Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

IHS Did Not Always Provide the Necessary Resources and Assistance To Help Ensure That Tribal Programs Complied With All Requirements During Early COVID-19 Vaccination Program Implementation

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Office of Inspector General

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Report in Brief
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

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Why OIG Did This Audit

This audit is part of OIG's COVID-19 response strategic plan. American Indians and Alaska Natives have experienced disproportionate rates of COVID-19 infection and mortality during the pandemic. Tribes have turned to the Indian Health Service (IHS) for leadership and resources. IHS and the Centers for Disease Control and Prevention (CDC) entered into a Memorandum of Agreement (MOA) that specifies the conditions for IHS to receive COVID-19 vaccines from CDC. In November 2020 IHS issued its COVID-19 *Pandemic Vaccine Plan* (Vaccine Plan) detailing how IHS would prepare for and operationalize the delivery of vaccines.

Our objective was to determine whether IHS followed the provisions of both the MOA and the Vaccine Plan to coordinate the distribution, allocation, and administration of the vaccines to Tribal health programs to protect American Indian and Alaska Native beneficiaries.

How OIG Did This Audit

We reviewed IHS's policies and procedures and evaluated measures implemented by 14 judgmentally selected Tribal health programs (Tribal programs) to distribute, allocate, and administer COVID-19 vaccines for the period December 11, 2020, through February 28, 2021. This audit period covered early efforts to implement the provisions of the MOA and the Vaccine Plan, both of which went into effect in November 2020.

What OIG Found

IHS did not fulfill all of the provisions outlined in the MOA and its Vaccine Plan to help ensure that the vaccination program was implemented appropriately at Tribal programs. Consequently, Tribal programs did not always comply with all program requirements during early program implementation. Specifically, IHS did not always provide the necessary resources and assistance to help ensure that Tribal programs: (1) met reporting requirements for vaccine administration data; (2) used billing practices that conformed to Centers for Medicare & Medicaid Services (CMS) and CDC requirements and American Medical Association guidance regarding reimbursement for vaccine administration fees; and (3) did not enter into unallowable dual-program agreements with both a State jurisdiction and IHS.

What OIG Recommends and IHS Comments

We recommend that IHS: (1) ensure that Tribal programs comply with vaccine program requirements by establishing formal reconciliation processes to ensure that the data that the Tribal programs submit on doses administered are correct and by addressing data management system incompatibilities; (2) work with CMS to disseminate guidance to Tribal programs on vaccine coding and billing; (3) work with CDC and one Tribal program to ensure that it returns funds to individuals who were billed inappropriately; and (4) work with CDC to develop and disseminate additional guidance related to dual enrollment and together implement a formal monitoring process to help ensure that Tribal programs do not enter into unallowable dual-program agreements for Federal programs.

IHS concurred with all of our recommendations and described corrective actions that it had taken and planned to take. For our first recommendation, IHS said that it had developed a series of reporting solutions to address data reconciliation and data management system incompatibilities. For our second recommendation, IHS stated that it continues to distribute and work with CMS on coding and billing guidance. For our third recommendation, IHS stated that it would be available to work with CDC and provide assistance as needed and if requested by the Tribal program. For our last recommendation, IHS stated that it had assisted CDC in developing new guidance related to dual enrollment. We commend IHS for the actions it has taken and plans to take to address our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

COVID-19 has created extraordinary challenges for the delivery of health care and human services to the American people. In particular, American Indians and Alaska Natives have experienced disproportionate rates of COVID-19 infection and mortality during the pandemic. As the oversight agency for the Department of Health and Human Services (HHS), the Office of Inspector General (OIG) oversees HHS's COVID-19 response and recovery efforts. This audit is part of OIG's COVID-19 response strategic plan.[1]

During the pandemic, Tribes and urban Indian organizations have turned to the Indian Health Service (IHS) for leadership and resources, and IHS has distributed funds appropriated in six supplemental bills to IHS-administered facilities, tribally administered facilities, and urban Indian program clinics.[2]

In addition to many public health measures that have been put in place, COVID-19 vaccination remains the most promising intervention to further reduce disease, morbidity, and mortality. IHS and the Centers for Disease Control and Prevention (CDC) entered into a Memorandum of Agreement (MOA) that specifies the conditions for IHS to receive COVID-19 vaccines from CDC. Furthermore, IHS issued its COVID-19 *Pandemic Vaccine Plan* (Vaccine Plan) detailing how the IHS health care system would prepare for and operationalize the delivery of vaccines. For this audit, we examined IHS's early efforts to implement the provisions of the MOA and its own Vaccine Plan.

OBJECTIVE

Our objective was to determine whether IHS followed the provisions of both the MOA and the Vaccine Plan to coordinate the distribution, allocation, and administration of the vaccines to Tribal health programs to protect American Indian and Alaska Native beneficiaries.

[1] OIG's COVID-19 response strategic plan and oversight activities can be accessed at HHS-OIG's Oversight of COVID-19 Response and Recovery | HHS-OIG.

[2] The six supplemental appropriations bills were the Coronavirus Preparedness and Response Supplemental Appropriations Act, P.L. No. 116-123 (Mar. 6, 2020); the Families First Coronavirus Response Act, P.L. No. 116-127 (Mar. 18, 2020); the Coronavirus Aid, Relief, and Economic Security Act, P.L. No. 116-136 (Mar. 27, 2020); the Paycheck Protection Program and Healthcare Enhancement Act, P.L. No. 116-139 (Apr. 24, 2020); the Coronavirus Response and Relief Supplemental Appropriations Act, P.L. No. 116-260 (Dec. 27, 2020); and the American Rescue Plan Act of 2021, P.L. No. 117-2 (Mar. 11, 2021).

BACKGROUND

Indian Health Service

Within HHS, IHS delivers clinical and preventative health services to American Indians and Alaska Natives. IHS provides a comprehensive health service delivery system for approximately 2.6 million American Indians and Alaska Natives who belong to 574 federally recognized Tribes in 37 States. IHS receives annual appropriations to fund these services.

