding resources for pandemic preparedness activities and GAO best practices for developing and managing program costs to determine whether the funding sources and costs were included. We supplemented our analysis with interviews with relevant HHS officials in ASPR, CDC, FDA, HRSA, IHS, and NIH. Further, we assessed the reliability of the agencies' funding data by incorporating data reliability questions in our interviews and correspondence with agency officials. For example, we sought clarification on how funding data were derived, maintained, and updated, and how the component agencies ensured their completeness and accuracy. We found these data to be sufficiently reliable for our reporting purposes.

Lastly, we identified best practices in GAO's IT workforce planning framework.[8] We then analyzed the HHS component agencies' system staffing documentation, including program staffing plans, organization charts, and contracts. We reviewed this information, including the number of staff and the type of staff (i.e., full-time, full-time equivalent, part-time, and contractor staff) dedicated to the operation and management of the

[6]The White House, *National Security Memorandum on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security*, NSM-15 (Washington, D.C.: Oct. 18, 2022). GAO, *Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Program Costs,* GAO-20-195G (Washington, D.C.: Mar. 12, 2020).

[7]The costs provided by the component agencies consisted of both appropriated funds and obligated funds and varied by component agency.

[8]GAO, *IT Workforce: Key Practices Help Ensure Strong Integrated Program Teams; Selected Departments Need to Assess Skill Gaps*, GAO-17-8 (Washington, D.C.: Nov. 30, 2016).

pandemic public health preparedness and response systems.[9] We compared the staffing information to the identified best practices to determine whether the staffing information was included. We supplemented our analysis with interviews with relevant HHS officials in ASPR, CDC, FDA, HRSA, IHS, and NIH.

Further, we assessed the reliability of the staffing data by incorporating data reliability questions in our interviews and correspondence with agency officials, such as how staffing data were derived, maintained, and updated, and how the component agencies ensured their completeness and accuracy. We found these data to be sufficiently reliable for our reporting purposes.

For the third objective, we identified federal requirements in the Privacy Act of 1974 and the E-Government Act of 2002 to identify key requirements for establishing privacy safeguards.[10] We also identified requirements for protecting personally identifiable information (PII) in guidance, including Office of Management and Budget's (OMB) Circular A-130: *Managing Information as a Strategic Resource*, OMB Memorandum M-03-22, *Guidance for Implementing the Privacy Provisions of the E-Government Act*, and National Institute of Standards and Technology (NIST) Special Publication 800-37 Rev. 2, *Risk Management Framework for Information Systems and Organizations: A System Life Cycle Approach for Security and Privacy*.[11]

We then analyzed HHS and the component agencies' documentation, including HHS privacy policies and memorandums, and compared the documentation to federal requirements for establishing dedicated privacy officials. From the lists of pandemic systems that the HHS component

[9]A full-time equivalent is a standard measure of labor that reflects the total number of regular straight-time hours (i.e., not including overtime or holiday hours) worked by employees divided by the number of compensable hours applicable to each fiscal year. See the Office of Management and Budget (OMB) Circular No. A-11, *Preparation, Submission, and Execution of the Budget* (Washington, D.C.: Aug. 11, 2023).

[10]Privacy Act of 1974, Pub. L. No. 93-579, 88 Stat. 1896 (1974) (codified as amended at 5 U.S.C. § 552a). E-Government Act of 2002, Pub. L. No. 107-347, § 208, 116 Stat. 2899, 2921 (2002) (44 U.S.C. § 3501 note).

[11]Office of Management and Budget, *Managing Information as a Strategic Resource*, Circular A-130 (Washington D.C.: July 28, 2016); *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*, M-03-22 (Washington, D.C.: Sept. 26, 2003); and National Institute of Standards and Technology SP 800-37, Revision 2: *Risk Management Framework for Information Systems and Organizations: A System Life Cycle Approach for Security and Privacy* (Gaithersburg, Md.: December 2018).

agencies provided, they identified 68 systems that included PII. The 68 systems included five ASPR systems, 31 CDC systems, 30 FDA systems, one HRSA system, and one NIH system. We then assessed all of the systems the component agencies identified and compared the privacy impact assessments for the systems against the federal requirements and guidance for establishing privacy impact assessments for systems that included PII. We worked with a methodologist to initially select 10 systems based on a random sample of systems from each component agency's list of pandemic public health preparedness and response systems that included PII. Because both HRSA and NIH identified one system that included PII (i.e., HRSA's Injury Compensation System and NIH's National COVID Cohort Collaborative), we selected those systems as part of our review. The 10 initially selected systems were:

- ASPR's ASPR Ready,
- ASPR's Electronic Medical Records System,
- CDC's COVID-19 Clearinghouse,
- CDC's Data Collation, and Integration for Public Health Event Response,
- CDC's Response Ready Enterprise Data Integration platform,
- FDA's Human Cell and Tissue Establishment Registration System,
- FDA's Biologics Information Tracking System-Compliance,
- FDA's Event-based Text-mining for Health Electronic Records,
- HRSA's Injury Compensation System, and
- NIH's National COVID Cohort Collaborative.

