

U.S. Department of Health and Human Services  
**Office of Inspector General**



# HHS's Suspension and Debarment Program Helped Safeguard Federal Funding, But Opportunities for Improvement Exist

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## Key Terms

**Awarding agencies** award Department of Health and Human Services (HHS) funds—e.g., grants and contracts.

**Non-awarding entities** within HHS do not fund awards, but often have oversight responsibilities. These entities include the Office of Inspector General (OIG), the Office of Recipient Integrity Coordination, the Office of Research Integrity, and the Office of General Counsel.

**Suspensions** are preliminary, immediate actions that exclude persons from receiving new funds.

**Debarments** are final determinations that exclude persons from receiving new funds for a specified time.

**Referrals** for suspension or debarment are made by awarding agencies and non-awarding entities if they suspect awardee misconduct.

**The Office of Recipient Integrity Coordination (ORIC)** receives referrals and manages the HHS suspension and debarment program. ORIC is part of HHS's Office of the Assistant Secretary for Financial Resources.

**The suspension and debarment official (SDO)**—part of ASFR—determines if any suspension or debarment action should be implemented.

## Why OIG Did This Review

As HHS is the largest Federal grant-making agency (\$531 billion in 2019) and the fourth-largest Federal contracting agency (\$39 billion in 2019), it is important for it to have a robust suspension and debarment program. If bad actors or poor performers are not prevented from receiving additional Federal awards in a timely manner, beneficiaries of public health and human services programs may suffer and taxpayer funds may be misused.

# HHS's suspension and debarment program helped safeguard Federal funding, but opportunities for improvement exist

## Key Takeaway

Most suspension and debarment referrals resulted in actions to protect Federal programs and funds, but HHS also has opportunities to improve the timeliness, efficiency, and effectiveness of its suspension and debarment program.

## What OIG Found

Between fiscal years (FYs) 2015 and 2019, 86 percent of referrals that HHS entities made to ORIC resulted in suspension, debarment, or other administrative action to protect Federal programs and funds. Nearly one-third of debarments involving grants had preceding suspensions. ORIC does not have complete guidance about the circumstances in which immediate action (i.e., suspension) may be appropriate while it awaits a debarment from the SDO. Most of the referrals for suspension or debarment came from HHS

non-awarding entities; many HHS awarding agencies made no referrals during the 5-year period we reviewed. Suspension and debarment actions often missed ORIC's internal timeliness goals. Delays resulted in part from ongoing criminal or appeals proceedings and challenges in obtaining necessary information about the person referred for suspension or debarment. Other factors that affected the timeliness, efficiency, and effectiveness of this program were (1) vacancies and turnover at both the staff and senior leadership levels; (2) a limited system for case management and tracking of referrals; and (3) incomplete guidance regarding the use and documentation of corrective actions for what are known as "fact-based" referrals (as distinguished from "conviction-based" referrals).

## What OIG Recommends and How the Agency Responded

To improve the timeliness, efficiency, and effectiveness of HHS's suspension and debarment program, we recommend that HHS's Office of the Assistant Secretary for Financial Resources (1) take steps to ensure that the program has more consistent senior leadership and sufficient staffing; (2) improve the case management and tracking of referrals; (3) develop and disseminate guidance regarding how to prepare and submit complete referrals; and (4) conduct outreach and provide additional training to HHS awarding agencies that make few or no referrals. ASFR concurred with all four of our recommendations.

## How OIG Did This Review

We analyzed multiple data sources to describe the outcomes, sources, and timeliness of suspension and debarment referrals during our review period, FYs 2015 through 2019. We also identified factors that may have affected the timeliness, efficiency, and effectiveness of HHS's suspension and debarment program. For example, we reviewed referral data and surveyed awarding agencies and non-awarding entities. We also interviewed ORIC and the SDO.

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# BACKGROUND

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## OBJECTIVES

1. To describe the outcomes, sources, and timeliness of referrals within the Department of Health and Human Services (HHS) for suspension and debarment.
  2. To identify factors that may affect the timeliness, efficiency, or effectiveness of HHS's program for suspension and debarment.
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As HHS is the largest grant-making agency in the Federal Government (\$531 billion in fiscal year (FY) 2019) and the fourth-largest contracting Federal agency (\$39 billion in FY 2019), it is important for HHS to have a robust suspension and debarment program.<sup>1,2</sup> If bad actors or poor performers are not prevented from receiving additional Federal awards in a timely manner, beneficiaries of public health and human services programs may suffer and taxpayer funds may be misused.

OIG has not previously evaluated HHS's suspension and debarment program to assess timeliness, efficiency, or effectiveness. A 2014 Government Accountability Office (GAO) report found that HHS had taken steps to implement components of an effective suspension and debarment program, such as having dedicated staffing; a system for case management and tracking; and training.

Now is an opportune time for HHS to consider how well its suspension and debarment program is working and identify opportunities for improvement. In January 2021, the Office of Management and Budget designated HHS as the Quality Service Management Office for grants across the Federal government. The Quality Service Management Office works across all Federal awarding agencies to modernize, automate, and standardize the processes and systems for grants management. Therefore, this evaluation is well-positioned to provide information for awarding agencies in HHS as well as across the Federal Government to use as agencies continue to improve their oversight of awards funding.

## Suspensions and debarments protect the integrity of Federal programs

Suspension and debarment programs help protect the integrity of Federal grants, contracts, and other covered transactions by ensuring that the Federal government does business only with responsible persons.<sup>3, 4, 5, 6</sup> (Regulations define a "person" as any individual, corporation, partnership, association, unit of government, or legal entity.) Suspensions and debarments are one of many optional and discretionary

administrative actions<sup>7</sup> that Federal departments may take against a person that is not “presently responsible”—i.e., a person that demonstrates a lack of honesty, a lack of integrity, or an unacceptable level of performance. Suspension and debarment actions are based on a person’s present responsibility to handle Federal funds. Generally, suspension or debarment action is initiated when an awarding agency or other entity (e.g., Office of Inspector General, or OIG) submits a referral to a Federal department’s program for suspension and debarment. Within HHS, the Office of Recipient Integrity Coordination (ORIC) receives referrals for suspension and debarment.

Suspensions and debarments are not mutually exclusive; a Federal department may pursue a suspension (a preliminary decision) while also pursuing a debarment (a final determination). When a Federal department decides to pursue a suspension or debarment against a person, that person is known as a **respondent**. Typically, the end goal is to debar a respondent. However, if a Federal department cannot initially meet the higher evidentiary standard required for debarment, or if it concludes that immediate action is necessary to protect the Federal government, it may first pursue a suspension. Below, Exhibit 1 provides an overview of suspensions and debarments, including the definitions, timeframes, and levels of evidence needed for each.<sup>8</sup>

### Exhibit 1: Overview of suspensions and debarments

	Suspensions	Debarments
Definition	Preliminary decision that a respondent is not presently responsible and is temporarily ineligible to obtain new awards, pending the completion of legal proceedings	Final determination that a respondent is not presently responsible and is unable to obtain new awards for a specific period
General Timeframe	Typically does not exceed 12 months	Typically does not exceed 3 years
Evidence	<ul style="list-style-type: none"> <li>(1) Must have adequate evidence that there may be cause for debarment</li> <li>(2) Must conclude that immediate action is necessary to protect the Federal government’s interest</li> </ul>	Must conclude, based on a higher evidentiary standard (i.e., preponderance of the evidence), that the respondent has engaged in conduct that warrants debarment

Source: Adapted from Federal Law Enforcement Training Center, *National Suspension and Debarment Training Program Student Handbook FY 2014*. Federal Acquisition Regulation and Nonprocurement Common Rule.

Suspensions and debarments are “prospective” (forward-looking) only, meaning that the respondent can continue current awards but cannot obtain new ones for a fixed term. In addition, suspensions and debarments have a government-wide reciprocal effect, meaning that respondents who are suspended or debarred by one Federal department are generally ineligible for awards from other Federal departments.<sup>9</sup> In this way, a Federal department that suspends or debars a respondent is helping to protect not just its own program integrity, but also those of other Federal departments that might fund that same respondent.

## Conviction-based and fact-based debarments

In addition, there are two types of debarments: conviction-based and fact-based. Conviction-based debarments can be initiated based on a criminal conviction or civil judgment. Once the conviction or civil judgment occurs, the conviction-based debarment may occur relatively quickly because the evidentiary threshold has likely already been established by the conviction or judgment. In contrast, fact-based debarments generally take longer than conviction-based debarments because they rely on a development of facts (e.g., search warrants, audit findings, or failures to disclose) to support the debarment rather than a judicial conviction or judgment.

## Causes for suspension and debarment

The Federal Acquisition Regulations and the Nonprocurement Common Rule specify several potential causes for suspension and debarment. These include fraud, theft, forgery, tax evasion, serious violations of a government contract (e.g., willful failure to perform or a history of unsatisfactory performance), or any other cause of a “serious or compelling nature” that impacts the respondent’s integrity.<sup>10</sup> Additionally, regulations note that Federal departments should exclude persons that are not “presently responsible,” but the regulations do not define this term.<sup>11</sup>

Federal departments have discretion on when to pursue suspensions or debarments. That is, the existence of one of the causes for suspension or debarment (e.g., a conviction for theft) does not require Federal departments to suspend or debar the person. Instead, Federal departments are directed to consider (a) the seriousness of the act or any aggravating factors and (b) any mitigating factors or actions the respondent has taken to address potential causes for suspension or debarment. To that end, Federal departments are responsible for establishing procedures for reporting, investigating, and referring potential suspension and debarment cases to their respective Suspension and Debarment Officials.

## Major actors involved in HHS’s suspension and debarment program

Each Federal department’s suspension and debarment program involves different actors responsible for protecting Federal funds against bad actors and poor performers. HHS’s suspension and debarment program involves several key actors: the HHS Operating Divisions (OpDivs) and Staffing Divisions (StaffDivs) that fund and oversee awards; ORIC (under the Assistant Secretary for Financial Resources (ASFR)); and the HHS Suspension and Debarment Official (also under ASFR). These actors are responsible for protecting the integrity of both grant and contract dollars.