IHS has a decentralized management structure that consists of two major components: headquarters (IHS HQ) in Rockville, Maryland, and 12 Area Offices. IHS HQ responsibilities include setting health care policy, ensuring the delivery of quality comprehensive health services, and advocating for the health needs and concerns of Tribal members. The Area Offices are responsible for distributing funds to programs within their geographical areas, monitoring operations of IHS Direct programs, and providing guidance and technical assistance to Direct, Tribal, and Urban Programs, which we discuss just below.

A graphic depiction of the IHS Areas appears as Appendix B.

IHS Programs

IHS Direct Programs

The Indian Health Care Improvement Act (IHCIA) authorizes IHS to provide health services to American Indians and Alaska Natives who are members of federally recognized Tribes. The IHCIA also authorizes funding for programs and facilities operated by Tribes and tribal organizations. IHS provides direct health services,[3] such as medical care and dental care, through IHS-operated facilities located within the Area Offices' geographic areas.

Tribal Health Programs

In 1975, Congress enacted the Indian Self-Determination and Education Assistance Act (ISDEAA).[4] ISDEAA allows Indian Tribes and Tribal organizations to have greater autonomy and to have the opportunity to assume the responsibility for programs and services administered to them on behalf of the Federal Government. ISDEAA ensures that Tribes have paramount involvement in the direction of services provided by the Federal Government in an attempt to target the delivery of such services to the needs and desires of the local communities. Tribal health programs authorized under the ISDEAA allow Indian Tribes and Tribal organizations to administer health care programs or services, which IHS would have otherwise provided, under

[3] The Indian Health Care Improvement Act, P.L. No. 94-437 (Sep. 30, 1976), as amended; codified under 25 U.S.C. chapter 18.

[4] The Indian Self-Determination and Education Assistance Act, P.L. No. 93-638 (Jan. 4, 1975), as amended; codified under 25 U.S.C. chapter 46.

self-determination contracts with IHS (Title I Tribal programs) or self-governance compacts with IHS (Title V Tribal programs). Area Offices are responsible for Title I Tribal programs, through which Tribes contract with IHS to provide one or more individual services. IHS's Office of Tribal Self-Governance develops and oversees the implementation of Tribal Self-Governance legislation and authorities within IHS under Title V.

Urban Programs

Urban programs authorized under Title V of the IHCIA receive IHS funds through grants and contracts with Area Offices; the contracts are subject to the provisions of the Federal Acquisition Regulation. These programs serve American Indians and Alaska Natives who do not have access to the resources offered through IHS or tribally operated health care facilities because they do not live on or near a reservation.

CDC COVID-19 Vaccination Program Coordinated by IHS

CDC recommended that all jurisdictions be prepared to immediately vaccinate identified critical populations when the earliest COVID-19 vaccines were granted emergency use authorizations and became available.[5] The Food and Drug Administration approved the Pfizer-BioNTech COVID-19 vaccine for emergency use authorization on December 11, 2020, and the Moderna COVID-19 vaccine for emergency use authorization on December 18, 2020. On October 29, 2020, CDC issued guidance to ensure that jurisdictions developed and implemented a comprehensive COVID-19 vaccination plan. The CDC *COVID-19 Vaccination Interim Playbook for Jurisdiction Operations* required jurisdictions to, among other things, describe their responsibilities for ensuring that vaccination-related activities are implemented, and submit vaccination plans to CDC.

In November 2020, IHS and CDC entered into an MOA that specified the conditions for IHS to receive COVID-19 vaccines from CDC. The MOA identified two roles for IHS. First, IHS was designated as a direct-care provider, which meant that it was authorized to administer vaccines to its employees and eligible recipients who received care from IHS-operated facilities. Second, IHS coordinated the vaccination efforts, in a manner similar to that of a State or other jurisdiction, for vaccine distribution to Tribal health programs and urban Indian organizations. Tribal health programs received vaccines through IHS or their State, but not both (as discussed below).

In addition, during this same timeframe, IHS issued its Vaccine Plan detailing how the IHS health care system would prepare for and operationalize the delivery of vaccines. Under the terms of this plan and in keeping with its decentralized management structure, IHS supported the

[5] The term "jurisdiction" refers to Federal immunization funding awardees and their State public health emergency preparedness counterparts that were tasked with developing COVID-19 vaccination plans for submission to CDC. Tribal health programs have two options to receive the vaccine: they can receive them from a State or local jurisdiction or from IHS, which is serving as a jurisdiction for tribal programs. For purposes of vaccine distribution, CDC recognized IHS as a "jurisdiction" similar to a State.

planning and monitoring of the Tribal health program response to COVID-19, including COVID-19 vaccine distribution, allocation, and administration. In addition, IHS created a COVID-19 Vaccine Task Force (VTF) to lead its COVID-19 vaccine activities.[6]

Furthermore, each Tribal health program that received COVID-19 vaccines through IHS was required to sign the "CDC COVID-19 Vaccination Program Tribal Health Program Agreement – Vaccines Coordinated through IHS" (Tribal Health Program Agreement). The MOA states that "IHS, as a coordinator, will require the execution of the applicable provider agreement by tribal health programs . . . for which IHS is coordinating distribution which compels compliance with all conditions in this [MOA]." The Vaccine Plan also states that Tribal Health Programs that choose to receive COVID-19 vaccines through IHS must complete a signed Tribal Health Program Agreement and that these agreements include all CDC COVID-19 vaccination program requirements. Tribal health programs signed the Tribal Health Program Agreements in November 2020.

IHS administered vaccines at IHS-operated Direct facilities and Tribal health programs administered vaccines at their facilities, but because Tribal health programs provide care to the majority of IHS beneficiaries, these programs could be expected to carry out most of IHS's vaccinations.[7] For the remainder of this report, we refer to all health care programs that are administered by Tribal health programs as "Tribal programs."

HOW WE CONDUCTED THIS AUDIT

We reviewed IHS's policies and procedures and evaluated measures implemented by Tribal programs during Phases 1A and 1B of their vaccination programs to distribute, allocate, and administer the Pfizer-BioNTech and Moderna COVID-19 vaccines for the period December 11, 2020, through February 28, 2021.[8] This audit period covered early efforts to implement the provisions of the MOA and the Vaccine Plan, both of which went into effect in November 2020.