After our initial selection of 10 systems, we removed FDA's Event-based Text-mining for Health Electronic Records system. FDA had initially included the system as one that included PII. After our review began, FDA analyzed the information stored by the system and determined that it did not include PII. Therefore, this system was removed from our final evaluation of privacy requirements, resulting in nine systems.

We compared security documentation, including system of records notices, privacy plans and controls, and system authorizations to

requirements for establishing privacy safeguards.[12] The findings from these systems for each component, while randomly selected, are not generalizable to all systems in that component. However, for the selected systems, we were able to assess whether there were instances of the agencies not meeting all of the privacy requirements. Additionally, we supplemented our analysis with interviews with relevant HHS officials in ASPR, CDC, FDA, HRSA, IHS, and NIH.

We conducted this performance audit from February 2023 to September 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[12]E-Government Act of 2002, Pub. L. No. 107-347, § 208, 116 Stat. 2899, 2921 (2002) (44 U.S.C. § 3501 note); Privacy Act of 1974, Pub. L. No. 93-579, 88 Stat. 1896 (1974) (codified as amended at 5 U.S.C. § 552a); Office of Management and Budget, Circular A-130, *Managing Information as a Strategic Resource* (Washington, D.C.: July 28, 2016); and National Institute of Standards and Technology SP 800-37, Revision 2: *Risk Management Framework for Information Systems and Organizations: A System Life Cycle Approach for Security and Privacy* (Gaithersburg, Md.: December 2018).

Appendix II: HHS Component Agencies Use Various Systems to Prepare for and Respond to Pandemic Public Health Emergencies

In response to public health emergencies, including pandemics, such as COVID-19, the Department of Health and Human Services uses pandemic public health preparedness and response systems to collect, analyze, and share data. The Administration for Strategic Preparedness and Response, the Center for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, and the National Institutes of Health identified 99 systems that support various pandemic public health preparedness and response activities.

Table 2 includes the various component agency systems, their description, fiscal year 2023 funding source and costs from highest to lowest costs, and staffing information.[1]

Table 2: Department of Health and Human Services (HHS) Pandemic Public Health Preparedness and Response Systems

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
Centers for Disease Control and Prevention (CDC)	Tiberius Platform	Aggregates COVID-19 data, including vaccine therapeutics, and logistics data, from various U.S. stakeholders in support of Operation Warp Speed, HHS Countermeasures Acceleration Group, and the HHS Coordination Operations Response Element.	Administration for Strategic Preparedness and Response (ASPR) funds, CDC COVID-19 funding, and program funds	$84,368,079.00	Total full-time equivalents (FTEs): 3 Total contractors: 80
CDC	National Healthcare Safety Network*	Tracks health care-associated infections, antimicrobial resistant infections, and antimicrobial use across health care settings. Examples of these data include catheter-associated urinary tract infections and central-line associated bloodstream infections.	Appropriated funding, supplemental funding, and interagency agreements receivables from Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, and the Food and Drug Administration	$63,400,000.00	Total FTEs: 34 Total contractors: 296[a]

[1]The costs provided by the component agencies consisted of both appropriated funds and obligated funds and varied by component agency.

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
National Institutes of Health (NIH)	National COVID Cohort Collaborative*	Collects deidentified clinical data for COVID-19 research. According to NIH, this system represents a shared vision for turning real-world data into the knowledge needed to address COVID-19 as the pandemic evolves.	NIH Office of the Director, Advanced Research Projects Agency for Health, and National Center for Advancing Translational Sciences, and Office of the Assistant Secretary for Planning and Evaluation funds.[b]	$50,100,000.00	Total FTEs: 1 Total contractors:15
CDC	National Syndromic Surveillance Program	Collects, shares, and uses electronic health data from local, state, territorial, and federal partners to provide situational awareness for various public health responses, such as outbreaks and disasters.	Appropriated funds including Surveillance, Epidemiology, and Public Health Informatics, Data Modernization Initiative (DMI) funding, American Rescue Plan Act funding, and CDC Centers, Institutes, and Offices program funds.	$39,300,000.00	Total FTEs: 15 Total contractors: 50
CDC	U.S. Influenza Vaccine Effectiveness Networks*	Estimates the effectiveness of influenza vaccines in preventing illness, severe outcomes, and transmission of illness.	Program funds, COVID-19 supplemental funds, and Prevention and Public Health Fund	$36,343,813.00	Total FTEs: 14.5 Total contractors: 3 Fellows: 4
CDC	National Notifiable Diseases Surveillance System	Tracks data on nationally notifiable diseases from approximately 3,000 health departments across the U.S.	Appropriated funds including, Surveillance, Epidemiology & Public Health Informatics; CDC Preparedness & Response Capability; DMI funding, and CARES Act funding	$32,100,000.00	Total FTEs: 33 Total contractors: 36