### **Awarding agencies (HHS OpDivs and StaffDivs that fund and oversee awards).**

HHS OpDivs and StaffDivs, such as the National Institutes of Health (NIH) and the Health Resources and Services Administration (HRSA), are responsible for monitoring the awards that they fund. Generally, when OpDivs and StaffDivs suspect misconduct and decide to pursue suspension and debarment, they refer the respondent for suspension and/or debarment. (The OpDiv or StaffDiv making the referral is thereafter referred to as a **referring entity**.)

### **Non-awarding entities (i.e., entities that do not fund persons referred for suspension and/or debarment).**

Non-awarding entities may also serve as referring entities. These entities often have oversight responsibilities within HHS and include OIG, ORIC, the Office of Research Integrity, and the Office of General Counsel (OGC). See Exhibit 2 for how these non-awarding entities’ involvement may lead to suspension or debarment referrals.

## Exhibit 2: HHS non-awarding entities involved in suspension and debarment

<b>OIG</b>	OIG initiates investigations or audits of fraud, waste, and abuse that may generate suspension or debarment referrals as a result of hotline complaints; OIG’s audit or evaluation work; or referrals of suspected misconduct from awarding agencies.
<b>ORIC</b>	ORIC, which is a part of ASFR, manages HHS’s suspension and debarment program. (ASFR provides advice and guidance to the Secretary on all aspects of budget, financial management, grants, and acquisition management.) ORIC conducts environmental scanning to identify misconduct that could serve as the basis of a suspension or debarment referral. In this way, ORIC is also a referring entity.
<b>Office of Research Integrity</b>	The Office of Research Integrity—part of the Office of the Assistant Secretary for Health (OASH)—reviews and monitors research misconduct investigations conducted by applicant and awardee institutions and intramural research programs. The Office of Research Integrity may submit suspension and/or debarment referrals to address research misconduct and protect Federal programs and funds.

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**OGC**

OGC provides representation and legal advice on a wide range of issues for HHS. In doing so, OGC may refer a person for suspension and/or debarment.

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Referring entities use their discretion on whether or when to pursue suspensions or debarments versus other administrative remedies. Some referring entities have their own corrective-action escalation processes that involve imposing other administrative actions before pursuing suspension or debarment, depending on the gravity of the offense. Because suspensions and debarments are among the tools in the program integrity toolbox, referring entities may decide to pursue other, less severe corrective actions that enable them to continue working with the person while they correct the behavior through various components of the agreement (e.g., ethics training). For example, both the Administration for Children and Families (ACF) and OASH reported that they pursue suspension and debarment only when all other remedies or corrective actions have been exhausted and those actions have not corrected the misconduct. In addition to or instead of these corrective-action escalation processes, some referring entities may also consult with OGC when deciding whether and when to pursue suspension or debarment.

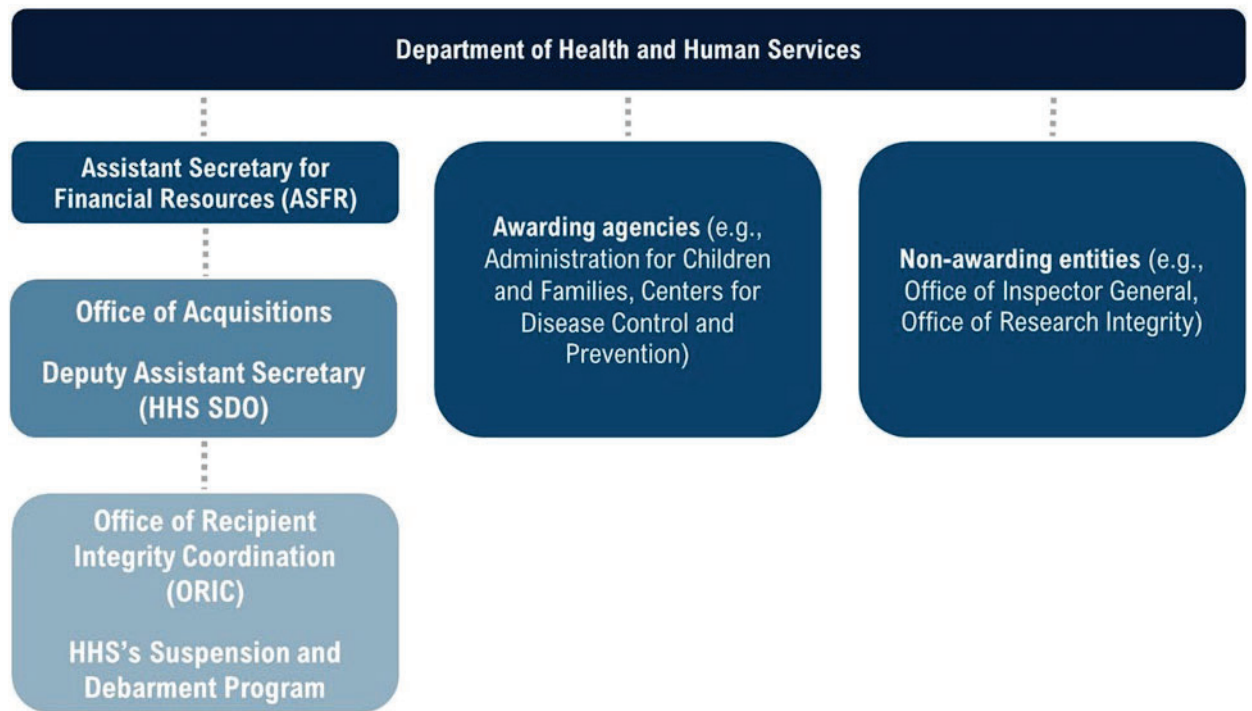
When submitting a referral, the referring entity should include all relevant information in the referral and recommend the appropriate action (e.g., suspension, debarment, other administrative action).

**ORIC.** When ORIC receives the referral, it reviews the included information to determine whether it is accurate and complete. ORIC follows up with the referring entity for clarifications and additional documentation, as needed. Then, ORIC develops an action referral memorandum for the Suspension and Debarment Official (SDO). ORIC handles all formal correspondence with the respondent and serves as the point of contact for entities making referrals for suspension or debarment. ORIC is also responsible for reporting its actions annually to the Interagency Suspension and Debarment Committee. This committee collects information from suspension and debarment programs across the Federal government and reports its findings to Congress annually.

**SDO.** Within HHS, the SDO is not a part of ORIC. Instead, the HHS SDO is the Deputy Assistant Secretary for the Office of Acquisitions within ASFR. As such, the HHS's SDO has responsibilities other than suspension and debarment. The SDO is the deciding official for any suspension or debarment action. Specifically, the SDO must sign any notices of action and final decisions. Once ORIC compiles the action referral memorandum, the SDO decides whether to suspend or debar a respondent and ORIC then implements any such action. The SDO must provide a written decision to either take or decline action against a respondent. See Exhibit 3 for an organization chart of major actors in HHS's suspension and debarment program.



### Exhibit 3: Organization of major actors in HHS’s suspension and debarment program



Source: OIG analysis of HHS suspension and debarment program, July 2021.

## HHS’s suspension and debarment process

When ORIC receives a referral from a referring entity, it will gather evidence and present it to the SDO. The SDO then reviews the evidence and decides what, if any, action to take. If the SDO decides to take action, ORIC will then implement the action. As such, ORIC sends a notice of action to the respondent and enters the action into the General Services Administration’s (GSA’s) System for Award Management, a governmentwide database containing information on all individuals or organizations debarred, suspended, declared ineligible, or excluded from Federal awards. Exhibit 4 provides an overview of how ORIC and the SDO work together during the suspension and debarment process. Appendix A contains more detailed information on suspension and debarment procedures.

## Exhibit 4: Overview of Suspension and Debarment Process Within HHS



Source: OIG analysis of ORIC's May 2014 *Discretionary Suspension and Debarment Program Guidance*.

Although suspensions and debarments follow similar processes, there are differences. Respondents have fewer due-process rights for suspensions than for debarments. Suspensions go into effect immediately, without giving respondents an opportunity to contest them, whereas respondents have the opportunity to contest proposed debarments before they take effect.<sup>12</sup>