We interviewed IHS HQ, IHS Area office, and Tribal program staff and gathered documentation that helped us evaluate IHS's early efforts to coordinate the CDC COVID-19 Federal Agency Vaccination Program implemented by Tribal programs.

[6] The VTF is under the direction of the IHS Incident Command Operations Officer/Chief Medical Officer and includes representatives from IHS HQ, Area Offices, and Service Units.

[7] All of the Alaska Native Tribes elected to receive their COVID-19 vaccines through the State of Alaska. As mentioned in the next section, we therefore did not select any Tribal health programs from IHS's Alaska Area for this audit.

[8] Under measures established by the CDC Advisory Committee on Immunization Practices, Phase 1A refers to persons serving in health care settings who have the potential for direct or indirect exposure to COVID-19 and are unable to work from home, and Phase 1B refers to other essential workers and people at higher risk, including people aged 65 and older.

We initially conducted work in a Tribal program in the Navajo Area. We then judgmentally selected 1 Tribal program from each of the 11 IHS Areas that participated in the CDC COVID-19 Federal Agency Vaccination Program coordinated by IHS (footnote 7). Additionally, we judgmentally selected two other Tribal programs: one from the Bemidji Area because we identified a Tribal program that had entered into a dual-program agreement, which is not permitted and is discussed later in this report; and one from the Nashville Area, which had the largest geographical area. In total, we selected 14 Tribal health programs for review. We did not select any IHS Direct or Urban programs for review because our audit specifically focused on IHS's coordination of vaccine distribution, allocation, and administration for Tribal programs.

We assessed program implementation by tracing the movement of COVID-19 vaccines through the process from procurement through reporting of the administered dose. We did so by judgmentally selecting 2 administered patient vaccine doses (for 2 different patients) for each of the 14 Tribal programs. We reviewed supporting documentation for the 28 selected administered doses.

We conducted this performance audit 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.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

IHS did not fulfill all of the provisions outlined in the MOA and its Vaccine Plan to help ensure that the vaccination program was implemented appropriately at Tribal programs. Consequently, Tribal programs did not always comply with all program requirements during early program implementation. Specifically, IHS did not always provide the necessary resources and assistance to help ensure that Tribal programs:

- met reporting requirements for vaccine administration data;

- used billing practices that conformed to Centers for Medicare & Medicaid Services (CMS) and CDC requirements and American Medical Association (AMA) guidance regarding reimbursement for vaccine administration fees; and

- did not enter into unallowable dual-program agreements with both a State jurisdiction and IHS.

Although Tribal programs were permitted to prioritize vaccines to protect their tribal members, IHS, as a jurisdiction, had responsibilities outlined in the MOA and its Vaccine Plan to ensure that the vaccination program was implemented appropriately.

IHS contributed to Tribal programs not meeting all vaccine program requirements because it did not: (1) have a consistent reconciliation process established to ensure that vaccine administration data the Tribal programs submitted were accurate, (2) provide sufficient assistance and guidance to Tribal programs for the billing of COVID-19 vaccine administration fees, and (3) adequately coordinate with CDC to develop and disseminate additional guidance to prevent Tribes from entering into dual-program agreements with both a State jurisdiction and IHS. Because of these deficiencies, the administration of the COVID-19 vaccine program was adversely impacted. For example, we noted that (1) total doses administered by Tribal programs could not always be verified for the applicable time period, and doses administered were not always reported in a timely manner; (2) some patients were directly billed for administration of the COVID-19 vaccine; and (3) some Tribal programs could have received vaccine doses from their State (in addition to the doses they received from IHS allocations).

These deficiencies could have led IHS to make less-than-optimal decisions on priorities and distribution. Tribal programs might have received more vaccines because they had an agreement with the State as well as IHS, which could have resulted in inequitable allocation of vaccine.

IHS DID NOT ENSURE THAT TRIBAL PROGRAMS ALWAYS COMPLIED WITH REPORTING REQUIREMENTS FOR VACCINE ADMINISTRATION DATA

The MOA states that Tribal programs operating under Tribal Health Program Agreements and receiving COVID-19 vaccines through IHS must submit their vaccine administration data to IHS. IHS, acting as a coordinator between the Tribal programs and CDC, must then submit these data to CDC via a secure system. The MOA further specifies the required data elements and states that IHS must submit these data within 24 hours of vaccine administration.[9]

The Vaccine Plan established a Data Management team as part of the VTF. The Plan requires the Data Management Team to: (1) ensure that data management systems are operational and that Tribal programs are onboarded to the critical data flows and electronic systems in advance of vaccine distribution, (2) provide ongoing technical support for Tribal programs to ensure that data reporting meets CDC requirements, and (3) maintain accurate data on vaccine administration and distribution. The Vaccine Plan specifies that the Data Management team will dedicate resources for Tribal programs to ensure export of data to IHS and CDC according to the required data reporting elements for COVID-19 vaccine administration.

For all 14 Tribal programs that we reviewed, the data totals for the number of vaccine doses administered were inconsistent between Tribal programs' reports (which were pulled from the programs' systems) and IHS's reports. Some Tribal programs report totals reflected more or less doses than did IHS report totals. For example, one Tribal program reported 11,821 doses

[9] Some Tribal programs were permitted to report the required vaccine administration data directly to CDC via the CDC Vaccine Administration Management System (VAMS). In addition, Tribes used VAMS to enter all information related to vaccines administered to IHS employees.

while the corresponding IHS report reflected 10,726 doses. The issues associated with the reporting of vaccine administration data—and the accuracy of those data, which is a requirement specified in the Vaccine Plan—primarily resulted from the lack of compatibility between IHS's and Tribal programs' data management systems. Tribal programs had different data management systems to track the vaccines that they administered, and these systems and IHS's systems were inconsistent in terms of how they tracked the vaccines administered. One Tribal program told us that it had problems with the accuracy of the data being pulled from its system, so it relied on manual counts to determine total administered doses. These different data management systems also made data entry errors inevitable, as lack of compatibility meant that data sometimes had to be manually transferred from one system to another. Some Tribal programs told us that at times, a lack of staffing and various technical difficulties also contributed to data reporting inconsistencies.