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
CDC	National Vital Statistics System*	Collects and analyzes data on vital events like births and deaths from all 50 states, the District of Columbia and New York City, and five territories.[c]	Operation funds (annual appropriations, CARES funds, and DMI funds) and modernization funds (CARES funds and DMI funds, and one-time funding to jurisdictions to support National Vital Statistics System modernization through CDC Epidemiology Laboratory Capacity Grant).	$31,600,000.00	Total FTEs: 90 Total contractors: 40
CDC	HHS Protect[d]*	Serves as the common operating picture and central hub to receive, integrate, and share COVID-19 data in near real time for the U.S. government. HHS Protect also receives national and state data on COVID-19 cases, laboratory testing, COVID-19 deaths, hospital capacity, personal protective equipment, COVID-19 treatment, and COVID-19 vaccine administration in the U.S.	CDC Wide Activities, CARES Act, HHS funding, ASPR funding, American Rescue Plan Act and Strategic National Stockpile funding	$28,891,986.28	Total FTEs: 1.5 Total contractors: 90
CDC	Data Collation and Integration for Public Health Event Response[d]*	Provides a collaborative environment for routine public health surveillance and outbreak responses.	CDC Wide Activities, CARES Act, HHS funding, Administration for Strategic Preparedness and Response funding. American Rescue Plan Act and Strategic National Stockpile funding	$24,049,638.81	Total FTEs: 1.5 Total contractors: 90
CDC	Surveillance of Emerging Threats to Pregnant People and Infants Network*	Identifies the impact of emerging and reemerging health threats, such as COVID-19 on pregnant people and their infants.	Congressional Base funding	$23,000,000.00	Total FTEs: 17 Total contractors: 8 Fellows: 4 Guest Researcher: 1

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
CDC	New Vaccine Surveillance Network – Acute Respiratory Illness	Monitors viral respiratory infections and associated syndromes in children less than 18 years of age across seven pediatric hospital systems.	Research cooperative agreement and COVID-19 funding	$19,250,000.00	Total FTEs: 3 Total contractors: 4
Food and Drug Administration (FDA)	Adverse Events and Product Problems*	Tracks adverse events related to human cells, tissues, and cellular- and tissue-based products and Center for Biologics Evaluation and Research (CBER) regulated devices and other product problems in real time.	Base, Prescription Drug User Fee Act (PDUFA), and COVID-19 funding from the Coronavirus Response and Relief Supplemental Appropriations Act (CRRSA)	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Biologics Compliance Information System*	Tracks and records data about Biological Product Deviation reports, to include electronic Biological Product Deviation Reporting and non-blood reports.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Biologics Information Tracking System – Animal, Biologics, and Chemical*	Tracks manufacturers and suppliers' information to provide CBER the ability to analyze risks related to ingredients in marketed products to better respond in an event of risk to public health.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Biologics Investigational and Related Application Management System*	Tracks the regulatory activity of Investigational and Related Applications submitted to CBER including new drug applications and emergency use authorizations.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Biologics Information Tracking System – Compliance*	Tracks the capture and processing of complaints and inspections associated with CBER's Office of Compliance and Biologics Quality.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Biologics Information– Tracking System - Device Submission Tracking*	Provides CBER with a modernized web application for review processes associated with medical device submissions.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
FDA	Biologics Information–Tracking System - Pre- Application Tracking*	Tracks sponsor materials and CBER documents associated with submissions that are not an application type defined in the Code of Federal Regulations.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Biologics Information–Tracking System - Unlicensed Requalification and Variance Requests*	Tracks and stores information on Blood Donor Requalification and Blood Variance Request document types.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Blood Establishment Registration*	Provides access to information in an efficient manner to perform regulatory mandated registration of blood establishments.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Blood Logging and Tracking*	Maintains information related to the status and review progress of applications for the clearance or approval of devices and products related to blood screening, transfusion, and other analogous products.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	CBER Adverse Events Reporting System*	Analyzes data of individuals adverse events not associated with vaccines.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	CBER Connect*	Provides users with the ability to search, view, and upload submissions, communications, and programmatic items.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	CBER Electronic Repository*	Stores, retrieves, and distributes electronic submissions to reviewers and interfaces with CBER regulatory databases.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	CBER Error and Accident Reporting System*	Provides a query-based system to display and print information from a database containing biological product deviation reports that has been submitted to CBER.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
FDA	CBER Regulatory Meetings Tracking System*	Tracks Regulatory Meeting information and internal CBER meetings and allows for the generation of customized reports.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Clinical Trials Modules*	Captures information from Form FDA 1572 or other submissions regarding investigation matters.i	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Electronic Blood Establishment Registration Internet Query*	Uses an internet query to review non-confidential Blood Establishment Registration information for active, inactive, and pre-registered firms.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Electronic Blood Establishment Registration System*	Used by blood product manufacturers to electronically register their establishments and provide information about the products they manufacture.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Electronic Human Cell and Tissue Establishment Registration System*	Used by manufacturers to electronically register establishments that engage in the recovery, processing, storage, labeling, packaging, or distribution of any Human Cells, Tissues, and Cellular and Tissue-Based Products.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Electronic Human Cell and Tissue Establishment Registration System Internet Query*	Uses an internet query to review non-confidential Electronic Human Cell and Tissue Establishment Registration information for active, inactive, and pre-registered firms.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Event-based Text-mining for Health Electronic Records	Supports ongoing research initiatives in the fields of text mining and natural language processing as a potential method for semi-automating the manual review of spontaneous adverse event reports provided by Medical Officers.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
FDA	Human Cell and Tissue Establishment Registration System*	Reports on facilities that have registered with FDA in compliance with the Federal Register Notifications for Human Cells, Tissues, and Cellular and Tissue-Based Products Establishment Registration.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Lot Distribution Database*	Detects potential problems associated with unusual concentrations of a particular adverse event in one or more production lots for individual CBER-regulated products.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Pattern-based and Advanced Network Analyzer for Clinical Evaluation and Assessment*	Detects safety signals associated with vaccines and provides a new method for analyzing the large amounts of data contained in vaccine spontaneous adverse event reports in support of the Vaccine Adverse Event Reporting System.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Regulatory – Management System - Biologics Licensing Applications*	Supports CBER's Managed Review Process for reviewing and approving applications for biological derived drugs, blood products, and in vitro diagnostics Test Kits.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Regulatory – Management System - Document Accountability and Tracking System*	Supports staff with receipt and routing of drug manufacturer submissions to reviewers and incoming and outgoing communications.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
FDA	Regulatory Management System – Lot Release System*	Collects meta-data including test results and protocols related to physical lots provided to CBER.	Base, PDUFA, and CRRSA funding	$16,346,526.71[e]	Total FTEs: 17 Total contractors: 150
CDC	Enterprise Data Analytics and Visualization Platform*	Allows staff to store, analyze, visualize, and publish data from a single location for both internal and external audiences.	CDC's Working Capital Fund, DMI, and program funding	$14,516,046.00	Total FTEs: 2