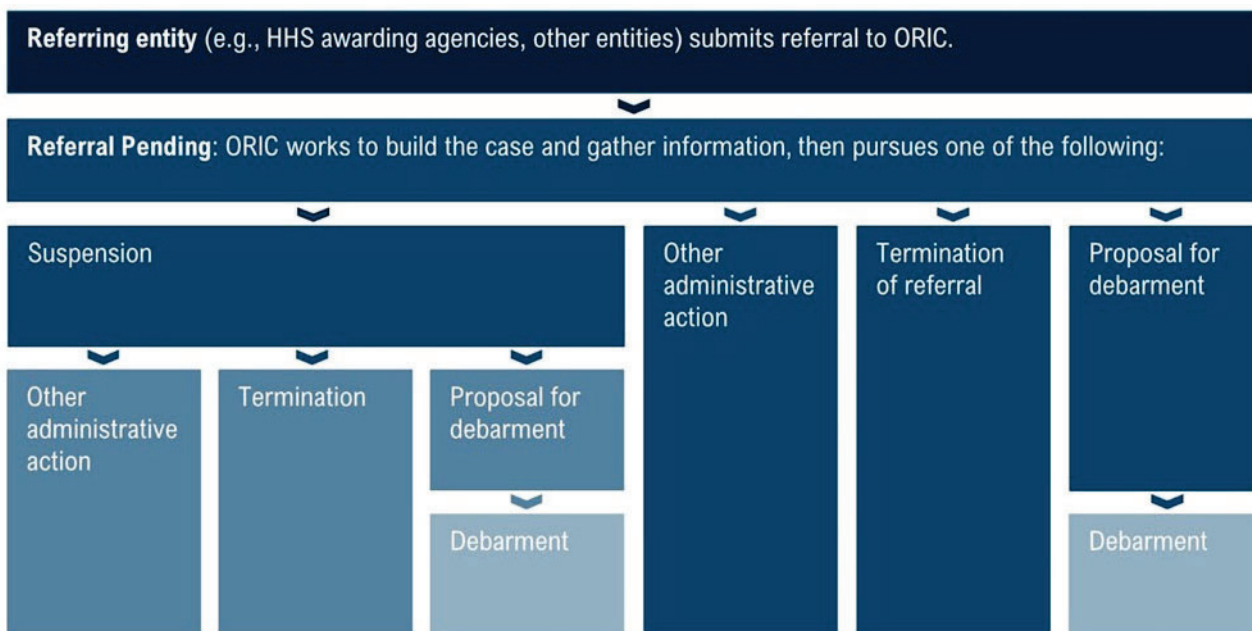
To ensure that respondents' rights are limited only in appropriate cases, a suspension is meant to be used only in cases where the SDO has cause to believe that immediate action is necessary to protect Federal interests. The SDO has broad discretion to determine which cases warrant suspension. For example, the SDO may determine that suspensions are appropriate, as outlined in the regulations, based on the nature of the misconduct, potential business relationships, or involvement with a program of the Federal government (e.g., knowledge that the respondent has recently applied for another Federal award).<sup>13</sup> The referring entity may request a suspension, or the SDO, in consultation with ORIC, may also determine that a suspension is warranted without a specific request from the referring entity.

The debarment process varies depending on the type of award (i.e., grants vs. contracts). Specifically, notices of proposed debarments made under the Federal Acquisition Regulation (i.e., involving contracts) have the same impact on the respondent as a suspension.<sup>14</sup> That is, once the SDO signs the notice of proposed debarment, those respondents become temporarily ineligible to receive additional government funding. Conversely, notices of proposed debarments made under the Nonprocurement Common Rule (i.e., involving grants) have no impact on the respondent's ability to obtain new awards. That is, those respondents do not become temporarily ineligible to receive additional government funding unless there was a preceding suspension or until the SDO's final determination to implement the debarment.

A referral for suspension or debarment may result in a variety of outcomes. Referrals that do not result in suspension or debarment may be terminated by the SDO or result in another administrative action. The SDO may terminate a referral because of a lack of evidence, because of a lack of timeliness in ORIC's processing of the referral,

or because the respondent has remedied the misconduct to the Department’s satisfaction. The SDO may pursue other administrative actions when it is in the best interest of HHS not to suspend or debar the respondent. For example, when a respondent is the only person that can provide a certain good or service in a specific geographic area, an administrative agreement allows HHS to more closely monitor the respondent while beneficiaries can still access the respondent’s goods or services. Additionally, if the respondent presents evidence that raises a genuine dispute over facts relevant to the suspension or debarment, the SDO must conduct additional proceedings to resolve those facts. Exhibit 5 shows the possible outcomes of a referral within HHS.

### Exhibit 5: Suspension and Debarment Referral Outcomes Within HHS



Source: OIG analysis of the Federal Acquisition Regulation and Nonprocurement Common Rule, July 2021.

### Timeliness of suspension and debarment actions

ORIC has developed internal timeliness goals for certain actions to protect the integrity of HHS awards. Specifically, ORIC stated that suspensions should take no longer than 60 days to implement from receipt of the referral. Further, ORIC stated that conviction-based debarments should take no longer than 100 days to implement from receipt of the referral. While regulations do not specify how long suspensions or conviction-based debarments should take to implement, these actions should be as timely as possible so as to prevent bad actors and poor performers from receiving additional Federal funds.

## Components of effective suspension and debarment programs

GAO and the Interagency Suspension and Debarment Committee (ISDC) have identified factors that contribute to the effectiveness of suspension and debarment programs.<sup>15</sup> These bodies note that the numbers of suspensions and debarments are not always indicative of an effective program.<sup>16</sup> Instead, GAO and the ISDC have focused on the following factors in assessing program effectiveness:

- *Dedicated staffing.* Active suspension and debarment programs have a dedicated suspension and debarment program with full-time staff and commitment from the agency's senior officials. Additionally, strong suspension and debarment programs need to have one SDO and a focused program. If a program has an SDO with many other responsibilities, suspension and debarment may become a lower priority. Further, suspension and debarment programs need to have buy-in from the top to show that suspension and debarment is a priority.
- *Case management and tracking.* An effective program has a case management process and uses a referral tracking system. The review process should be open and streamlined to optimize program resources. Further, Federal departments may use a system or database to track where referrals are in the review process and ensure that any necessary followup is completed.<sup>17</sup> Additionally, as a program processes a referral, an effective program's staff should be responsive to referring entities and other investigative/legal stakeholders. Staff could also proactively communicate status updates during the referral review process and facilitate regular meetings among key stakeholders.<sup>18</sup>
- *Guidance and training.* An effective program trains its staff to follow consistent practices and develops detailed written guidance, policies, and procedures to share with referring entities. It also provides formal training to key stakeholders on how to identify and refer respondents for potential suspension or debarment.<sup>19</sup>

## Methodology

We analyzed multiple data sources to describe the outcomes, sources, and timeliness of referrals and to identify factors that may affect the timeliness, efficiency, and effectiveness of HHS's suspension and debarment program during our period of review, FYs 2015 through 2019 (i.e., October 1, 2014, through September 30, 2019).

To describe the outcomes, sources, and timeliness of referrals, we used (1) information from ORIC's system for case management and tracking; (2) referral documentation from ORIC's SharePoint site; and (3) publicly available electronic data from GSA's System for Award Management.

To identify factors that may affect the timeliness, efficiency, and effectiveness of the program, we (1) reviewed ORIC's suspension and debarment data; (2) interviewed ORIC staff; and (3) surveyed all of the 26 HHS OpDivs and StaffDivs that funded

awards (i.e., grants or contracts) during our review period.<sup>20</sup> We used previous work (e.g., GAO and ISDC reports) to help inform interview and survey questions. We reviewed selected case files to determine reasons for delays in implementing suspensions and debarments.

As we proceeded with data collection and analysis, we followed up with ORIC and/or survey respondents to request additional information and documentation, as needed.

## Limitations

In some instances, data from ORIC's system for case management and tracking were missing. In these instances, we attempted to complete or clarify such information using GSA's System for Award Management or additional records from ORIC. For example, in some instances, it was not clear when ORIC received the referral. In those cases, we used the date the referral first appeared in ORIC's system for case management and tracking as the referral date. As a result, our timeliness analysis may underestimate the length of time it took to implement certain actions. Additionally, ORIC's system for case management and tracking crashed in 2016 and subsequently experienced some data loss, which we were unable to quantify. In select cases, our numbers may not coincide with ISDC reports from the same period because ORIC was not able to recover all of the data and files that the ISDC used to create its reports, and therefore was not able to provide us with all of those data and files.

For data that were not missing in the tracking system, we relied on what was captured in ORIC's tracking system and did not independently verify such data.

## Standards

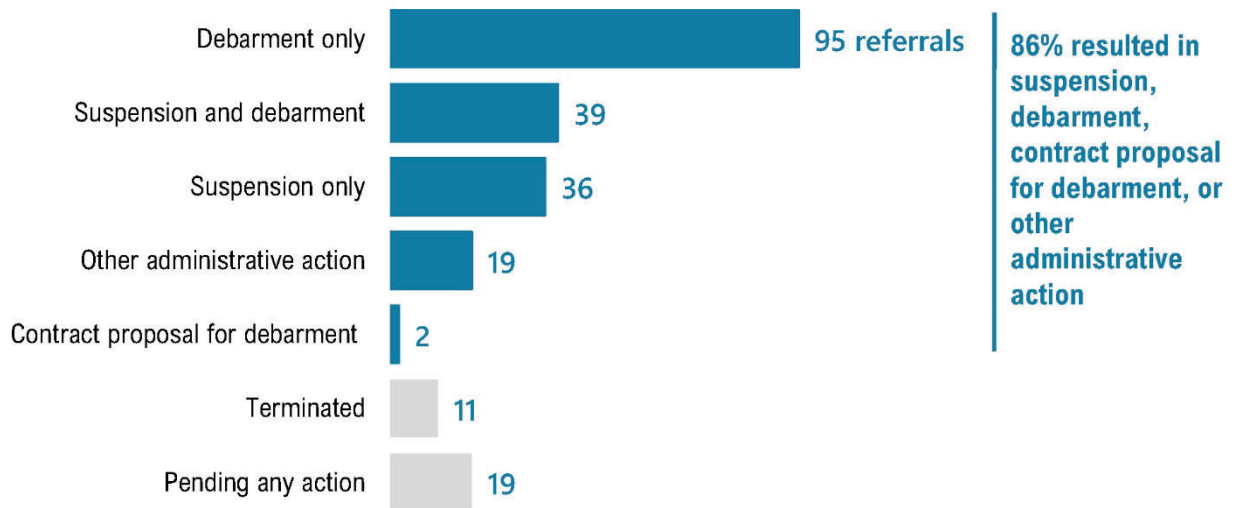
We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

# FINDINGS

## From FY 2015 through 2019, 86 percent of suspension and debarment referrals resulted in actions to protect Federal Programs and funds

Of the 221 referrals that ORIC received during our period of review, 86 percent (191 referrals) resulted in action to protect Federal programs and funds (i.e., suspension, debarment, or other administrative action).<sup>21</sup> The remaining referrals were either terminated or were pending action (i.e., pending suspension, pending debarment, or pending another type of administrative action) as of September 30, 2019. Exhibit 6 shows the types of actions for referrals during our review period. See Appendix B for additional information about the referrals that ORIC received from FY 2015 through FY 2019.

