



November 2016

MEDICARE

Initial Results of Revised Process to Screen Providers and Suppliers, and Need for Objectives and Performance Measures

Accessible Version

GAO Highlights

Highlights of [GAO-17-42](#), a report to the Ranking Member, Special Committee on Aging, U.S. Senate

Why GAO Did This Study

An effective provider and supplier enrollment process is a cornerstone of ensuring Medicare program integrity and limiting improper payments. The Patient Protection and Affordable Care Act contained provisions designed to strengthen CMS's enrollment screening process. In response, CMS implemented a revised screening process on March 25, 2011, that assigned all providers and suppliers to one of three risk categories—limited, moderate, or high—and based screening on the level of potential risk of fraud, waste, and abuse they present. The process is used to screen prospective, and revalidate enrolled, providers and suppliers. In September 2011, CMS began its first large scale revalidation effort to verify all enrolled providers' and suppliers' information and determine whether they remain eligible to bill Medicare. As of March 2016, it had begun its second large scale revalidation effort.

GAO was asked to examine the revised enrollment screening process. GAO examined 1) the results of the 2011 revised screening process, 2) CMS's implemented or planned modifications to the process, and 3) CMS's monitoring of the revised process. GAO examined enrollment data from March 25, 2011, through December 31, 2015, reviewed CMS policies and procedures, and interviewed CMS and Medicare contractor officials.

What GAO Recommends

To improve the revised screening process, CMS should establish objectives and performance measures for assessing progress toward achieving its goals.

View [GAO-17-42](#). For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

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What GAO Found

GAO's analysis of the Centers for Medicare & Medicaid Services' (CMS) Medicare enrollment data found that CMS used its revised enrollment screening process to screen and revalidate over 2.4 million unique new applications and existing enrollment records. GAO's analysis showed that the screening resulted in over 23,000 new applications being denied or rejected and over 703,000 existing enrollment records being deactivated or revoked. CMS estimates the revised process avoided \$2.4 billion in Medicare payments to ineligible providers and suppliers from March 2011 to May 2015 and resulted in other benefits, such as more accurate provider and supplier enrollment data. In June 2015, GAO reported some inaccuracies in the enrollment data after the revised process took effect, such as potentially ineligible practice location addresses, which CMS has taken action to address.

Since 2011, CMS has implemented some modifications to the revised screening process and made operational modifications to its revalidation efforts. For example, CMS eliminated automatic approvals of provider and supplier requests to extend the deadline for submitting enrollment information for revalidation. CMS officials stated that they plan to implement further modifications, but have not yet identified these future modifications. CMS officials said that they are waiting to see the results of the previous modifications before modifying the enrollment process further.

CMS has set goals and conducted monitoring of the enrollment screening process, but those monitoring activities lack objectives and performance measures for assessing progress toward those goals. CMS officials said they want to assess the screening process but they are uncertain of what objectives and performance measures to establish, in part because they are concerned that some measures would be inappropriate. While there may be challenges in developing objectives and performance measures, there are opportunities to do so that would allow CMS to better monitor the enrollment screening process without setting specific targets that could create inappropriate incentives for contractors. For example, CMS could focus on developing objectives and performance measures related to its goals for enrollment screening, such as keeping enrollment information up to date. Federal internal control standards and leading practices specify defining objectives and establishing performance measures so that an agency can monitor progress toward achieving desired goals. Without objectives and performance measures to use in ongoing monitoring, CMS will be unable to measure the progress it has made toward achieving its goals.