IHS Area Offices monitored the data that Tribal programs reported on the doses they administered, and the VTF Data Management Team was responsible for, among other things, ensuring the accuracy of the data on vaccine administration and distribution. Generally, the VTF Data Management Team provided data management troubleshooting, if errors were identified, and some periodic training, but it did not have a formalized reconciliation process established for all IHS Areas to ensure that the data submitted by Tribal programs were correct. One way to ensure and enhance the accuracy of data is by reconciling data conveyed in the various systems. The lack of an established, formalized reconciliation process to monitor the vaccine administration data on a standard basis, during early program implementation, contributed to the untimely identification of errors.

Given the vaccine administration data reporting deficiencies, IHS could not rely on this information to provide an accurate representation of IHS's vaccination progress. An accurate representation would include verifying the total doses administered for the applicable time period and ensuring timely reporting of the doses administered to achieve a complete reporting of the information at any point in time. We noted that some Tribal vaccine administration data did not reach CDC in a timely manner because of these inaccuracies. For example, one Tribal program provided documentation that there was a delay of at least 4 months in submitting the data, which was well beyond the 24-hour timeframe requirement included in the MOA. Having timely and accurate reporting of COVID-19 vaccine data is critical during a pandemic as various Federal, State, and other partners use vaccine administration data to inform decisions about COVID-19 vaccination priorities and distribution.[10]

IHS DID NOT TIMELY PROVIDE ASSISTANCE ENSURING THAT TRIBAL PROGRAM BILLING PRACTICES FOR VACCINE ADMINISTRATION FEES CONFORMED TO FEDERAL GUIDANCE

The Vaccine Plan states that billing of COVID-19 vaccine administration fees requires coordination between medical coding staffs, the IHS Office of Information Technology, and

[10] These included CDC and other Federal agencies; vaccination providers; State, local, and territorial public health departments; and Tribal programs across the country.

billing/patient business departments. According to the Tribal Health Program Agreement, Tribal programs may not seek any reimbursement, including through balance billing, from a vaccine recipient.[11] Additionally, the AMA established Current Procedural Terminology (CPT) coding guidance specific to COVID-19 vaccines and vaccine administration fees, and CMS adopted these codes.

Three Tribal programs billed in a manner that was not consistent with AMA guidance and CMS and CDC requirements established for COVID-19 vaccine administration fees. One of these Tribal programs directly billed individuals for the administration of the COVID-19 vaccine, which violated program requirements. Two other programs used an evaluation and management services CPT code even though COVID-19 vaccine administration (which uses a different CPT code) was the only service provided.

These Tribal programs did not bill in accordance with AMA guidance and CMS requirements because upon implementation of the vaccine administration program, IHS did not provide sufficient assistance and guidance to Tribal programs for the billing of COVID-19 vaccine administration fees. The Vaccine Plan states that although, as part of IHS's planning efforts, the VTF Vaccine Administration Team "is working to identify third-party billing reimbursement potential for vaccine administration fees, vaccination must be offered to all individuals regardless of their insurance status or ability to pay for the vaccination administration fees." The Vaccine Plan added that this team "is working to identify [CMS] guidance documents and resources to understand the potential billing of vaccine administration fees for Medicare and Medicaid beneficiaries." Tribal program staff, however, told us that upon program implementation, they did not receive guidance from IHS regarding the billing of COVID-19 vaccine administration fees. Some Tribal program staff told us that they received some guidance from IHS months after the vaccine program had been implemented.

Because Tribes did not receive adequate billing guidance upon program implementation, some individual patients were directly billed for administration of the COVID-19 vaccine. Furthermore, the use of nonstandard CPT codes for billing of vaccination administration fees could have resulted (through balance billing) in patient cost-sharing for vaccine administration. Patients seeking vaccines from Tribal programs may have been deterred from requesting and getting the vaccine if they believed that there was an associated out-of-pocket cost. Finally, the delay in billing guidance caused some Tribal programs to delay or forgo the billing of administration fees to Medicare and Medicaid, which resulted in those programs receiving untimely or no reimbursement for administering the vaccines.

[11] The term "balance billing" generally refers to a practice whereby a health care provider bills a patient the difference between the provider's charge and the allowed amount.

IHS DID NOT COORDINATE WITH CDC TO ENSURE THAT TRIBAL PROGRAMS DID NOT ENTER INTO UNALLOWABLE DUAL-PROGRAM AGREEMENTS WITH BOTH A STATE JURISDICTION AND IHS

The CDC *COVID-19 Vaccination Interim Playbook for Jurisdiction Operations* directs that jurisdictions such as IHS should reach out to Tribal nations for involvement in planning efforts and include each Tribe's preference for COVID-19 vaccine distribution to ensure that the vaccine is effectively delivered to Tribal nations and their communities. Tribal programs have two options for receiving vaccine: from IHS or from their State. The MOA more specifically directs that "IHS will notify [Tribes] that choose to receive COVID-19 Vaccines through IHS that they will not be allowed to enroll in the CDC COVID-19 vaccination program through another jurisdiction," such as a State. In addition, the Tribal Health Program Agreement requires participating Tribal programs to certify that they will not also sign participation agreements for that program through a State or local jurisdiction.

Two Tribal programs (associated with two different Tribes) of the 14 that we reviewed entered into program agreements with the State of Michigan at the same time that they had Tribal Health Program Agreements coordinated by IHS.

Although IHS informed Tribal programs that they were not allowed to enter into dual-program agreements, it did not adequately coordinate with CDC to monitor the programs to ensure that Tribes did not proceed with other participation agreements in cases when the States in which they were located had contacted the Tribal programs regarding allocations of vaccines.

The Tribal programs with dual-program agreements could have received vaccine doses from their States in addition to the doses they received from the IHS allocations. These additional doses may therefore have created an inequitable distribution of vaccines among the Tribes, which could have led IHS to make less-than-optimal decisions on priorities and distribution.