### Exhibit 6: 86 percent of referrals that ORIC received resulted in action to protect Federal programs and funds.



Source: OIG analysis of ORIC files from FY 2015 to FY 2019.

Two referrals initially resulted in a proposal for debarment involving contracts; such a proposal has the same effect as a suspension. However, these two referrals were later terminated—for one referral, because the respondent provided credible information that disputed material facts, and for the other referral, because the respondent died.

A small portion of referrals (11 referrals) were terminated without any preceding suspension or debarment action. These referrals were terminated because the legal case serving as the cause for debarment was dismissed (three referrals), the

respondents provided credible information that disputed material facts (two referrals), the Office of Small and Disadvantaged Business Utilization advised against taking action (two referrals), the SDO determined that grant funds were not harmed by the respondents' actions (one referral), OGC advised that the facts did not meet the necessary evidentiary threshold (one referral), or the respondent died (one referral).

Finally, 19 referrals were pending action as of September 30, 2019. ORIC received these referrals but was still processing them by the end of FY 2019, when our review period ended. Of these pending referrals, 13 had been received in 2019, 2 had been received in 2018, and 4 had been received in 2017.

### **Of the 130 debarments involving grants, nearly one-third had preceding suspensions, but ORIC does not have complete guidance about the circumstances in which immediate actions may be appropriate**

Of the 134 debarments that ORIC implemented during our review period, almost all (130) involved grants and nearly one-third (39) had a preceding suspension. In the cases with a preceding suspension, the SDO determined that immediate action was necessary to protect Federal interests. These suspensions prevented the respondents from obtaining new Federal awards while ORIC processed the debarment. Debarments with a preceding suspension took a median of 811 days for ORIC to implement, with an average of 761 days and a range of 168 to 973 days.

The remaining two-thirds of the debarments involving grants (91 debarments) did not have a preceding suspension. As a result, respondents in these cases remained eligible to receive new Federal funding until the debarment was implemented, unless the awarding agency chose not to award new Federal funds to the respondent for other reasons. For example, awarding agencies may choose not to give new awards to applicants with certain criminal convictions or civil actions.<sup>22</sup> From the time ORIC received the referral to the implementation of the debarment, these 91 debarments took a median of 182 days for ORIC to implement, with an average of 249 days and a range of 20 to 1251 days.<sup>23</sup> Of these 91 debarments, almost all (83 debarments) were conviction-based.<sup>24</sup>

For cases involving contracts, proposed debarments have the same effect as a suspension, once the respondent receives the notice of proposed debarment. During our review period, ORIC implemented four debarments involving contracts. From the time ORIC received the referral to the time it sent the notice of proposed debarment, these referrals took a median of 199 days for ORIC to implement, with an average of 222 days and a range of 12 to 477 days.<sup>25</sup>

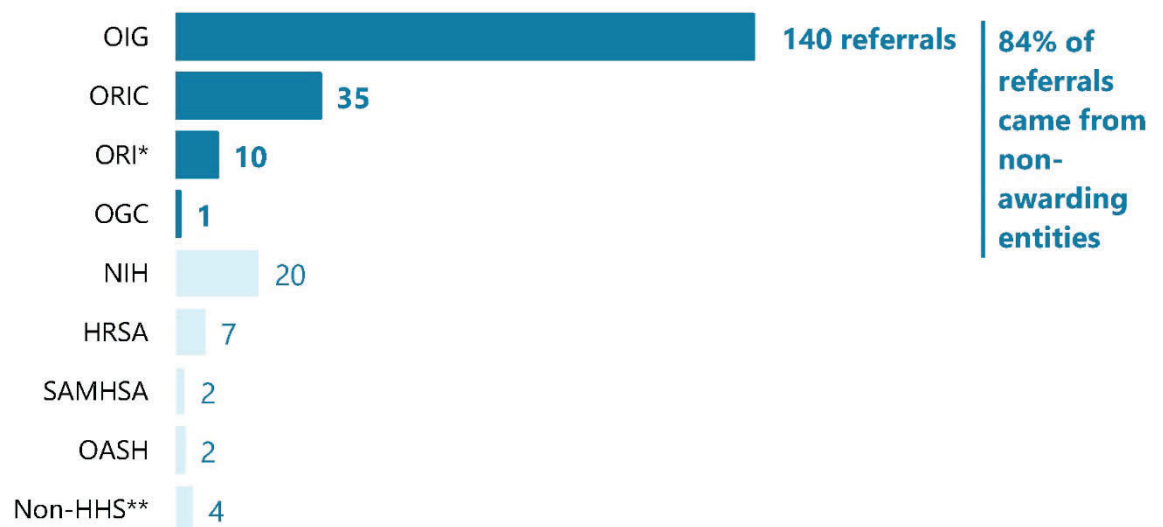
ORIC does not have guidance that includes all of the circumstances outlined in regulations in which the SDO may determine that suspensions are appropriate (e.g., the nature of the misconduct or potential business relationships), and the SDO made different decisions about whether to suspend respondents in circumstances that

appeared similar.<sup>26</sup> ORIC reported that suspensions are most often based on indictments but also stated that each decision to suspend a respondent should be grounded upon the unique facts of a matter. ORIC stated that when the SDO is determining whether to suspend a respondent, the SDO may also work with OGC or request additional information from the referring entity.

## HHS non-awarding entities were the sources of most referrals for suspension and debarment, while many HHS awarding agencies made no referrals

Non-awarding entities at four HHS offices (i.e., OIG, ORIC, the Office of Research Integrity, and OGC) were the sources of 84 percent of all referrals to ORIC from FY 2015 through FY 2019. Only four awarding agencies—NIH, HRSA, OASH, and the Substance Abuse and Mental Health Services Administration (SAMHSA)—also submitted referrals during our review period. No other awarding agency submitted suspension or debarment referrals during our review period, despite ORIC’s hosting annual, but optional, training on suspension and debarment. See Exhibit 7 for the percentages of referrals by source from FY 2015 to FY 2019. See Appendix B for a more detailed breakdown of referrals by source and basis (i.e., conviction-based or fact-based).

**Exhibit 7: 84 percent of referrals in FYs 2015–2019 came from non-awarding entities.**



Source: OIG analysis of FY 2015–2019 ORIC data, 2021.

\* ORI is OASH’s Office of Research Integrity.

\*\* Non-HHS referring entities were the General Services Administration (two referrals), the Department of the Treasury (one referral), and the Department of Homeland Security (one referral). In these cases, the referring entity found that the respondent had received HHS funding and referred the respondent to ORIC for suspension and debarment consideration.



Although awarding agencies in HHS are not required to pursue suspension and debarment, the proportion of referrals from non-awarding entities raises questions about potential missed opportunities among these awarding agencies for additional suspension and debarment referrals. In particular, the fact that so many referrals are coming from non-awarding entities rather than from awarding agencies raises questions about whether the awarding agencies are doing enough to identify bad actors or poor performers. In addition, those awarding agencies that did not submit referrals during our review period were among the HHS awarding agencies with the highest dollar values of funds awarded during this same timeframe. See Exhibit 8 for a comparison of HHS awarding agencies with the highest award funding amounts, as well as the source and number of their referrals from FYs 2015 through 2019. See Appendix C for detailed funding amounts from all HHS awarding agencies.

**Exhibit 8: Top 10 HHS awarding agencies by total HHS award funding and corresponding numbers of referrals by referral source, FYs 2015–2019**

<b>Awarding Agency</b>	<b>Total HHS Awards Funded, FY 2015 Through 2019 (in Billions)</b>	<b>Number of Referrals From Non-Awarding Entities</b>	<b>Number of Referrals from Awarding Agency</b>
Administration for Children and Families (ACF)	\$271.2	95	0
NIH	\$147.6	29	20
Centers for Disease Control and Prevention (CDC)	\$59.0	8	0
HRSA	\$47.8	18	7
SAMHSA	\$22.0	10	2
Indian Health Service (IHS)	\$16.0	19	0
Administration for Community Living (ACL)	\$10.1	1	0
Centers for Medicare and Medicaid Services (CMS)	\$9.2*	1*	0*
Food and Drug Administration (FDA)	\$7.5	4	0
Assistant Secretary for Administration (ASA)	\$6.4	1	0
<b>TOTAL</b>	<b>\$596.8</b>	<b>186</b>	<b>29</b>

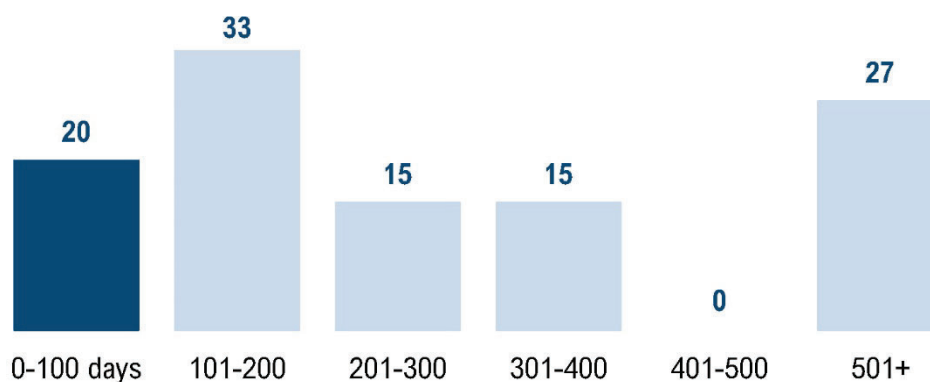
Source: OIG analysis of FY 2015–2019 HHS award data, 2021.

\* This figure does not include grants awarded through entitlement programs (i.e., Medicaid and the Children’s Health Insurance Program). Additionally, referrals are for suspensions and debarments only and do not include Medicare and Medicaid program exclusions, which have similar results (i.e., limiting the ability to conduct business with the Federal government). From FY 2015 through 2019, approximately 15,700 individuals and/or businesses were excluded from conducting business with the Medicare and Medicaid program. HHS OIG, *List of Excluded Individuals/Entities (LEIE) Downloadable Databases “06-2021 Updated LEIE Database,”* Accessed at [https://oig.hhs.gov/exclusions/exclusions\\_list.asp](https://oig.hhs.gov/exclusions/exclusions_list.asp) on July 21, 2021.