In commenting on this report, the Department of Health and Human Services agreed with GAO's recommendation.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
HHS	Department of Health and Human Services
MAC	Medicare Administrative Contractor
PECOS	Provider Enrollment, Chain and Ownership System
PTAN	Provider Transaction Access Number

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November 15, 2016

The Honorable Claire McCaskill
Ranking Member
Special Committee on Aging
United States Senate

Dear Senator McCaskill:

An effective provider and supplier enrollment process is a cornerstone of ensuring program integrity and limiting improper payments in Medicare, the federal health insurance program for persons aged 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease.¹ The Centers for Medicare & Medicaid Services (CMS)—the agency within the Department of Health and Human Services (HHS) that administers the Medicare program—screens prospective providers and suppliers and enrolls those it determines are eligible to bill Medicare for services they provide to beneficiaries. In fiscal year 2015, Medicare payments totaled \$568.9 billion, and CMS estimates that \$59.6 billion was paid improperly. Partly due to its susceptibility to improper payments, we have designated Medicare as a high-risk program for more than 20 years.²

CMS has made efforts to reduce improper payments and strengthen program integrity by moving away from a traditional “pay and chase” approach to a more preventive strategy, in part by using authorities

¹Providers and suppliers include entities such as hospitals and health-care facilities, physician and nonphysician practitioners who provide health-care services to Medicare beneficiaries, certain entities such as mammography centers and portable X-ray facilities, as well as entities that supply Medicare beneficiaries with Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). An improper payment is any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements. It includes any payment to an ineligible recipient, any payment for an ineligible good or service, any duplicate payment, payment for a good or service not received (except for such payments where authorized by law), and any payment that does not account for credit for applicable discounts. Improper Payments Elimination and Recovery Act of 2010, Pub. L. No. 111-204, § 2(e), 124 Stat. 2224, 2227 (codified at 31 U.S.C. § 3321 note).

²See GAO, *High-Risk Series: An Update*, [GAO-15-290](#) (Washington, D.C.: February 2015).

granted by the Patient Protection and Affordable Care Act (PPACA).³ In response to PPACA, on March 25, 2011, CMS implemented a revised enrollment screening process for new and existing providers and suppliers based on the potential risk of fraud, waste, and abuse that each presents; CMS implemented this process to help ensure that only eligible providers and suppliers bill Medicare. Using this revised screening process, CMS undertook its first program-wide effort to rescreen, or revalidate, the enrollment records of about 1.5 million existing providers and suppliers, and determine whether they remain eligible to bill Medicare. As of March 2016, CMS has begun its second program-wide revalidation effort.

You asked us to examine the revised enrollment screening process CMS put into place in 2011. This report examines

- 1) the results of the 2011 revised enrollment screening process,
- 2) the modifications CMS has implemented or planned to the revised enrollment screening process since 2011, and
- 3) the extent to which CMS monitors the revised enrollment screening process.

To examine the results of the 2011 revised enrollment screening process, we analyzed data from the Provider Enrollment, Chain and Ownership System (PECOS), CMS's centralized database for Medicare enrollment information. We analyzed PECOS data from March 25, 2011, through December 31, 2015, to determine (1) the number of enrollment records and enrollment applications to which CMS applied the revised screening process, (2) the number of approved, denied, and rejected new enrollment applications, (3) the number of deactivated or revoked existing enrollment records, and (4) the number of enrollment records associated

³"Pay and chase" refers to the labor-intensive and time-consuming practice of trying to recover improper payments after they have already been made rather than preventing improper payments in the first place.

See, for example, Pub. L. No. 111-148, § 6401(a) 124 Stat. 119, 747 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1304, 124 Stat. 1029, 1058 (2010). Collectively, we refer to PPACA as amended by the Health Care and Education Reconciliation Act of 2010 as PPACA.

with providers and suppliers eligible to bill Medicare.⁴ We did not independently verify the accuracy of the PECOS data; however, we checked the PECOS data for obvious errors and omissions, compared analysis results to CMS's publicly reported information on screening process outcomes, and interviewed CMS officials to resolve any identified discrepancies. On the basis of these actions, we determined that the PECOS data were sufficiently reliable for the purpose of this report. We also interviewed CMS officials and officials from each of the Medicare Administrative Contractors (MAC), which conduct enrollment screening and reach decisions on the applications of prospective providers and suppliers, about the results of the enrollment screening process put into place in 2011.⁵ See appendix I for more detail on the scope and methodology used for our PECOS data analysis.