RECOMMENDATIONS

We recommend that Indian Health Service:

- ensure that Tribal programs comply with vaccine program requirements by:
    - establishing formal reconciliation processes for all IHS Areas to ensure that the data that the Tribal programs submit on doses administered are correct and
    - addressing data management system incompatibilities between Tribal programs and IHS;
- work with CMS to disseminate guidance to Tribal programs on vaccine coding and billing;

- work with CDC and the appropriate Tribal program to ensure that it returns funds to those individuals who were balance-billed inappropriately; and

- work with CDC to develop and disseminate additional guidance related to dual enrollment and together implement a formal monitoring process to assist in ensuring that Tribal programs do not enter into unallowable dual-program agreements for Federal programs.

IHS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, IHS concurred with all of our recommendations and described corrective actions that it had taken or planned to take.

IHS pointed out that it has "limited options to enforce Tribal compliance with vaccine program requirements." For our first recommendation, IHS stated: "As the COVID-19 response has evolved nationally over the past year and a half, the IHS continues to provide technical support and data tools to [Tribal programs] receiving vaccine from the IHS jurisdiction." IHS agreed with the importance and need for Tribes to comply with vaccine reporting requirements and employ effective reconciliation tools and processes. IHS also described the steps it had taken to address data management system incompatibilities between Tribal programs and IHS. IHS stated that it had developed a series of "Business Intelligence and reporting solutions" since our audit period. IHS said that it has continued to mature the tools to meet agency and site reporting requirements and added that "near real-time information" was available for IHS leadership, Area offices, and Tribal stakeholders. IHS described the following solutions:

- Data Training: IHS described "numerous opportunities" that it offered, on either a twice-weekly or weekly basis both before and during the timeframe of our audit, for data management training, troubleshooting, and education for Tribal programs receiving COVID-19 vaccines through IHS.

- Data Reports: IHS described various reports that were available to Tribal programs to identify incorrect data submissions and to assist in the reconciliation of data on vaccines given as compared to vaccines reported. IHS added that it had made available a file processing report showing errors.

- Vaccine Administration Reports: IHS said that it had developed and made available a dashboard to provide insight into vaccine data processed.

- Vaccine Reporting: IHS said that it had also developed a "COVID Vaccine Reporting solution" that includes daily statistics on all vaccines administered by Tribal programs for both patients and employees.

IHS summed up its description of these and other Business Intelligence solutions by saying that it had developed them to empower users to track vaccine administration data and to facilitate internal and external reporting to IHS and the CDC.

For our second recommendation, IHS stated that it "continues to work with Federal partners to disseminate appropriate coding and billing guidance to [Tribal programs] receiving vaccines from the IHS jurisdiction." Specifically, "IHS works closely with CMS concerning billing of Medicare and Medicaid. The audit period documents the early pandemic response when the focus was on ensuring communities received the vaccine and there may have been cases where Federal guidance, specific to Tribes, was pending." IHS added that it continues to distribute and work with CMS on published coding and billing guidance.

For our third recommendation, IHS stated that it "will be available to work with CDC and provide assistance to the [Tribal program] as needed, and if requested by the Tribe."

Lastly, IHS also concurred with our fourth recommendation but said that actions taken to date "fully address this recommendation" and that therefore IHS did "not agree that a formal monitoring process is needed." IHS stated that "the State of Michigan was told by the CDC and the IHS that it was inappropriate for the State to be enrolling [Tribal programs] that have CDC agreements in which the vaccines were coordinated through IHS." In addition, IHS said that CDC developed, "with the IHS's assistance," new guidance related to dual enrollment, which CDC released on February 26, 2021 (near the end of our audit period). "Thus, the State of Michigan and the Michigan [Tribal programs] were told within eight days to stop dual enrollments, and the CDC issued guidance a little over one month after the first notice."

IHS's comments appear in their entirety as Appendix C.

We commend IHS for the actions it has taken and plans to take to address our recommendations. We encourage IHS to continue to monitor Tribal programs across the Nation to help ensure that they do not enter into unallowable dual-program agreements for the COVID-19 vaccination program and for other Federal programs.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed IHS's policies and procedures and evaluated measures implemented by Tribal programs during Phases 1A and 1B of their vaccination programs to distribute, allocate, and administer the Pfizer-BioNTech and Moderna COVID-19 vaccines for the period December 11, 2020, through February 28, 2021 (footnote 8). This audit period covered early efforts to implement the provisions of the MOA and the Vaccine Plan, both of which went into effect in November 2020.

We interviewed IHS HQ, IHS Area office, and Tribal program staff and gathered documentation that helped us evaluate IHS's early efforts to coordinate the CDC COVID-19 Federal Agency Vaccination Program implemented by Tribal programs.

We focused our work on Tribal programs and did not select any IHS Direct or Urban programs for review because our audit focused on IHS's coordination of vaccine distribution, allocation, and administration for Tribal programs.

We determined that IHS's control environment, control activities, and information and communication were significant to our audit objective. We reviewed IHS's organizational structure, assignment of responsibilities, and delegation of authority. We also reviewed the design of the information system and technology infrastructure related to the vaccine program. Finally, we reviewed both the external and internal communications regarding the vaccine program.

We performed audit work from March 2021 through August 2022.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance, including the MOA, the Vaccine Plan, and the Tribal Health Program Agreement.

- We interviewed IHS HQ staff and gathered documentation to determine how IHS planned, monitored, and supported the distribution, allocation, and administration of vaccines to Tribal programs.

- We assessed the design and implementation of internal controls applicable to our objective.

- We obtained a list of Tribal programs that had designated IHS as coordinator for the CDC COVID-19 Federal Agency Vaccination Program for our audit period (December 11, 2020, through February 28, 2021).

- We obtained IHS reports of distributed and administered doses for these Tribal programs.

- We initially conducted a survey, interviewed staff, and gathered documentation to evaluate IHS coordination of COVID-19 vaccine allocation, distribution, and administration in a Tribal program in the Navajo Area. We then judgmentally selected 1 Tribal program from each of the 11 IHS Areas that participated in the CDC COVID-19 Federal Agency Vaccination Program coordinated by IHS, to evaluate their implementation of IHS policies and procedures (footnote 7).