## Suspension and debarment actions often missed ORIC’s internal timeliness goals

ORIC’s implementation of suspensions and debarments often did not meet ORIC’s established internal timeliness goals of 100 days for conviction-based debarments and 60 days for suspensions. Most of the debarments implemented during our review period (110 of 134 debarments) were conviction-based (i.e., were based on a criminal conviction or civil judgement). Of these conviction-based debarments, 82 percent (90 of 110 debarments) took longer than ORIC’s goal of 100 days from receiving the referral to implementing the debarment. Conviction-based debarments during our review period took a median of 205 days to implement, with an average of 326 days and a range of 20 to 946 days. See Exhibit 9 for more information about how long conviction-based debarments took to implement during our review period.

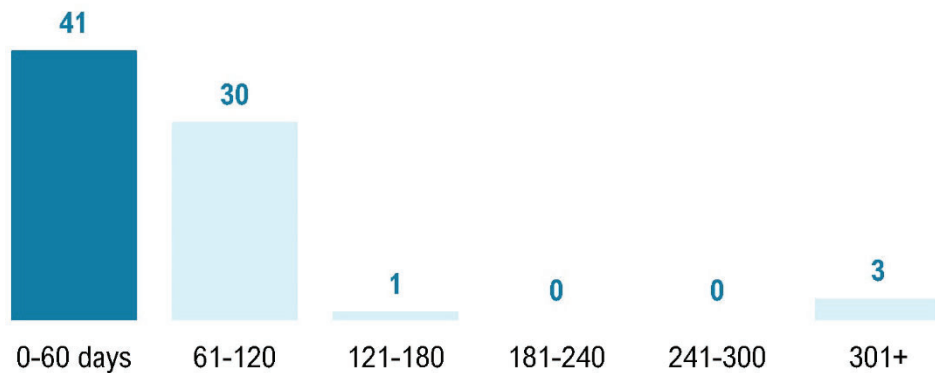
**Exhibit 9: Three-fourths of conviction-based debarments implemented during our review period did not meet ORIC’s 100-day goal.**



Source: OIG analysis of FY 2015–2019 ORIC data, 2021

Nearly half of the 75 suspensions (34) implemented during our review period did not meet ORIC’s internal goal of 60 days from referral received to suspension implemented.<sup>27</sup> These 75 suspensions took a median of 46 days for ORIC to implement, with an average of 82 days and a range of 0 to 702 days. See Exhibit 10 for more information about how long suspensions took to implement during our review period.

**Exhibit 10: Nearly half of suspensions implemented during our review period did not meet ORIC’s 60-day goal.**



Source: OIG analysis of FY 2015–2019 ORIC data, 2021

## **Delays resulted in part from ongoing criminal or appeals proceedings and challenges in obtaining necessary respondent information**

For referrals that took longer to process, delays often stemmed from ongoing criminal or appeals proceedings or difficulty in obtaining information from or about respondents. Some actions were delayed by simultaneous criminal or appeals proceedings. For example:

- *Seizure of Evidence by Criminal Investigations.* Conviction-based suspensions and debarments often happen at the same time as criminal investigations. In one instance, a respondent’s lawyer stated that the respondent could not provide evidence to dispute the suspension because investigators had seized such documents. The lawyer therefore requested an extension, which delayed the subsequent suspension. This case resulted in a suspension during our review period, but as of September 30, 2019, it had been pending debarment for 1141 days.<sup>28</sup>
- *Research Misconduct Appeals Process.* When the Office of Research Integrity—the HHS office that handles cases of research misconduct—refers a case to ORIC for suspension or debarment action, the respondent may pursue an appeal process to dispute the Office of Research Integrity’s findings. Because the research misconduct is the basis of the suspension or debarment referral, if an appeal is filed, ORIC cannot move forward until the HHS Departmental Appeals Board rules on the basis of the Office of Research Integrity’s findings. For example, the longest fact-based debarment took 1251 days—over 3 years—to implement because the respondent requested a hearing with the Departmental Appeals Board. The board took nearly 2 years to provide ORIC with a summary judgment.<sup>29</sup>

- *Delayed Criminal Proceedings.* Although indictments often serve as the basis for suspensions, the SDO must wait until the respondent is convicted to proceed with a conviction-based debarment. However, the criminal proceedings against a respondent can take a long time. In one instance, a respondent was convicted nearly 19 months after being indicted. This case took 809 days from receipt of referral received to implementation of the debarment.<sup>30</sup>

Additionally, ORIC reported that often it must go back and forth with a respondent multiple times to obtain information necessary to implement a suspension or debarment. In these cases, respondents may continue to provide additional information to dispute the cases against them. We found several instances of actions that resulted in these types of delay, including:

- *Show-Cause Letters.* In some cases in which ORIC is considering suspension or debarment action, it may choose to first send a show-cause letter to the respondent. A show-cause letter gives the respondent an opportunity to present evidence as to why HHS should not begin formal suspension or debarment proceedings. One case began with a referral for a fact-based debarment. On receipt of the referral, ORIC first decided to send the respondent a show-cause letter to gather more information. In response to the show-cause letter, the respondent continued to provide additional information, which significantly lengthened the time it took ORIC to ultimately implement the suspension. This case took 702 days from receipt of referral to implementation of the suspension.
- *Difficulty Finding Respondent's Address.* ORIC policies require ORIC to send every notice of action to the respondent via certified mail with a return-receipt request. In at least one instance, the referral did not contain the respondent's current address and the notice of action to the respondent was returned to ORIC multiple times as not being deliverable. As a result, ORIC used additional resources to locate the appropriate mailing address for the respondent, which delayed action. This case took 133 days from receipt of referral to implementation of the debarment.

## Opportunities exist to improve the timeliness, efficiency, and effectiveness of HHS's suspension and debarment program

ORIC's timeliness, efficiency, and effectiveness in processing referrals have also been affected by several internal factors: staffing vacancies and turnover; limitations with the system for case management and tracking; and incomplete guidance on what should be included in a high-quality fact-based referral.

## Vacancies and turnover—at both the staff and senior leadership levels of the suspension and debarment program—create challenges

From FY 2015 through 2019, ORIC faced a high rate of staff vacancies and turnover. Staff vacancies reduce the number of referrals that ORIC can process and increase the time it takes to process each referral. In addition, high turnover reduces the amount of time that ORIC can spend on processing referrals because staff must dedicate limited resources to onboarding and training new personnel.

ORIC faced a high rate of staff vacancies during our review period, limiting its ability to process referrals. Specifically, as of November 2020, only one current employee had been with ORIC longer than 1.5 years. When ORIC is fully staffed, it consists of four employees. However, ORIC reported that it was frequently not fully staffed during our review period, and at certain points only had one or two employees. ORIC worked to temporarily fill vacancies by bringing on detailees throughout the 5-year period of our review (i.e., it brought on two detailees for 4 and 6 months, respectively).

Additionally, the SDO changed often during our review period. Specifically, seven different people served as HHS's SDO from FY 2015 through FY 2019, with an average tenure of less than 9 months. Further, HHS's SDO as of November 2020, who began serving in this role in August 2019, reported that because of his other job responsibilities, he spent less than 10 percent of his time on suspension and debarment activities. The SDO serves as the Senior Procurement Executive for HHS, so his other job responsibilities include serving as the contracting authority for all HHS OpDivs; handling other Executive Branch and Office of Management and Budget interests in acquisitions; and overseeing policy and data systems pertaining to contracting.

## Limitations in ORIC's system for case management and tracking add administrative burden and hinder effective communication

ORIC's current system for case management and tracking is a semistructured Excel spreadsheet that does not consistently track all aspects of referral data. ORIC lacks policies and procedures as to which referral data are required to be entered into its system, which may contribute to the variation as to which aspects of referral data are entered. Additionally, shortcomings in ORIC's system for case management and tracking limit the effectiveness and efficiency of communication within ORIC and between ORIC and its referring entities.

**Inconsistent data entry.** ORIC's current tracking system does not require that all referral data be captured or uniformly tracked across referrals. That is, certain characteristics of referrals are clearly defined and consistently entered (e.g., the referring entity and the awarding agency), whereas other aspects (e.g., dates of action, communication with the respondent) are not clearly defined and/or are entered either

inconsistently or not at all. Additionally, only one analyst can work in the tracking system at a time. ORIC stated that this makes version control a significant challenge, as multiple analysts may try to input their own data in various versions of the Excel worksheet that must later be merged manually. Further, ORIC is required to report to the Interagency Suspension and Debarment Committee (ISDC) the number of actions it takes; the ISDC then reports those actions annually to Congress. Therefore, ORIC needs to have a system that has well defined fields, contains data that is entered consistently among staff, and is accurate, so that it can accurately track the volume, progress, and status of its caseloads and ensure that the numbers it reports to the ISDC are correct.

**Lack of policies and procedures.** ORIC does not have current policies or procedures detailing how staff should enter and track important case information and milestones. Although ORIC reported to us that its standard operating procedures provide such instructions, these instructions reference an old tracking system that has not been used since 2016. ORIC's standard operating procedures show how to record certain kinds of data—for example, multiple respondents from referrals that stem from the same instance of misconduct—into the *previous* tracking system, but these steps are not applicable for ORIC's current tracking system. Because there are no up-to-date procedures indicating how multiple respondents associated with the same case should be tracked, there is variation across staff as to how they enter this information into the tracking system. That is, it is not immediately clear how many respondents are associated with the same case. This can make it difficult for ORIC to determine the number of respondents or the number of actions associated with that particular entry, as actions are tracked at the respondent level outside of the tracking system (e.g., in ORIC's reports to the ISDC).