To examine the modifications CMS has implemented or planned to the revised enrollment screening process since 2011, we reviewed documentation on actions it has implemented or planned, such as CMS memoranda and instructions about process modifications, a performance work plan, a press release, a CMS blog post, and provider education and outreach materials. We also interviewed CMS and MAC officials about actions to modify the process.

To examine the extent to which CMS monitors the revised enrollment screening process, we obtained and analyzed documentation on the extent to which the agency has monitored and evaluated the effectiveness of the screening process, such as CMS proposed and final rules, and CMS memoranda and instructions about process modifications. We interviewed CMS officials regarding the agency's monitoring and evaluation efforts, including the following: CMS's goals for the process; information CMS is using to assess its effectiveness; any challenges faced and lessons learned; and the extent to which the agency is establishing different goals for the next cycle of revalidation. We also interviewed Medicare contractor officials about challenges faced and lessons learned regarding the effectiveness of the enrollment screening process. We then compared CMS's efforts to set goals and

⁴Enrollment application information is used to create the provider's or supplier's enrollment record in PECOS. An individual provider or supplier may have more than one enrollment record.

⁵A different contractor, the National Supplier Clearinghouse, screens and enrolls DMEPOS suppliers. For the purposes of this report, MAC refers to both MACs and the National Supplier Clearinghouse unless otherwise noted.

measure the effectiveness of the process in meeting those goals to identified federal standards for internal control related to monitoring and leading practices for performance management.⁶

We conducted this performance audit from July 2015 to November 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

To become eligible to bill for services provided to Medicare beneficiaries, prospective Medicare providers and suppliers apply to the program by completing an online enrollment application in PECOS or by submitting a paper enrollment application that is manually entered into PECOS.⁷ Application information, such as name, address, specialty area, licensure, and accreditation, is used to create the provider's or supplier's enrollment

⁶See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999), GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

We have previously stated that performance goals and measures are important management tools that can serve as leading practices for planning at lower levels within federal agencies, such as individual programs or initiatives. For example, see GAO, *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, [GAO-12-77](#) (Washington, D.C.: Oct. 6, 2011); *Federal Prison System: Justice Could Better Measure Progress Addressing Incarceration Challenges*, [GAO-15-454](#) (Washington, D.C.: July 19, 2015); *DHS Training: Improved Documentation, Resource Tracking, and Performance Measurement Could Strengthen Efforts*, [GAO-14-688](#) (Washington, D.C.: Sept. 10, 2014); *Program Evaluation: Strategies to Facilitate Agencies' Use of Evaluation in Program Management and Policy Making*, [GAO-13-570](#) (Washington, D.C.: June 26, 2013); *Performance Measurement and Evaluation: Definitions and Relationships*, [GAO-11-646SP](#) (Washington, D.C.: May 2011); *Managing for Results: Enhancing Agency Use of Performance Information for Management Decision Making*, [GAO-05-927](#) (Washington, D.C.: Sept. 9, 2005).

⁷Medicare providers and suppliers furnish services payable under Parts A and B of Medicare. In October 2016, CMS announced a phased approach beginning in 2017 to enforce its regulation requiring physicians and other eligible professionals who write prescriptions for Medicare beneficiaries with Part D drug coverage to enroll or formally opt-out of Medicare. See 42 C.F.R. 423.120(c)(6) (2015). CMS plans full enforcement of the Part D prescriber requirements beginning January 1, 2019.

record in PECOS.⁸ An individual provider or supplier may have more than one enrollment record; for example, a provider may have one enrollment record for a practice in one state and another enrollment record for a practice in another state.

CMS places all provider and supplier types into risk categories—limited, moderate, or high—based on CMS’s assessments of the potential risk of fraud, waste, and abuse each provider and supplier type poses to Medicare program integrity. CMS also designates specific screening activities for each risk category.⁹ See table 1 for the types of Medicare providers and suppliers assigned to each enrollment screening risk category.