- We judgmentally selected two other Tribal programs: one from the same Area (Bemidji) as another Tribal program that had entered into a dual-program agreement and the other to ensure that we were providing greater coverage of the Area (Nashville) with the largest geographical area.[12] Thus, we selected a total of 14 Tribal programs for review. We did not select any IHS Direct or Urban programs for review because our audit focused on IHS's coordination of vaccine distribution, allocation, and administration for Tribal programs.

- We conducted a survey, interviewed Area Office staff, and gathered documentation for judgmentally selected Tribal programs to gain an understanding of their policies and procedures for assisting in data collection and planning for Tribal programs.

- We conducted a survey and interviewed Tribal program staff of all 14 judgmentally selected Tribal programs to evaluate IHS coordination of COVID-19 vaccine distribution, allocation, and administration for Tribal programs.

- We assessed program implementation by tracing the movement of COVID-19 vaccines through the process from procurement through reporting of the administered dose. We did so by judgmentally selecting 2 administered patient doses (for 2 different patients) for each of the 14 Tribal programs. We reviewed supporting documentation for the 28 selected administered doses.

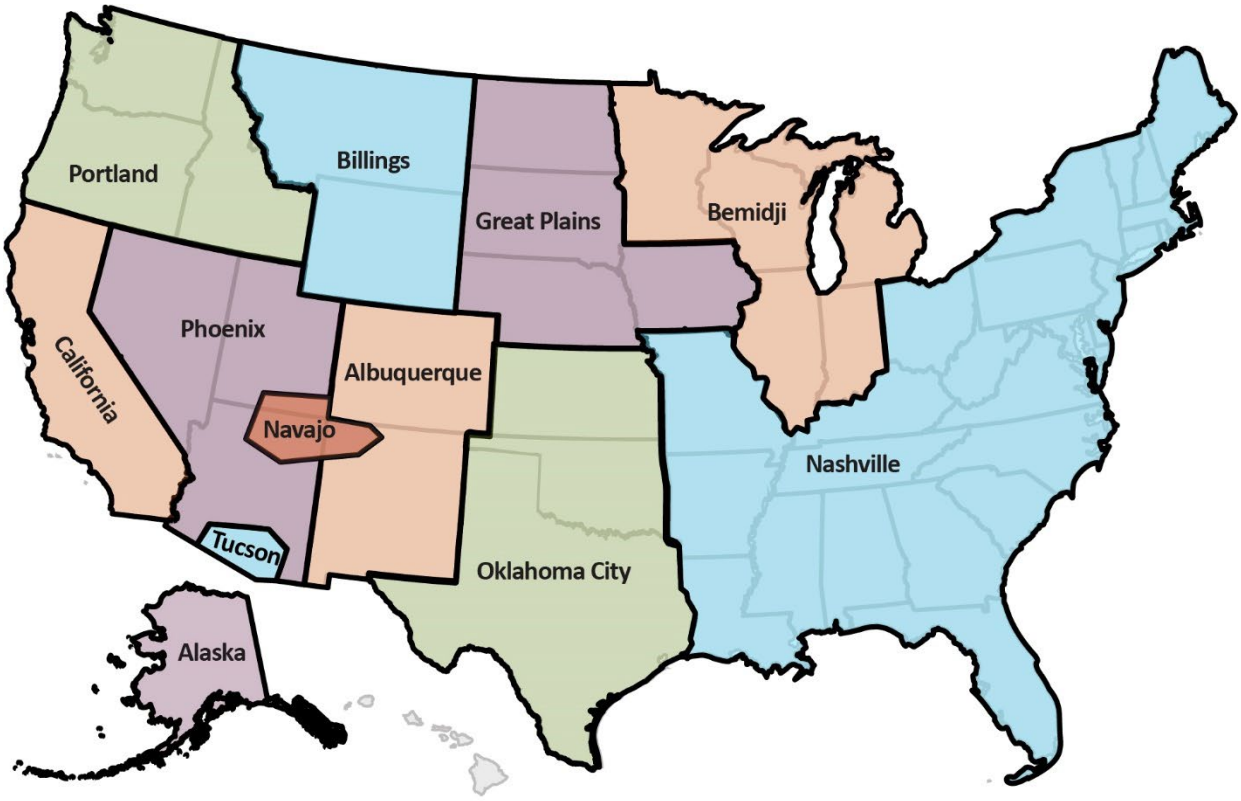
- We discussed the results of our audit with IHS officials on March 30, 2022.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain

[12] Our discussion of the finding in the Bemidji Area appears earlier in "IHS Did Not Coordinate With CDC To Ensure That Tribal Programs Did Not Enter Into Unallowable Dual-Program Agreements With Both a State Jurisdiction and IHS."

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.

APPENDIX B: MAP OF IHS AREA LOCATIONS



NOTE—No Tribes in the Alaska Area participated in the CDC COVID-19 Federal Agency Vaccination Program coordinated by IHS (footnote 7). In addition, Texas is within the Oklahoma City Area but also includes programs that report to the Albuquerque and Nashville Areas. In addition, IHS does not have any direct service, tribal, or urban Indian organization sites in Hawai'i, but the California Area does have a contract to provide limited services at one facility in Hawai'i.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Indian Health Service
Rockville, MD 20857

DATE: September 14, 2022

TO: Inspector General

FROM: Acting Director

SUBJECT: IHS Response to Draft OIG Report: *IHS Did Not Always Provide the Necessary Resources and Assistance to Help Ensure That Tribal Programs Complied with All Requirements during Early COVID-19 Vaccination Program Implementation, (A-07-21-04125*), dated August 9, 2022

We appreciate the opportunity to provide our official comments on the Draft Office of Inspector General (OIG) Report entitled, *IHS Did Not Always Provide the Necessary Resources and Assistance to Help Ensure That Tribal Programs Complied with All Requirements during Early COVID-19 Vaccination Program Implementation, (A-07-21-04125*), dated August 9, 2022. The Indian Health Service (IHS) concurs with the four OIG recommendations discussed below.

Recommendation Number 1: IHS concurs with the recommendation.

We recommend that IHS ensure that Tribal programs comply with vaccine program requirements by establishing formal reconciliation processes to ensure that the data that the Tribal programs submit on doses administered are correct and by addressing data management system incompatibilities.