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
CDC	COVID-19 Associated Hospitalization Surveillance Network (commonly referred to as COVID-NET)	Collects demographic, clinical, and outcome data on laboratory-confirmed COVID-19 hospitalization data for children and adults.	COVID-19 funding	$13,600,000.00	Total FTEs: 8 Total contractors: 2.5
ASPR	Supply Chain Control Tower	Monitors and provides end-to-end visibility of the U.S. medical supply chain to identify supply chain issues and to inform decision-making for HHS leadership, ASPR, and relevant agencies.	COVID-19 supplemental funding	$13,000,000.00	Total FTEs: 2.5 Total contractors: 27
FDA	FDA Adverse Event Reporting System*	Contains adverse event reports, medication error reports and product quality complaints resulting in adverse events that were submitted to FDA.	User fees and budget authority	$12,985,384.39	Total FTEs: 11.25 Total contractors: 66.5
CDC	Vaccine Administration Management System*	Manages various vaccine administration tasks, such as patient registration and appointment scheduling once the vaccine arrives at the clinic.	COVID-19 supplemental funding	$11,869,811.00	Total FTEs: 10 Total contractors: 65
CDC	Active Bacterial Core Surveillance	Provides an infrastructure for further public health research, which may include special studies to identify disease risk factors, evaluate vaccine efficacy, and monitor the effectiveness of prevention policies.	Extramural funding	$10,931,603.00	Total FTEs: 5 Total contractors: 5
CDC	Influenza-Associated Pediatric Mortality Surveillance System*	Collects pediatric mortality rates associated with influenza.	National Domestic Influenza Surveillance Program funding[f]	$10,378,702.40	Total FTEs: 16 Total contractors: 5 Total CDC-funded state, tribal, local, and territorial (STLT) personnel: 73

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
CDC	Influenza Virologic Surveillance – World Health Organization Collaborating Laboratories and the National Respiratory and Enteric Virus Surveillance System*	Monitors influenza activity data from approximately 100 public health and 300 clinical laboratories throughout all 50 states, Puerto Rico, Gaum, and the District of Columbia.	National Domestic Influenza Surveillance Program funding[f]	$10,378,702.40	Total FTEs: 16 Total contractors: 5 Total CDC-funded STLT personnel: 73
CDC	Surveillance for Novel Influenza A Viruses*	Monitors cases of novel influenza A virus.	National Domestic Influenza Surveillance Program funding[f]	$10,378,702.40	Total FTEs: 16 Total contractors: 5 Total CDC-funded STLT personnel: 73
CDC	U.S. Outpatient Influenza-like Illness Surveillance Network	Monitors information on outpatient visits to health care providers related to influenza like illnesses.	National Domestic Influenza Surveillance Program funding[f]	$10,378,702.40	Total FTEs: 16 Total contractors: 5 Total CDC-funded STLT personnel: 73
CDC	Vaccine Finder	Shares information about health care sites and pharmacies, such as their locations and COVID-19 inventory data to assist consumers in obtaining the vaccine.	COVID-19 supplemental funding	$9,961,714.22	Total contractors: 35
CDC	Data Lakehouse Platform	Provides a cloud-based centralized data respiratory, which receives COVID-19 data from other internal systems, to support efforts in distributing COVID-19 vaccines.	COVID-19 funding and program funding	$8,681,356.00	Total FTEs: 3 Total contractors: 30.25
CDC	Influenza Hospitalization Surveillance Network*	Monitors for laboratory-confirmed influenza-associated hospitalizations in children and adults.	Program funding, Coronavirus and Other Respiratory Viruses Division funds	$6,326,265.00	Total FTEs: 3 Total contractors: 2 Fellows: 2
CDC	National Wastewater Surveillance System	Tracks COVID-19 through wastewater testing data.	COVID-19 American Rescue Plan Act supplemental funds	$6,300,000.00	Total FTEs: 15