Table 1: Types of Medicare Providers and Suppliers Designated to Risk Categories for Enrollment Screening

Risk category	Types of Medicare providers and suppliers
Limited	Physician or nonphysician practitioners and medical groups or clinics, with the exception of physical therapists and physical therapy groups. Ambulatory surgical centers, competitive acquisition programs/Part B vendors, end-stage renal disease facilities, federally qualified health centers, histocompatibility laboratories, hospitals, including critical access hospitals, Indian Health Service facilities, mammography screening centers, mass immunization roster billers, ^a organ procurement organizations, pharmacies newly enrolling or revalidating, radiation therapy centers, religious nonmedical health care institutions, rural health clinics, and skilled nursing facilities.
Moderate	Ambulance suppliers, community mental health centers, comprehensive outpatient rehabilitation facilities, hospice organizations, independent diagnostic testing facilities, independent clinical laboratories, physical therapists and physical therapy groups, portable X-ray suppliers, currently enrolled home health agencies, and currently enrolled suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).
High	Prospective (newly enrolling) home health agencies and prospective (newly enrolling) DMEPOS suppliers.

Source: 42 C.F.R. § 424.518 (2015). | GAO-17-42.

^aMass immunization roster billers are providers and suppliers who enroll in the Medicare program to offer the influenza (flu) vaccinations to a large number of individuals.

Under contract to CMS, MACs screen providers and suppliers in all risk categories to verify that they meet Medicare eligibility requirements, such

⁸Licensure is a mandatory process by which a state government grants permission to an individual practitioner or health care organization to engage in an occupation or profession. Accreditation is a formal process by which a recognized body, usually a nongovernmental organization, assesses and recognizes that a health care organization meets applicable predetermined standards.

⁹An individual provider or supplier placed in the limited- or moderate-risk category can be elevated to the high-risk category for reasons such as having Medicare billing privileges revoked at any time within the past 10 years.

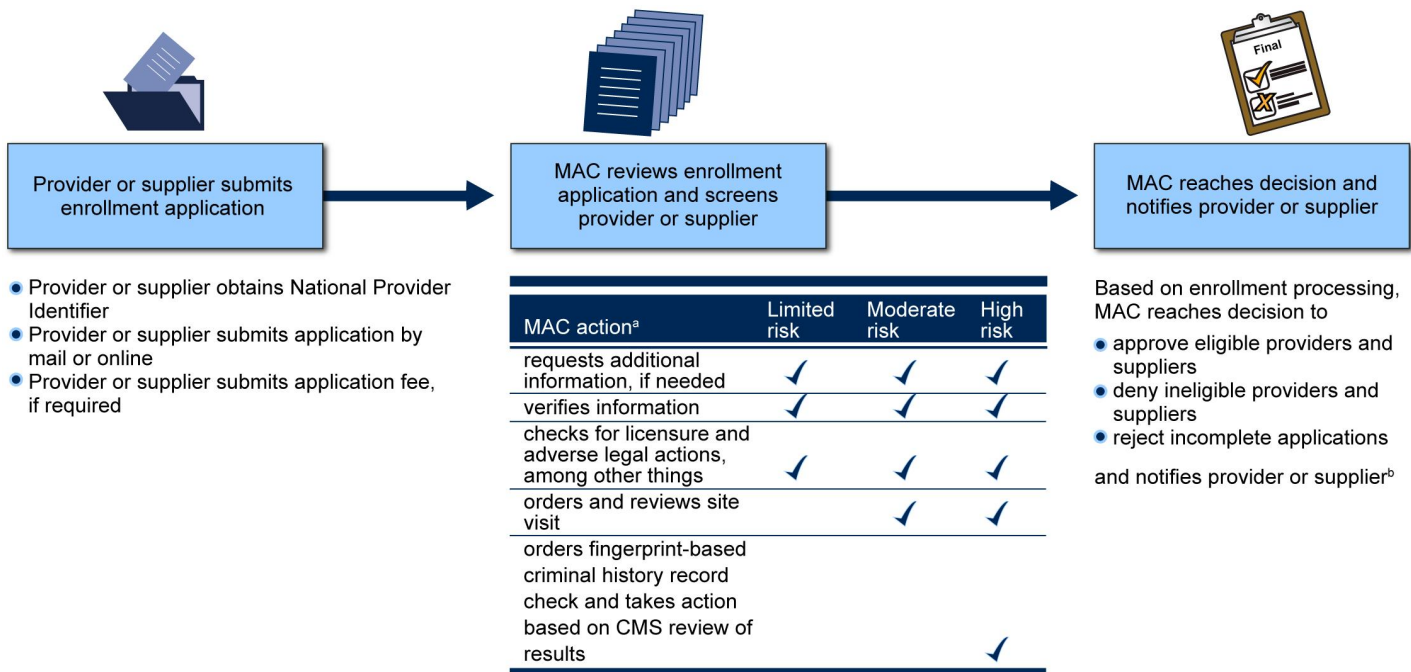
as having current federal or state licenses or accreditation. Medicare regulations require that site visits be conducted for all high- and moderate-risk providers and suppliers. Those conducting the site visits determine whether the reported practice locations are operational and meet requirements such as specified hours of operation.¹⁰ In addition to these site visits, high-risk providers and suppliers also are subject to a fingerprint-based criminal background check.¹¹ In the course of this screening, MACs may request additional information from the prospective provider or supplier. Upon completion of screening, the MAC reaches a decision to approve eligible providers and suppliers, deny ineligible providers and suppliers, or reject incomplete applications.¹² Figure 1 shows the enrollment process, including the screening conducted for each risk category.