Planned and completed actions:

While the IHS has limited options to enforce Tribal compliance with vaccine program requirements, the IHS agrees with the importance and need for Tribes to comply with vaccine program requirements and to employ effective reconciliation tools and processes. As the COVID-19 response has evolved nationally over the past year and a half, the IHS continues to provide technical support and data tools to IHS operated facilities, Tribal Health Programs, and Urban Indian organizations (I/T/Us) receiving vaccine from the IHS jurisdiction. This response to the OIG audit includes a summary of efforts to date to fully address this recommendation.

IHS has taken a variety of steps to facilitate and promote Tribal compliance regarding the integrity of the data that the Tribal programs submit on doses administered, and to address data management system incompatibilities between Tribal programs and IHS. The IHS has developed a series of Business Intelligence and reporting solutions since the time the OIG conducted its review from December 11, 2020, through February 28, 2021, and has continued to mature the tools to meet agency and site reporting requirements.

With respect to timely reporting, the IHS developed and hosted several COVID-19 vaccination training sessions for Area and Tribal end users. The IHS also developed dashboards using a series of Business Intelligence and reporting solutions that informs leadership and provides actionable insights into vaccine administration information reported to the IHS and the Centers for Disease Control and Prevention (CDC). This near real-time information is available for IHS leadership, IHS Area and Tribal stakeholders to view, on-demand, or via daily static reports that are auto-generated and distributed via email. The IHS reporting solutions were strenuously tested and validated with various stakeholders from the IHS Office of Information Technology (OIT), IHS Areas and Tribal Health Programs.

Data Trainings: Before and during the audit timeframe, the IHS offered numerous opportunities for data management training, trouble shooting, and education for I/T/Us receiving vaccines through the IHS jurisdiction. The IHS worked diligently to get electronic data reporting pathways established for reporting of administered COVID-19 vaccine doses for I/T/Us in accordance with CDC requirements. Trainings were offered twice weekly from mid-December 2020 through mid-January 2021, then weekly in February 2021. The training and support activity opportunities were widely circulated to technical staff, informaticists, and clinical stakeholders. In addition, the sessions were recorded for post-session review and accessible on the IHS webpage. In November 2020, prior to the audit time period, a COVID-19 Vaccine Data Management Kickoff training was offered for each IHS Area, attended by participants from I/T/Us. In addition, COVID-19 Data Management Drop in Office Hours were held twice weekly from mid-December 2020 through mid-January 2021, then transitioned to weekly in February 2021. Separate COVID-19 Vaccine Data Management Series sessions were offered and reviewed HL7 Messaging for Non-RPMS Sites (on 12/3/2020 and 12/10/2020), documentation in the CDC Vaccine Administration Management System (VAMS) systems for I/T/Us (on 12/4/2020, 12/7/2020, 12/9/2020, 12/10/2020, 12/16/2020) and several other clinically based topics were offered throughout January and February 2021. Overall, there was a great deal of access to the IHS Data Management group offered to I/T/Us before and during the OIG audit period. This includes 47 hours of "drop-in" office hours that were offered in December 2020 and four hours in January 2021 to address site level concerns.

Data Reports: For Tribal Health Programs participating in the Central Aggregation Server (CAS) reporting process, a File Processing Report is available to the programs to identify incorrect data submissions and to assist in the reconciliation of vaccines given to vaccines reported. Reports were sent to the health program at the time of submitting their vaccination event message files to an e-mail distribution list provided by each health program during the on-boarding process.

A file processing report showing errors was also made available. Using the Message ID and Order number, the health program would be able to identify the patient associated with the message in the source file that produced the error and using the explanation of the error code(s) adjust the immunization event record(s) and re-submit.

Other reports that included personal identifiable information data were made available to health programs requesting them. The reports provided information such as the events received or events with errors for a given date range.

If a health program was unable to utilize CAS, they were instructed to utilize the VAMS tool developed by the CDC to report their immunization events. During trainings regarding the reporting mechanisms, attendees were informed that they should not report the same immunization event to both CAS and VAMS.

Vaccine Administration Reports: The OIT developed a COVID Vaccine Administration File Tracking and Management solution that provides hourly statistics on file receipt and processing of all vaccine administrations reported by Tribal Health Programs. The dashboard provides an enterprise view of all reported vaccine administration information to IHS, by reporting date. Additionally, the dashboard provides insights into data processed by CAS, and sent to the CDC for reporting. Status, statistics on files state, and success and error information are additional metrics provided for end user consumption.

Vaccine Reporting: The OIT also developed a COVID Vaccine Reporting solution that includes daily statistics on all vaccines administered by Tribal Health Programs, reported in the CDC and VAMS immunization systems, for both patients and employees. The dashboard also provides an enterprise view of all reported vaccine administration information to the IHS and the ability to customize their user population universe. Additionally, the dashboard provides insights into vaccine types, demographics, total doses administered, partial vaccinations, full vaccinations, refused vaccinations by dose number, additional doses and/or boosters by area, service unit, and individual facilities and reporting date.

The IHS Headquarters, IHS Area Offices, and any Tribal user with a network account have access to the COVID Vaccine Administration File Tracking and Management and the COVID Vaccine Reporting dashboards. Tribal users that do not have access to the IHS network receive daily auto-generated reports that provided insights into the vaccine administration information. Access to the reports were granted upon request. The IHS OIT developed the Business Intelligence solutions described above to empower users to track vaccine administration data, facilitate internal and external reporting to the IHS and the CDC.

Recommendation Number 2: IHS concurs with the recommendation

We recommend that IHS work with Centers for Medicare & Medicaid Services (CMS) to disseminate guidance to Tribal programs on vaccine coding and billing.

Planned and completed actions:

As the COVID-19 response has evolved nationally since the time the OIG conducted its review from December 11, 2020, through February 28, 2021, the IHS continues to work with Federal partners to disseminate appropriate coding and billing guidance to I/T/Us receiving vaccines

from the IHS jurisdiction. This response to the OIG audit includes a summary of efforts to date to fully address this recommendation.