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
CDC	Respiratory Virus Laboratory Emergency Department Surveillance*	Collects demographic, clinical, and laboratory information from patient electronic medical records who visited selected emergency departments with acute respiratory illness.	COVID-19 funding	$5,111,077.00	Total FTEs: 3.5
CDC	V-Safe*	Shares web-based surveys with vaccinated individuals to obtain data to ensure the safety of vaccines.	COVID-19 funding	$4,290,000.00	Total FTEs: 10 Total contractors: 10
CDC	Vessel Sanitation Program[g]*	Assists to prevent and control the transmission and spread of gastrointestinal illnesses on cruise ships.	Congressional appropriations, user fees	$4,000,000.00	Total FTEs:3 Total Contractors: 1.3
CDC	Respiratory Syncytial Virus – Associated Hospitalization Surveillance Network (commonly referred to as RSV-NET)*	Monitors for laboratory confirmed Respiratory Syncytial Virus associated hospitalizations among children and adults.	Program funding	$4,000,000.00	Total FTEs: 8 Total Contractors: 2.5
CDC	CDCReady	Collects data associated with emergency responses, such as response staffing and equipment requests.	DMI funding	$3,964,527.55	Total FTEs: 2
FDA	Office of Regulatory Affairs Reporting, Analysis, and Decisions Support System*	Provides a central data warehouse of integrated, standardized, and cleansed data for inspections, shipment histories, samples, and recalls to conduct analysis.	Base, PDUFA, and CRRSA funding	$3,927,000.00	Total FTEs: 1.25 Total contractors: 15.4
CDC	Vaccine Adverse Event Reporting System*	Monitors for unusual or unexpected reporting patterns of adverse events following a patient's vaccination.	Vaccine Adverse Event Reporting System core funding, National Center for Immunization and Respiratory Diseases Pan Flu funding, National Center for Immunization and Respiratory Diseases Vaccines for Children funding, and COVID-19 funding	$3,843,448.00	Total FTEs: 8 Total contractors: 53

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
Health Resources and Services Administration (HRSA)	The Health Center COVID-19 Survey	Collects responses from health centers to track capacity and the impact of COVID-19 on the health center operations, patients, and staff.	Funding for the Bureau of Primary Health Care's use of the Salesforce platform	$3,589,941.00	Total FTEs: 2 Total contractors: 1
CDC	National Molecular Subtyping Network for Foodborne Disease Surveillance (commonly referred to as PulseNet)	Serves as a national network of public health laboratories that perform DNA fingerprinting of food-borne bacteria to detect outbreaks.	Division and Advanced Molecular Detection funding	$3,500,000.00	Total FTEs: 12 Total contractors: 10 Fellows: 6
ASPR	Health Partner Order Portal	Manages, monitors, and reports data associated with the ordering and distribution of vaccines deemed critical to national emergency, such as COVID-19.	HHS Coordination Operations and Response Element programmatic dollars	$3,500,000.00	Total FTEs: 1 Total contractors: 4
ASPR	ASPR Ready*	Streamlines agency collaboration, information, and data management, and provides the Common Operating Picture for ASPR's preparedness and response missions.	Med-Surge supplemental funding, COVID-19 supplemental funding, HHS Coordination Operations and Response Element fiscal year funding	$3,000,000.00	Total FTEs: 1 Total contractors: 8
CDC	National Human Immunodeficiency Virus (HIV) Behavioral Surveillance – Data Coordinating Center and Web-based Integrated Surveillance Management System*	Supports two key HIV surveillance systems in collecting patient data, such as demographics and sexual behaviors.	Operations and maintenance (O&M)-Data Coordination Center, Development, Modernization, and Enhancement-Data Coordination Center, and O&M-Web-based Integrated Surveillance Management System contract costs	$2,812,327.00	Total FTEs: 14 Total contractors: 6.5

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
CDC	COVID-19 Clearinghouse*	Provides a secure space for state, tribal, local, or territorial jurisdictions and other National Provider Organizations to upload and store COVID-19 vaccination data collected from provider organizations systems, such as electronic health records.	CRRSA	$2,749,629.00	Total FTEs: 1.5 Total contractors: 4.5
NIH	OpenData COVID-19 Portal	Shares COVID-19 drug screening data, including from the National Center for Advancing Translational Sciences, to improve the access to drug testing data needed by the research community to address COVID-19.[b]	COVID-19 supplemental funding	$2,200,000.00	Total FTEs: 1 Total contractors: 4
CDC	Influenza Lab Information Management System*	Supports sharing, storing, and analyzing laboratory and epidemiology-related data.	Program funding and Coronavirus and Other Respiratory Viruses Division funding	$1,982,841.00	Total FTEs: 1 Total contractors: 6
CDC	National HIV Case Surveillance – Enhanced HIV Acquired immunodeficiency syndrome Reporting System*	Collects, stores, and manages HIV case surveillance data from various jurisdictional partners.	Contract funding including tasks of project management, system O&M, and user support	$1,620,000.00	Total contractors: 9
FDA	506J Database*	Collects and stores information from manufacturers during a public health emergency regarding supply chain disruptions and product discontinuances of medical devices.	COVID-19 supplemental funding	$1,326,646.00	Total FTEs: 0.5 Total contractors: 5.25
CDC	National Tuberculosis Surveillance System*	Supports the integration of data from state operated Tuberculosis programs using common and custom developed data collection tools.	Contract funding including tasks of project management, system O&M, system Development, Modernization and Enhancement, and user support	$1,304,000.00	Total contractors: 0.6