**Communication challenges.** The current system for case management and tracking poses communication challenges that limit efficiency and effectiveness. For example, only ORIC has access to the system, so it must communicate with referring entities outside of the system to gather information necessary to process the referral and then must manually input relevant information from referring entities into the system. In addition, according to ORIC, it would improve program efficiency and effectiveness if ORIC had a system with a central repository that automatically captured complete and consistent information and tracked correspondence with referring entities. Although ORIC periodically sends out versions of its tracking system to update stakeholders on referral progress, stakeholders cannot update the system itself by adding requested documentation. As a result, the current system for case management and tracking does not allow for centralized communication with referring entities.

Because ORIC lacks a centralized information management system to automatically communicate with referring entities, it must find other ways—often more burdensome ones—to communicate with referring entities and obtain necessary referral information. For instance, ORIC reported that when it has to follow up with a

referring entity, it must internally coordinate any referral followup to ensure that analysts are informed of any such updates.

Most referring entities that pursued suspension and debarment during our review period reported being satisfied with ORIC's communication and assistance after sending a referral. However, most respondents reported needing to follow up with ORIC multiple times, most often to (1) request information about the timeline of ORIC's action and (2) provide additional information at ORIC's request. Although ORIC's following up with referring entities is an important and necessary part of building a strong case, it can lengthen the amount of time it takes to process a referral. In part because of its limited system for case management and tracking, ORIC may have limited capacity to address the competing needs of meeting its internal timeliness goals while also communicating vital information to—and receiving vital information from—referring entities.

### **Guidance is needed regarding the use and documentation of corrective actions for fact-based referrals**

Although fact-based referrals generally take longer to process because they rely on a development of facts, ORIC told us that these referrals can take longer for additional reasons. Specifically, suspension and debarment regulations do not include information on which documents should be included in fact-based referrals. In addition, ORIC said that—for referring entities that have a process for escalating corrective actions—a high-quality fact-based referral should include documentation that the referring entity followed that process. This documentation demonstrates that the referring entity tried to correct the misconduct before sending the referral and helps establish a pattern of behavior that demonstrates that the person is not acting in a "presently responsible" manner. However, awarding entities do not all follow the same corrective-action escalation processes.

ORIC reported that not all referring entities include documentation in their referrals to show that they followed their own corrective-action escalation processes. As a result, ORIC was unable to suspend or debar several respondents.

When we reviewed ORIC's guidance materials for developing a referral for suspension and debarment, we did not find language that instructed referring entities to document—when they submit a referral—that they had followed their respective corrective-action escalation process. While ORIC's guidance materials do include a list of potential documents for referring entities to consider including in the referral, the guidance does not distinguish between what should be included for a conviction-based referral versus a fact-based referral.

Materials from an optional training state that referrals for fact-based debarments should show documentation and analysis of progressive corrective action(s) as appropriate. These training materials do not provide information on when these supporting documents are appropriate.

# CONCLUSION AND RECOMMENDATIONS

HHS's suspension and debarment program works to protect Federal programs and funds, but HHS has opportunities to improve the timeliness, efficiency, and effectiveness of the program. For example, most referrals from FYs 2015 through 2019 resulted in suspension, debarment, or other administrative action to safeguard Federal funds. However, most of the referrals came from non-awarding entities, such as OIG. Many HHS awarding agencies did not submit any referrals during our 5-year review period, even though ORIC hosted annual training on suspension and debarment. This may indicate that these awarding agencies missed opportunities to use suspension and debarment as program integrity tools.

Further, if ORIC does not process referrals in a timely manner, bad actors may remain eligible for government funding until the SDO decides to suspend or debar a respondent. During our review period, suspension and debarment actions were often not timely. Factors that contributed to delays were ongoing criminal or appeals proceedings and challenges in obtaining necessary respondent information frequently contributed to delays. Internal factors that also affected the timeliness, efficiency, and effectiveness of this program were (1) vacancies and turnover at both the staff and senior leadership levels; (2) a limited system for case management and tracking; and (3) incomplete guidance regarding the use and documentation of corrective actions for certain referrals (i.e., for fact-based referrals as opposed to conviction-based referrals).

As the home for HHS's suspension and debarment program and the new Quality Service Management Office for grants across the Federal government, ASFR is uniquely positioned to address these vulnerabilities to help protect the integrity of Federal programs and funds.

We offer the following recommendations to improve the timeliness, efficiency, and effectiveness of HHS's suspension and debarment program.

We recommend that ASFR:

## **Take steps to ensure that HHS's suspension and debarment program has more consistent senior leadership and sufficient staffing**

As our findings note, seven different people served as HHS's SDO from FY 2015 through FY 2019, with an average tenure of less than 9 months. ASFR should take steps to promote more stable leadership of this critical function and to ensure that the SDO is able to devote sufficient attention to—among the SDO's other responsibilities—suspension and debarment activities. ORIC also experienced



frequent turnover and staff vacancies. ASFR should take steps to recruit and maintain sufficient staff in ORIC to effectively manage the referrals that ORIC receives and for ORIC to implement suspensions and conviction-based debarments within its established timeliness goals.

## **Improve the case management and tracking of referrals**

ASFR should establish policies and procedures for uniform data entry into structured fields. These procedures should include how to enter data into the tracking system and how often analysts should update the progress of cases.

ASFR should also assess the costs and benefits of adopting a new system for case management and tracking to reduce the likelihood of human error, decrease the amount of time that analysts spend entering data, and improve the quality of tracked data. A new system for case management and tracking that is more centralized and that contains structured, well-defined fields would help ensure that data are complete and would allow ORIC to better track referrals and their progress; communicate the status of referrals to referring entities; and ensure efficiency and accuracy when conveying performance metrics to the ISDC for annual reports to Congress.

## **Develop and disseminate guidance regarding how to prepare and submit complete referrals**

Additionally, ASFR should work with referring entities to develop more detailed guidance on the necessary components of a high-quality fact-based referral. Specifically, ASFR should provide more detailed guidance on the circumstances in which documentation of following a corrective-action escalation process must be included in the referral, and under what circumstances (if any) referring entities should deviate from their corrective-action escalation processes to address egregious misconduct. For example, ASFR could distinguish in its guidance what documents to include for a conviction-based referral versus a fact-based referral. In addition, for fact-based referrals, the guidance could detail what documentation is helpful in demonstrating that the awarding entity has followed its corrective-action escalation process, how it has done so, and if it has not done so, why. The guidance could also provide more information on what types of information from referring entities would help inform the SDO's decisions about whether immediate action via suspension is warranted in a given case (e.g., nature of the misconduct, potential business relationships).

## **Conduct outreach and provide additional training about the suspension and debarment program to HHS awarding agencies that make few or no referrals**

To ensure that HHS awarding agencies are aware of and know the circumstances in which suspension and debarment may be best suited to address misconduct, ASFR should develop additional training for awarding agencies that make few or no referrals. In doing so, ASFR should consider soliciting awarding agencies' input in developing this training to ensure that it covers how suspension and debarment fits into the agencies' specific oversight processes. Finally, ASFR could require that HHS grant and contract staff take this training on a regular basis (e.g., annually).

# AGENCY COMMENTS AND OIG RESPONSE

ASFR concurred with all four of our recommendations.

ASFR concurred with our recommendation to take steps to ensure that HHS's suspension and debarment program has more consistent senior leadership and sufficient staffing. ASFR noted that it will initiate a review to address staffing levels in HHS's suspension and debarment program.

ASFR concurred with our recommendation to improve the case management and tracking of referrals. ASFR stated that it has secured funding for a case management system and that the estimated deployment date of that system is March 29, 2022.

ASFR concurred with our recommendation to develop and disseminate guidance regarding how to prepare and submit complete referrals. ASFR stated that it has reviewed its suspension and debarment guidance materials and has consolidated them into a single document with an updated template regarding how to prepare and submit referrals. ASFR indicated that this guidance document is expected to be released in late January 2022.

Lastly, ASFR concurred with our recommendation to conduct outreach and provide additional training about the suspension and debarment program to HHS awarding agencies that make few or no referrals. ASFR stated that it conducts outreach to HHS awarding agencies through various channels, including the Executive Committee on Grants Administration Policy and Head of Contracting Activity communities. ASFR announces and registers suspension and debarment training through the Federal Acquisition Institute's Cornerstone on Demand training system, which is used across awarding agencies. Additionally, ASFR will continue to consider strategies to encourage referrals from awarding agencies that make few or no referrals.