¹⁰CMS contracts with a national site visit contractor to conduct site visits for all types of providers and suppliers, except for DMEPOS suppliers. DMEPOS provider and supplier site visits are conducted by the National Supplier Clearinghouse. Providers and suppliers must have a qualified physical practice location to be considered operational and able to furnish Medicare covered items or services, among other things.

¹¹In July 2014 CMS awarded a contract to conduct fingerprint-based background checks and screen out providers with certain criminal convictions. CMS may deny or revoke a provider's or supplier's enrollment in the Medicare program if, for example, within the 10 years before enrollment or revalidation of enrollment, the provider, supplier, or any owner or managing employee of the provider or supplier was convicted of a federal or state felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries.

¹²Enrollment applications are denied when the enrolling provider or supplier has been determined to be ineligible for Medicare billing privileges. Enrollment applications are rejected when they are not processed due to incomplete information or when the enrolling provider or supplier does not provide complete information in a timely manner. For certified providers and suppliers, MACs make recommendations to CMS about whether to approve enrollment applications.

Figure 1: Medicare Enrollment Process



Source: GAO analysis of CMS information. | GAO-17-42

^aMedicare Administrative Contractors (MAC) conduct enrollment screening and reach decisions on the applications of prospective providers and suppliers. A different contractor, the National Supplier Clearinghouse, screens and enrolls suppliers of durable medical equipment, prosthetics, orthotics, and supplies. For the purposes of this figure, MAC refers to both MACs and the National Supplier Clearinghouse. These MAC actions represent the minimum requirements for provider enrollment screening. Other actions may be added as deemed appropriate.

^bFor certified providers and suppliers, MACs make recommendations to the Centers for Medicare & Medicaid Services (CMS) about whether to approve enrollment applications.