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
ASPR	Electronic Medical Record System*	Reports of all medical care provided during a national disaster deployment and enables automation of medical logistics data-entry, collection, retrieval, reporting and transfer.	Annual appropriations and COVID-19 supplemental funding	$1,095,892.00[h]	Total contractors: 7
ASPR	Joint Patient Assessment Tracking System*	Provides real time accountability of patients seen by emergency support personnel by tracking every patient moved by the federal government through all phases of the patient's movement.	Annual appropriations and COVID-19 supplemental funding	$1,095,892.00[h]	Total contractors: 7
ASPR	Response Management System*	Manages, prepares, trains, and tracks responders deployed for disasters and national special security events.	Annual appropriations and COVID-19 supplemental funding	$1,095,892.00[h]	Total contractors: 7
CDC	Epidemic Information Exchange*	Provides web-based communications to connect public health professionals involved in identifying, investigating, and responding to public health threats.	CARES Act	$1,085,587.20	Total FTEs: 3 Total contractors: 5
CDC	National Notifiable Diseases Surveillance System Analytic Database*	Collects epidemiological and clinical information such as demographics, hospitalization, and vaccination history to transform into an analyzable dataset.	Program funding	$1,083,812.48	Total FTEs: .5 Total contractors: 5.5
HRSA	Injury Compensation System*	Stores medical expense and employment records used to support claims of patients alleging injuries or deaths from countermeasures, such as COVID-19 vaccines and ventilators.	Annual appropriations[i]	$836,434.00	Total FTEs: 9
CDC	National HIV Case Surveillance – Secure HIV-Transmission Cluster Engine	Provides a tool for health departments to analyze genetic sequences and other data collected by the National HIV Surveillance System.	Contract funding including tasks of project management, system O&M, system Development, Modernization, and Enhancement, and user support	$720,000.00[j]	Total contractors: 2.4

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
ASPR	GeoHealth/ Geospatial Health System	Collects public health incident and federal disaster information from response partners and open sources to create geospatial visuals (e.g., maps and dashboards) for enhanced situational awareness capabilities.	Fiscal year funding	$650,075.00	Total FTEs: 2 Total contractors: 8
CDC	National Arboviral Surveillance System*	Collects reported arboviral disease cases from state health departments to combine the data and provides mapping capabilities.	Programmatic funding	$634,503.00	Total FTEs: 3.3
CDC	Outbreak Event Surveillance	Provides various reporting partners (e.g., state health departments and reporting site administrators at the state and local level) the ability to enter data about enteric disease outbreaks caused by food, water, animal, and person-to-person contact.	Program funding	$500,000.00	Total FTEs: 6 Total contractors: 3 Fellows: 3
CDC	Vessel Sanitation Program Inspection Reporting System[g]*	Collects administrative information and provides a platform to schedule and conducts ship inspections and releases inspection scores.	Congressional appropriations, user fees	$500,000.00	Total FTEs: 4 Total contractors: 1
CDC	Maritime Illness Database Reporting System[g]*	Receives information electronically through a web-based reporting portal related to acute gastroenteritis cases during the duration of a ship's voyage.	Congressional appropriations, user fees	$500,000.00	Total FTEs: 4 Total Contractors: 1
Indian Health Service (IHS)	Influenza-like Illness Awareness System	Collects select electronic health record data sourced from participating IHS and tribal sites that utilize the IHS Electronic Health Record system.	One-time CARES Act funds	$466,880.40	Total FTEs: 0.05 Total contractors: 1

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
CDC	CryptoNet	Facilitates the sharing of laboratory data among state and local public health laboratories to improve the investigations of foodborne and waterborne outbreaks of cryptosporidiosis in the United States.	Advanced Molecular Detection and Emerging Infectious Diseases and Food Safety Program funds	$456,000.00	Total FTEs: 2 Total contractors: 3 Fellows: 1
CDC	Dengue Laboratory Sample Database*	Monitors occurrences of dengue in Puerto Rico and uses a database to contain patient information and laboratory results from the dengue diagnostic lab.	Programmatic funding	$405,938.00	Total FTEs: 4.95
CDC	National Rabies Surveillance System	Collects laboratory reporting data associated with animal rabies.	Emerging Infectious funds	$340,000.00	Total FTEs: 1
CDC	Viral Hepatitis Surveillance – Global Hepatitis Outbreak Surveillance Technology	Allows public health laboratories to upload viral sequences via a web-based tool, to rapidly respond to outbreaks of hepatitis C.	Contract funding including tasks of project management, system O&M, and user support	$303,000.00	Total contractors: 4.3
CDC	National Respiratory and Enteric Virus Surveillance System	Monitors circulation patterns of respiratory and enteric viruses.	National Disease Surveillance Program funding	$270,985.00	Total FTEs: Not available Total contractors: Not available
CDC	MicrobeNet*	Consolidates information and provide access to CDC subject matter expertise to outside stakeholders such as public health laboratories related to bacterial and fungal pathogens.	Global Public Health Protection funding and CDC Preparedness and Response funding	$248,359.33	Total FTEs: 3 Total Contractors: 1
ASPR	Cooperative Agreement and Accountability Management Platform*	Supports the management of certain Office of Health Care Readiness cooperative agreements and supplemental funding.	Health Care Readiness and Recovery budget line	$199,999.72	Total FTEs: 0.5 Total contractors: 0.5
ASPR	HHS emPOWER Map	Operates as a public, interactive map that displays monthly updated population data for at-risk Medicare beneficiaries that use certain types of life-maintaining electricity-dependent medical equipment, devices, and health care services.	National Disaster Medical System annual appropriation funding	$104,824.00	Total FTEs: 1 Total Contractors: 2