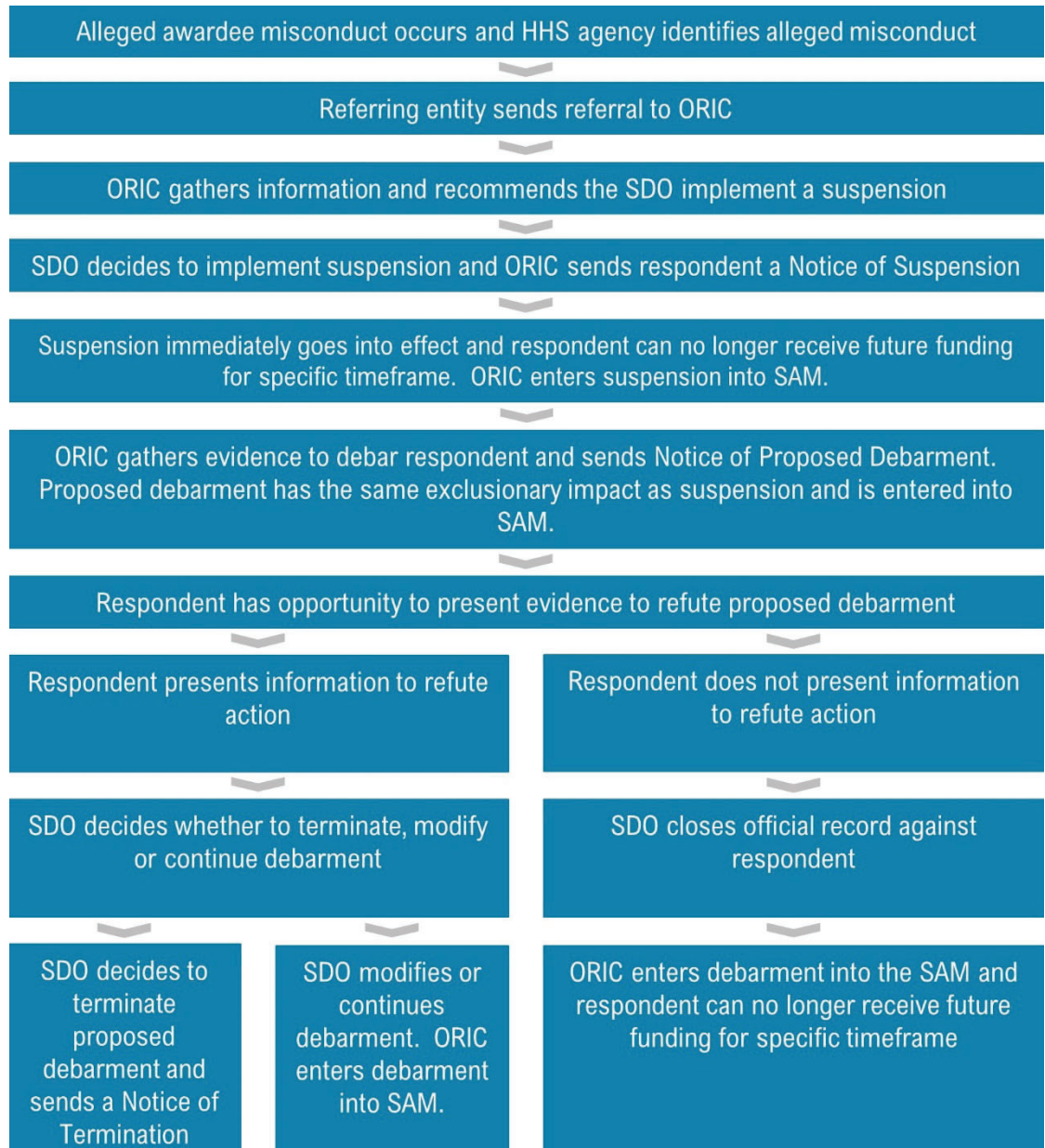
We appreciate ASFR's commitment to address these important issues. OIG encourages ASFR to continue strengthening HHS's suspension and debarment program and protect the integrity of Federal funds. We encourage ASFR to consider—as part of its efforts to conduct outreach and provide additional training to awarding agencies that make few or no referrals—soliciting awarding agencies' input in developing this training and to consider requiring that HHS grant and contract staff take suspension and debarment training on a regular basis (e.g., annually). Doing so would help ensure that appropriate HHS staff are aware of suspension and debarment as program integrity tools.

For the full text of ASFR's response, see Appendix D.

# APPENDICES

## Appendix A: Detailed procedures for suspensions and debarments

### Appendix A-1: Suspensions and debarments under the Federal Acquisition Regulation



Source: OIG analysis of Federal Acquisition Regulation, 2021. This flow chart shows a respondent that is both suspended and debarred, which is not always the outcome of a referral. A respondent may be suspended or debarred only, or the referral may be terminated earlier in the process.

## Appendix A-2: Suspensions and debarments under the Nonprocurement Common Rule



Source: OIG analysis of Nonprocurement Common Rule, 2021. This flow chart shows a respondent that is both suspended and debarred, which is not always the outcome of a referral. A respondent may be suspended or debarred only, or the referral may be terminated earlier in the process.

## Appendix B: Additional information on referrals received during our review period

Exhibit B-1: Number of referrals for suspension and debarment action submitted to ORIC, FYs 2015–2019, by referring entity

Referring entity	Number of referrals					Total number of referrals	Percentage of total referrals
	2015	2016	2017	2018	2019		
OIG	57	23	14	27	19	140	64%
ORIC	0	30	3	2	0	35	16%
NIH	14	5	1	0	0	20	9%
OASH	4	2	3	3	0	12	5%
HRSA	0	6	0	0	1	7	3%
Non-HHS	1	0	3	0	0	4*	2%
SAMHSA	0	2	0	0	0	2	<1%
OGC	0	0	1	0	0	1	<1%
<b>Total</b>	<b>76</b>	<b>68</b>	<b>25</b>	<b>32</b>	<b>20</b>	<b>221</b>	<b>100%</b>

Source: OIG analysis of FY 2015–2019 ORIC data, 2021.

\*Two of these referrals came from the General Services Administration, one came from the Department of Treasury, and another came from the Department of Homeland Security.

Exhibit B-2: Number of conviction-based and fact-based referrals for suspension and debarment action submitted to ORIC, FYs 2015–2019, by referring entity

Referring entity	Number of conviction-based referrals	Number of fact-based referrals*	Total referrals
OIG	116	24	140
ORIC	32	3	35
NIH	1	19	20
OASH	0	12	12
HRSA	3	4	7
Non-HHS	1	3	4
SAMHSA	0	2	2
OGC	1	0	1
<b>Total</b>	<b>154</b>	<b>68</b>	<b>221</b>

Source: OIG analysis of FY 2015–2019 ORIC data, 2021.

\*The referrals sent by OASH include those from the Office of Research Integrity that were based on findings of research misconduct. In this table, referrals based on research misconduct are included in the column for fact-based referrals.

## Appendix C: Annual funding amounts (in billions) for grants and contracts, by awarding agency

Awarding Agency	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	Total Funding FYs 2015-2019
ACF	\$52.6	\$51.4	\$56.7	\$52.2	\$58.3	\$271.2
NIH	\$28.8	\$28.3	\$27.3	\$29.7	\$33.4	\$147.6
CDC <sup>1</sup>	\$11.4	\$12.9	\$12.0	\$11.4	\$11.4	\$59.0
HRSA	\$9.0	\$9.2	\$9.4	\$9.9	\$10.2	\$47.8
SAMHSA	\$3.5	\$3.7	\$3.9	\$5.4	\$5.5	\$22.0
IHS <sup>2</sup>	\$0.7	\$3.3	\$3.5	\$4.0	\$4.5	\$16.0
ACL <sup>3</sup>	\$2.0	\$1.9	\$1.9	\$2.0	\$2.2	\$10.1
CMS <sup>4</sup>	\$2.3	\$2.5	\$1.2	\$1.2	\$1.9	\$9.2
FDA <sup>5</sup>	\$1.3	\$1.2	\$1.6	\$1.6	\$1.7	\$7.5
ASA <sup>6</sup>	\$2.0	\$2.0	\$0.4	\$0.8	\$1.3	\$6.4
ASPR <sup>7</sup>	\$0.8	\$1.2	\$0.2	\$0.6	\$1.7	\$4.5
OASH	\$0.4	\$0.4	\$0.4	\$0.4	\$0.4	\$2.0
AHRQ <sup>8</sup>	\$0.4	\$0.3	\$0.3	\$0.3	\$0.3	\$1.6
OIG	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1
ASPE <sup>9</sup>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
ONC <sup>10</sup>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
HHS/OS <sup>11</sup>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>TOTAL<sup>12</sup></b>	<b>\$115.2</b>	<b>\$118.3</b>	<b>\$118.8</b>	<b>\$119.7</b>	<b>\$133.0</b>	<b>\$604.9</b>

Source: OIG analysis of FY 2015–2019 data on contracts and Federal assistance, 2021.

<sup>1</sup> Centers for Disease Control and Prevention

<sup>2</sup> Indian Health Service

<sup>3</sup> Administration for Community Living

<sup>4</sup> Centers for Medicare and Medicaid Services. This figure does not include grants awarded through entitlement programs (i.e., Medicaid and the Children’s Health Insurance Program).

<sup>5</sup> Food and Drug Administration

<sup>6</sup> Assistant Secretary for Administration

<sup>7</sup> Assistant Secretary for Preparedness and Response

<sup>8</sup> Agency for Healthcare Research and Quality

<sup>9</sup> Assistant Secretary for Planning and Evaluation

<sup>10</sup> Office of the National Coordinator for Health Information Technology

<sup>11</sup> Department of Health and Human Services / Office of the Secretary

<sup>12</sup> Values in this row do not sum to totals because of rounding.


# Appendix D: Agency Comments



Department of Health and Human Services

Office of the Secretary  
Washington, DC 20201

**To:** Suzanne Murrin  
Deputy Inspector General

**From:** Norris Cochran   
Acting Assistant Secretary for Financial Resources  
Department of Health and Human Services

**Subject:** HHS Comments on OIG Draft Report “HHS’s Suspension and Debarment Program Helped Safeguard Federal Funding, But Opportunities for Improvement Exist”, OEI-04-19-00570

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the **Office of Inspector General’s** (OIG) draft report “HHS’s Suspension and Debarment Program Helped Safeguard Federal Funding, But Opportunities for Improvement Exist”, OEI-04-19-00570.

HHS is committed to effectively administering the HHS Discretionary Suspension and Debarment program to ensure protection of **Federal funds and HHS’s** programs against fraud, waste, and abuse. The Office of the Assistant Secretary for Financial Resources (ASFR) concurs with the recommendations provided by the HHS OIG and will work to equip and strengthen the suspension and debarment program with the appropriate resources.

### **OIG Recommendation 1:**

We recommend that ASFR take steps to ensure that HHS’s suspension and debarment program has more consistent senior leadership and sufficient staffing.

### **HHS Response:**

HHS concurs with this recommendation. ASFR will initiate a review to address staffing levels in HHS’s suspension and debarment program.

### **OIG Recommendation 2:**

We recommend that ASFR improve the case management and tracking of referrals.

### **HHS Response:**

HHS concurs with this recommendation. Funding for a case management system has been secured, and the estimated tool deployment date is March 29, 2022.