Tribal Health Programs were notified of how to code and bill for vaccine. As stated in the *CDC COVID-19 Vaccination Program Tribal Health Program Agreement – Vaccines Coordinated through IHS*, Tribal Health Programs must certify that:

> *Tribal Health Program must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees or coverage status. Tribal Health Program must ensure that any federal funding, including from IHS, that it intends to use for the costs of administering the COVID-19 Vaccine is authorized for that purpose and, if applicable, for services to non-beneficiaries. Tribal Health Program may seek reimbursement, to the extent authorized, from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient. Tribal Health Program may not seek any reimbursement, including through balance billing, from the vaccine recipient.*

The IHS recognizes that the American Medical Association (AMA) established and CMS adopted coding guidance specific to COVID-19 vaccines and vaccine administration fees were issued early in the public health emergency. The IHS works closely with CMS concerning billing of Medicare and Medicaid. The audit period documents the early pandemic response when the focus was on ensuring communities received the vaccine and there may have been cases where Federal guidance, specific to Tribes, was pending.

Early in the response, the IHS worked with CMS and Tribal workgroups to address Medicare and Medicaid billing concerns for COVID-19 visits. The IHS Vaccine Task Force (VTF) continuously worked to address issues identified by I/T/Us. The COVID-19 Vaccine Administration Workgroup held office hours twice a week to answer implementation questions from I/T/U staff. The IHS worked with CMS to address issues, questions, and provide proper guidance to I/T/U facilities. In addition to working with CMS and I/T/U staff to address concerns, the IHS also held regular national calls with staff from I/T/Us prior to and for months after the start of vaccine distribution advising on a variety of vaccine topics including coding and billing.

The IHS issued COVID-19 vaccination billing guidance to IHS Areas and on the IHS web page. Additionally, billing resources specific to COVID-19 vaccinations were made available on the IHS website and other resources from the CDC, CMS, and other Federal partners on this topic and were shared and disseminated across the health care system. To date, the IHS and CMS have issued sufficient guidance regarding COVID-19 vaccine coding and billing. The IHS distributes coding and billing materials to IHS Area business office coordinators who in turn distribute information to their respective IHS Area contacts which includes Tribal business offices. The IHS continues to distribute and work with CMS on published coding and billing guidance.

Recommendation Number 3: IHS concurs with the recommendation

We recommend that IHS work with CDC and one Tribal program to ensure that it returns funds to individuals who were billed inappropriately.

Planned and completed actions:

While the IHS has limited options to enforce a corrective action related to the Tribe's improper billing, the IHS will be available to work with CDC and provide assistance to the Tribal Health Program as needed, and if requested by the Tribe.

Recommendation Number 4: IHS concurs with the recommendation

We recommend that IHS work with CDC to develop and disseminate additional guidance related to dual enrollment and together implement a formal monitoring process to help ensure that Tribal programs do not enter into unallowable dual-program agreements for Federal programs.

Planned and completed actions:

The IHS concurs with this recommendation to work with CDC to develop and disseminate additional guidance related to dual enrollment, to ensure and confirm/certify understanding by Tribal Health Programs that they cannot enter into unallowable dual-program agreements for Federal programs; and to take remedial action if exceptions are found. However, due to the actions completed to date, the IHS does not agree that a formal monitoring process is needed. The information below provides a summary of actions taken to date to fully address this recommendation.

The *CDC COVID-19 Vaccination Program Tribal Health Program Agreement – Vaccines Coordinated through IHS* requires Tribal Health Programs to certify that:

> *Having chosen to participate in the CDC COVID-19 Vaccination Program coordinated through IHS, Tribal Health Program certifies that it will not sign participation agreements in the CDC COVID-19 Vaccination Program through a state or local jurisdiction.*

On December 20, 2020, the IHS VTF issued the C*DC COVID-19 Vaccine Redistribution Agreement for Tribal Health Programs and Urban Indian Organizations for Vaccines Coordinated through IHS*, and an *IHS Supplemental Redistribution Guidance and Worksheet*. The redistribution agreement and worksheet facilitated the transfer of vaccine between IHS-operated facilities and facilities operated by Tribal Health Programs and Urban Indian Organizations participating in the CDC COVID-19 vaccination program coordinated through IHS. On January 20, 2021, IHS was told that the State of Michigan was allowing dual enrollment for receipt of COVID-19 vaccine, both through IHS and the State of Michigan. The IHS immediately notified the CDC.

As of January 28, 2021, the Michigan Tribal Health Programs that had CDC agreements in which the vaccines were coordinated through IHS were told not to sign agreements with the State of Michigan, and thus, have dual jurisdiction. Likewise, the State of Michigan was told by the CDC and the IHS that it was inappropriate for the State to be enrolling Tribal Health Programs that have CDC agreements in which the vaccines were coordinated through IHS.

In addition, the CDC began working on guidance related to dual enrollment with the IHS's assistance. On February 26, 2021, the CDC released the *CDC COVID-19 Vaccine Allocation Transfer and Redistribution Guidance for IHS-operated facilities and facilities operated by Tribal Health Programs and Urban Indian Organizations Participating in the CDC COVID-19 Vaccination Program coordinated through Indian Health Service*. This document was posted on the CDC's COVID-19 Pandemic website. The State of Michigan was advised that the CDC developed the *CDC COVID-19 Vaccine Allocation Transfer and Redistribution Guidance* specifically to allow for seamless transfer of vaccines to and from state jurisdictions through two mechanisms to meet Tribal Health Programs need for vaccine. The State of Michigan agreed to destroy the Tribal Health Programs' CDC Agreements with Michigan and proceeded with allocation transfers to the IHS, which were applied to specific Michigan Tribal Health Programs. At the time, the matter was considered closed.

Thus, the State of Michigan and the Michigan Tribal Health Programs were told within eight days to stop dual enrollments, and the CDC issued guidance a little over one month after the first notice that allowed Michigan Tribal Health Programs to get additional vaccines from the State without dual enrollment. Further, the CDC issued sufficient guidance and the CDC and the IHS provided technical assistance to appropriately resolve the dual enrollment issue with the State of Michigan.

Thank you for the opportunity to review and comment on this draft report. Please refer any follow up questions you have regarding our comments to Ms. Athena Elliott, IHS Chief Compliance Officer by email at athena.elliott@ihs.gov.

Elizabeth A. Fowler
Acting Director