Component agency	System name	System description	Fiscal Year 2023 funding source	Fiscal Year 2023 cost	System staffing
CDC	National Antimicrobial Resistance Monitoring System	Collects susceptibility data on foodborne and diarrheal organisms (Salmonella, Shigella, E. Coli, Campylobacter, non-cholerae Vibrio).	Program funding, Combating Antibiotic Resistant Bacteria, and Advanced Molecular Detection funding	$100,000.00	Total FTEs: 6 Total contractors: 3 Fellows: 3
CDC	Global Emerging Infections Sentinel Network	Collects travel related data from selected members of the International Society of Travel Medicine sites around the world to monitor travel associated diseases.	Appropriated funding	$100,000.00	Total contractors: 2
FDA	Allegation of Regulatory Misconduct Online Report Form*	Collects allegations of regulatory misconduct/complaints from medical device manufacturers, consumers, health care workers and other entities from the public.	Budget authority	$34,284.00	Total contractors: 2
CDC	Drug Activity Reporting System*	Provides inventory management and record keeping associated with restricted pharmaceutical and biologics released from CDC Drug Service.	Program funding and DMI supplemental funding	$28,150.00	Total FTEs: 4 Total contractors: 3
CDC	Case Isolate Surveillance*	Contains all national surveillance efforts including enhanced case surveillance data and laboratory-based surveillance.	Not available	Not available	Total FTEs: 2 Total contractors: 3 Fellows: 4
CDC	CDC Red Sky	Gathers data and information about public health events and displays the data in a real-time dashboard and global map that is intended to track active health events and improve situational awareness.	Not available	Not available	Total FTEs: 1 Total contractors: 5
IHS	Central Aggregator Server	Collects and combines data from various IHS federal and tribal systems.	Not available	Not available	Total FTEs: Not available Total contractors: Not available
IHS	COVID-19 Disease Surveillance Reporting Systems	Provides the agency insights into COVID testing and immunization tracking of data reported by electronic health record systems.	Not available	Not available	Total FTEs: Not available Total contractors: Not available

Legend: * = systems the component agencies identified as including personally identifiable information.

Source: GAO analysis of HHS data. | GAO-24-106638

Note: The costs provided by the component agencies consisted of both appropriated funds and obligated funds and varied by component agency.

[a]According to CDC officials, the reported staffing for the National Healthcare Safety Network includes the staffing for the larger National Healthcare Safety Network program.

[b]The National Center for Advancing Translational Sciences mission is to turn research observations into health solutions through translational science. The vision is more treatments for all people more quickly.

[c]The five territories are Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

[d]According to the CDC officials, CDC HHS Protect is managed through a program management office that supports both the Data Collation and Integration for Public Health Event Response (DCIPHER) and HHS Protect.

[e]According to FDA officials, $16,346,526.71 is the cost for all 27 CBER systems in the list. According to these officials, it is not possible to report the cost of each individual system. In addition, these officials stated that the 17 FTES and 150 contractors work on all of the CBER systems and are not assigned to individual systems.

[f]Total fiscal year 2023 funding for the entire National Domestic Influenza Surveillance Program (i.e., all components) consists of $10,378,702.40. The 16 FTEs, 5 contractors, and 73 STLT personnel cover all systems in the program.

[g]The Vessel Sanitation Program data system consists of the two applications (i.e., Vessel Sanitation Program Inspection Reporting System and the Maritime Illness Database Reporting System). Program total appropriations in FY23 were $4 million, which includes all staffing/other costs associated with conduction cruise ship inspections. The approximate estimate for operating Vessel Sanitation Program Inspection Reporting System and Maritime Illness Database Reporting System is $500,000. The 4 FTEs and 1 contractor covers the entire system.

[h]According to ASPR officials, the funding for the National Disaster Medical System applications (i.e., the Electronic Medical Record System, the Joint Patient Assessment and Tracking System, and the Response Management System) consists of $1,095,892.00. In addition, a team of seven contractors provides staffing support across the National Disaster Medical System Application Suite.

[i]The Injury Compensation System's first direct appropriation was in FY 2022.

[j]According to CDC officials, the cost for HIV-Transmission Cluster Engine is estimated, and the contract has not been awarded yet.