**OIG Recommendation 3:**

We recommend that ASFR develop and disseminate guidance regarding how to prepare and submit complete referrals.

**HHS Response:**

HHS concurs with this recommendation. After review of the most recent HHS Discretionary Suspension and Debarment Program Guidance and Desk Reference materials, ASFR has consolidated the two documents and provided an updated template regarding how to prepare and submit referrals. The guidance document is expected to be released in late January 2022.

**OIG Recommendation 4:**

We recommend that ASFR conduct outreach and provide additional training about the suspension and debarment program to HHS awarding agencies that make few or no referrals.

**HHS Response:**

HHS concurs with this recommendation. ASFR conducts outreach to the HHS awarding agencies through various channels, including the Executive Committee on Grants Administration Policy (ECGAP) and Heads of the Contracting Activity (HCAs) across HHS. ASFR announces and registers Suspension and Debarment training through the Federal Acquisition Institutes Cornerstone on Demand training system, which is used across awarding agencies. Additionally, ASFR will continue to consider strategies to encourage referrals from awarding agencies that make few or no referrals.

# ACKNOWLEDGMENTS AND CONTACT

## Acknowledgments

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To obtain additional information concerning this report, contact the Office of Public Affairs at [Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov). OIG reports and other information can be found on the OIG website at [oig.hhs.gov](http://oig.hhs.gov).

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# ABOUT THE OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

**The Office of Audit Services (OAS)** provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

**The Office of Evaluation and Inspections (OEI)** conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

**The Office of Investigations (OI)** conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

**The Office of Counsel to the Inspector General (OCIG)** provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

# ENDNOTES

<sup>1</sup> US Department of Health and Human Services Grants. Accessed at <https://www.hhs.gov/grants> on April 23, 2021.

<sup>2</sup> In FY 2019 HHS awarded approximately \$531 billion in grants and \$39 billion in contracts according to HHS's Tracking Accountability in Government Grants System (TAGGS), Grants by OPDIV FY2019 report, and [USASpending.gov](https://www.usaspending.gov), Object Class, Contractual Spending and Supplies, FY2019, respectively.

<sup>3</sup> Other covered transactions include loans or loan guarantees, subawards, subcontracts, insurance, and other assistance programs.

<sup>4</sup> The Federal Acquisition Regulation and Nonprocurement Common Rule provide parallel suspension and debarment processes for contracts and nonprocurement transactions (i.e., grants or other assistance), respectively. The Federal Acquisition Regulation and the Nonprocurement Common Rule note that contractors and nonprocurement transaction persons are not presently responsible if they demonstrate a lack of honesty, integrity, and business performance. 48 CFR §§ 9.406-2 and 9.407-2. OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement), 2 CFR § 180.800. The threshold for what is determined to be not presently responsible for all persons (including contractors) is left to the discretion of individual suspension and debarment programs.

<sup>5</sup> Although suspension and debarment actions are often referred to as "exclusions," they are separate and distinct program integrity tools from health care exclusions enacted under Sections 1128 and 1156 of the Social Security Act.

<sup>6</sup> 2 CFR § 180.985 defines "person" as any individual, corporation, partnership, association, unit of government, or legal entity, however organized.

<sup>7</sup> Other administrative actions include administrative agreements and voluntary exclusions. Administrative agreements generally allow a person to remain eligible for new awards but enable HHS to more closely monitor the person through predetermined stipulations. Voluntary exclusions occur when a person agrees to be excluded (i.e., ineligible for future awards) in lieu of suspension and/or debarment. Collectively, administrative actions aim to fix and prevent wrongdoing and recover award money inappropriately spent. In contrast, civil or criminal actions may be pursued, in addition to or instead of administrative actions, in more egregious cases of wrongdoing to recover funds or punish those persons.

<sup>8</sup> 48 CFR § 2.101 and 2 CFR § 180.900 define "adequate evidence" as "information sufficient to support the reasonable belief that a particular act or omission has occurred." 48 CFR § 2.101 and 2 CFR § 180.990 define "preponderance of the evidence" as "proof by information that, compared that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

<sup>9</sup> If a person is suspended or debarred, the person is not entirely prohibited from receiving new awards. If a Department determines that the benefits of funding the person outweigh the risks, the Department can justify awarding new funds to the person despite the suspension or debarment and provide an exception or waiver to the person (Federal Acquisition Regulations 9.405(a) and 2 CFR § 180.135).

<sup>10</sup> 48 CFR § 9.406-2 and 2 CFR § 180.800.

<sup>11</sup> 31 CFR § 19.110 (b).

<sup>12</sup> Although proposed debarments under the Federal Acquisition Regulations also limit a respondent's due process rights because they are effective without giving the respondent an opportunity to contest them, proposed debarments involving contracts have a higher evidentiary standard (preponderance of the evidence) than suspensions.

<sup>13</sup> 2 CFR § 180.705(c).

<sup>14</sup> In some cases, the SDO may still elect to impose a suspension on a respondent while processing the proposal for debarment. In these cases, the SDO may identify that immediate action is necessary to protect Federal interests and act to

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suspend the respondent but may not be able to meet the higher evidentiary standard required for the proposal for debarment until or unless it gathers more information.

<sup>15</sup> ISDC brings together suspension and debarment program staff across the Federal government to share best practices and increase transparency and consistency through training, engagement, and outreach. Interagency Suspension and Debarment Committee. FY 2018 873 Report. October 2019.

<sup>16</sup> The ISDC, in particular, notes that the number of suspensions and debarments fluctuate from year to year because they are considered and used as necessary to protect the Federal government's business interests. ISDC. FY 2018 873 Report. October 2019.

<sup>17</sup> GAO. *Some Agency Programs Need Greater Attention, and Governmentwide Oversight Could Be Improved*, GAO-11-739, August 2011. GAO noted that Departments with active suspension and debarment programs included components of case management and tracking of referrals. For example, the Department of Homeland Security had detailed policies and procedures for tracking cases in its database. Immigration and Customs Enforcement used a case management system that allowed for tracking and followup on all referrals for consideration of suspension and debarment.

<sup>18</sup> GAO. *Agencies Have Taken Steps to Improve Suspension and Debarment Programs*, GAO-14-513, May 2014. GAO noted that several agencies have scheduled monthly standing meetings for coordination with relevant stakeholders.

<sup>19</sup> Ibid. GAO noted that several agencies increased the number of suspension and debarment actions as a result of providing additional resources for training.

<sup>20</sup> We collected data on both grants and contracts from each awarding OpDiv and StaffDiv. In some cases, this resulted in one unified survey response for one or more OpDivs or StaffDivs because the respondent reported being responsible for overseeing grants and contracts at multiple OpDivs or StaffDivs. In other cases, this resulted in multiple responses for the same OpDiv or StaffDiv because separate offices are involved in overseeing grants and contracts for those OpDivs and StaffDivs. Several smaller OpDivs and StaffDivs that awarded contracts opted to have the Assistant Secretary for Administration's Program Support Center complete the survey on their behalf because the Program Support Center handles their contracts. In addition, we separately surveyed components within OIG that are involved in submitting suspension and debarment referrals. OIG components we surveyed were the Office of Investigation, Office of Audit Services, and the Office of Counsel to the Inspector General.

<sup>21</sup> Other administrative actions included administrative agreements, show-cause letters, and voluntary exclusions.

<sup>22</sup> Although awarding agencies are required to check whether an applicant has a history of any criminal or civil proceedings, the presence of such action alone does not automatically preclude the applicant from receiving new awards. Specifically, the Federal Awardee Performance and Integrity System (FAPIS) is a Federal database that is intended to serve as a governmentwide source of information about the prior performance of Federal contractors, grantees, and cooperative agreement holders. For any awardee receiving over \$500,000 in grants or contracts, FAPIS must include information on any criminal or civil proceeding, or award termination in the past 5 years. Federal agencies are required to check FAPIS prior to issuing an award, and they can use the information in deciding whether to fund new awards to applicants. Further, the HHS Grants Policy Administrative Manual states that for new or renewal awards, the applicant must indicate in its application whether or not any of its principals have been (a) convicted within the preceding 3 years of any of the offenses listed in 2 CFR § 180.800(a); (b) had a civil judgment rendered against the organization or the individual for one of those offenses within that time period; or (c) is presently indicted for, or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses listed in 2 CFR § 180.800(a). If the application does not indicate the existence of any of the above circumstances and the grants official's check of System for Award Management and other available information indicates that any of these circumstances do exist, this may be considered a false certification and the OpDiv/StaffDiv may take action against an applicant on that basis.

<sup>23</sup> The case that took 1251 days was referred to ORIC for research misconduct. The respondent requested a hearing with the HHS Departmental Appeals Board, which took nearly 2 years to provide ORIC with a summary judgment.

<sup>24</sup> Of these 83 debarments, 20 met ORIC's 100-day goal.

<sup>25</sup> Of these debarments, two were conviction-based and neither met ORIC's 100-day goal.

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<sup>26</sup> ORIC's guidance includes information about what is considered *not* sufficient to demonstrate immediate action (i.e., merely stating that the respondent's misconduct is serious and concluding that there is an immediate need). The guidance also directs referring entities to consider whether the respondent may obtain new awards, which may be a basis for immediate action. However, the guidance does not include other circumstances in which the SDO may determine that suspensions are appropriate, as outlined in the regulations. Specifically, 2 CFR § 180.705(c) directs the SDO to consider such things as the nature of the circumstances giving rise to a cause for suspension and potential business relationships.

<sup>27</sup> Over half of the 75 suspensions resulted in later debarment. The suspensions that did not result in a debarment as of December 2019 were either terminated (12) or the debarment was still being considered (24).

<sup>28</sup> The suspension was for a grant.

<sup>29</sup> There was not a preceding suspension before the debarment in this case, and the debarment was for a grant.

<sup>30</sup> There was a preceding suspension before the debarment in this case, and the debarment was for a grant.