Appendix III: HHS Component Agency Comments on the Impact of Pandemic Funding

The Department of Health and Human Services (HHS) component agencies provided comments on how future funding levels may be impacted by the loss of pandemic-related funding, such as funding supplemented by the CARES Act. Specifically,

- Officials from the Administration for Strategic Preparedness and Response stated that the component agency has made improvements in data management and data analytics capabilities throughout the COVID-19 response. According to the officials, no longer having COVID-19 funding would significantly reduce HHS' ability to collect, share, and analyze data, and would limit interoperability with other jurisdictional and federal systems.
- Officials from the Centers for Disease Control and Prevention stated that enhancements have been made to data collection and reporting, data processing and management, and data analytic capabilities during the COVID-19 public health emergency response with COVID-19 supplemental funding. According to the officials, the loss of COVID-19 supplemental funding would significantly reduce HHS' long-term ability to collect, manage, share, and analyze data for response and would slow data system modernization. These officials stated that they are assessing the sustainability of current capabilities using other funding sources, including program funding and other appropriations, but that significant gaps in funding would remain.
- Officials from the Food and Drug Administration stated that the component agency received $105 million as one-time, supplemental funding to address the COVID-19 pandemic. The officials stated that the funds went towards a postmarket surveillance program during the pandemic.[1] According to these officials, the remaining supplemental funds were obligated in fiscal year 2023, so the scope of the program will be reduced for fiscal year 2024.
- Officials from the Health Resources and Services Administration stated that COVID-19 funding for the Countermeasures Injury Compensation Program is projected to be exhausted by the end of

[1]Postmarket refers to the time period after introduction of a device into the market for patient and provider use.

fiscal year 2024.[2] According to these officials, the lack of additional funding could impact necessary future upgrades and maintenance and may cause slow processing times for the program.

- Officials from the Indian Health Service stated that the component agency obligated large percentages of COVID-19 supplemental funding to combat the pandemic and to address the component agency's infrastructure needs. These officials stated that the lack of these funds has impacted the component agency's ability to invest in long-term improvements, such as public health infrastructure grants.
- Officials from the National Institutes of Health also expressed funding challenges with their systems, such as the National COVID Cohort Collaborative.[3] The officials stated that the lack of sustained and dedicated funding could result in the loss of staff and limit system operations and maintenance of key pandemic systems.

[2]According to officials from the Health Resources and Services Administration, the Countermeasures Injury Compensation Program collects data from claims that allege injuries or deaths from certain countermeasures, such as COVID-19 vaccine and ventilators. Further, its purpose is to provide compensation to individuals for covered serious injuries or deaths that occur as the direct result of the administration or use of countermeasures covered by a federal declaration under the Public Readiness and Emergency Preparedness Act.

[3]According to officials from the National Institutes of Health, the National COVID Cohort Collaborative collects deidentified clinical data for COVID-19 research. According to NIH, this system represents a shared vision for turning real-world data into the knowledge needed to address COVID-19 as the pandemic evolves.

Appendix IV: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

July 30, 2024

Jennifer Franks
Director, Center for Enhanced Cybersecurity
Information Technology and Cybersecurity
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Franks:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"COVID-19: HHS Needs to Identify Duplicative Pandemic IT Systems and Implement Key Privacy Requirements" (GAO-24-106638).**

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT ENTITLED: COVID-19: HHS NEEDS TO IDENTIFY DUPLICATIVE PANDEMIC IT SYSTEMS AND IMPLEMENT KEY PRIVACY REQUIREMENTS (GAO-24-106638)

The Department of Health & Human Services (HHS) appreciates the opportunity to respond to the draft report.

We stand in agreement that all our systems should fully secure and appropriately govern personally identifiable information (PII) in accordance with applicable standards and authorities. HHS components will continue to develop required privacy and security compliance materials for all information systems including the public health preparedness and response systems noted in GAO's recommendations. Examples include security categorization and control assessments, Privacy Impact Assessments, Authorization to Operate decision memorandums, Security Assessment Reports and System Security and Privacy Plans. Across HHS, privacy and security subject matter experts already examine systems, map agency PII holdings and ensure publication of System of Records Notices when required under the Privacy Act of 1974. Going forward, responsible programs will continue to seek opportunities to strengthen practices, ensure comprehensive compliance and promote public trust.

HHS fully concurs with the stated goal of identifying duplication, overlap and fragmentation of data systems that support our effort in effectively and efficiently responding to pandemics. However, GAO may not have fully considered that the selected HHS systems that it reviewed have public health data, but not all of it is related to pandemic preparedness and response and therefore, the purpose of those systems are not solely related to pandemic public health preparedness and response efforts. Also, attempting to isolate funding and staffing information may not be feasible.

Meanwhile, HHS will undertake its own cost/benefit analysis to determine how best to reduce unnecessary duplication and enhance efficiencies in public health data systems that support HHS's pandemic preparedness and response efforts.

HHS will continue to update GAO on its progress as it completes actions, when it responds to the final report, and thereafter until all recommendations have been closed.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Jennifer R. Franks at (404) 679-1831 or franksj@gao.gov

Staff Acknowledgments

In addition to the contact named above, Freda Paintsil (Assistant Director), Darron Smallwood (Analyst in Charge), Ibrahim Suleman (Analyst in Charge), Deirdre Brown, Jillian Clouse, Donna Epler, Hayden Huang, Franklin Jackson, Nicole Jarvis, Smith Julmisse, Susanna Kuebler, Susan Murphy, Amber Sinclair, Shannon Slawter Legeer, Adam Vodraska made key contributions to this report.

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