Once enrolled, to remain eligible to bill Medicare providers and suppliers must continue to meet CMS’s enrollment requirements, and they must report to CMS any changes to their enrollment information, including final adverse actions taken against them, such as a suspension or licensure revocation by a state licensing authority. In addition, providers and suppliers periodically are required to resubmit enrollment information to the MAC to update their enrollment records. The MAC revalidates the provider’s or supplier’s enrollment record using the enrollment screening process, to determine whether the provider or supplier remains eligible to bill Medicare. Upon completing the revalidation process, the MAC reaches a decision to

- approve providers and suppliers that remain eligible;

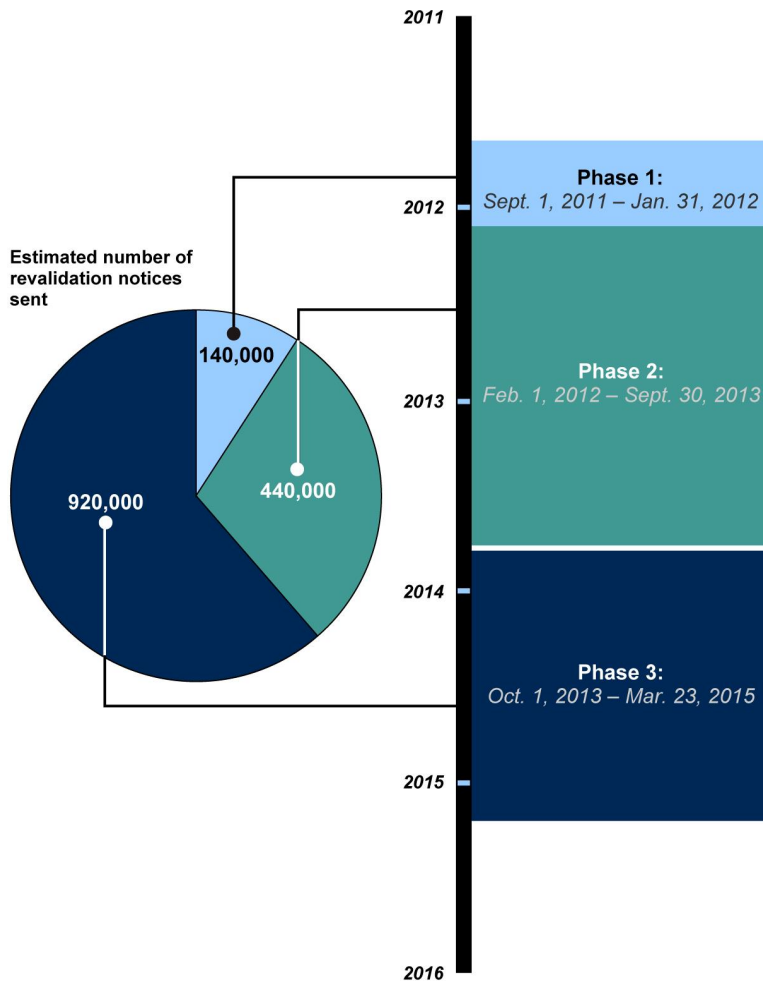
-
- deactivate billing privileges for providers and suppliers that have not responded to a request to resubmit enrollment information or have not submitted all required information—privileges that may be reactivated upon submission of a new enrollment application or recertifying that current enrollment information is correct; or
 - revoke billing privileges for providers and suppliers determined ineligible.¹³

Providers and suppliers must submit updated information for their enrollment records for revalidation every 5 years, with the exception of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers, which must submit their information every 3 years.¹⁴ CMS initiated the first program-wide revalidation effort for all providers and suppliers enrolled in Medicare prior to March 25, 2011, by mailing notices to providers and suppliers in three phases, from September 2011 through March 2015, as shown in figure 2.

¹³A provider or supplier with an enrollment record revoked may attempt to re-enroll by submitting a new enrollment application after the re-enrollment bar, which may last up to 3 years, has ended.

¹⁴CMS also may require a provider or supplier to revalidate at additional times, including when certain compliance-related concerns arise. PECOS data must also be updated when there is a change of address or other change to provider or supplier status.

Figure 2: Phases of the First Revalidation Cycle, Including Estimated Number of Revalidation Notices Mailed, the Types of Providers and Suppliers, and the Time Frame for Each Phase



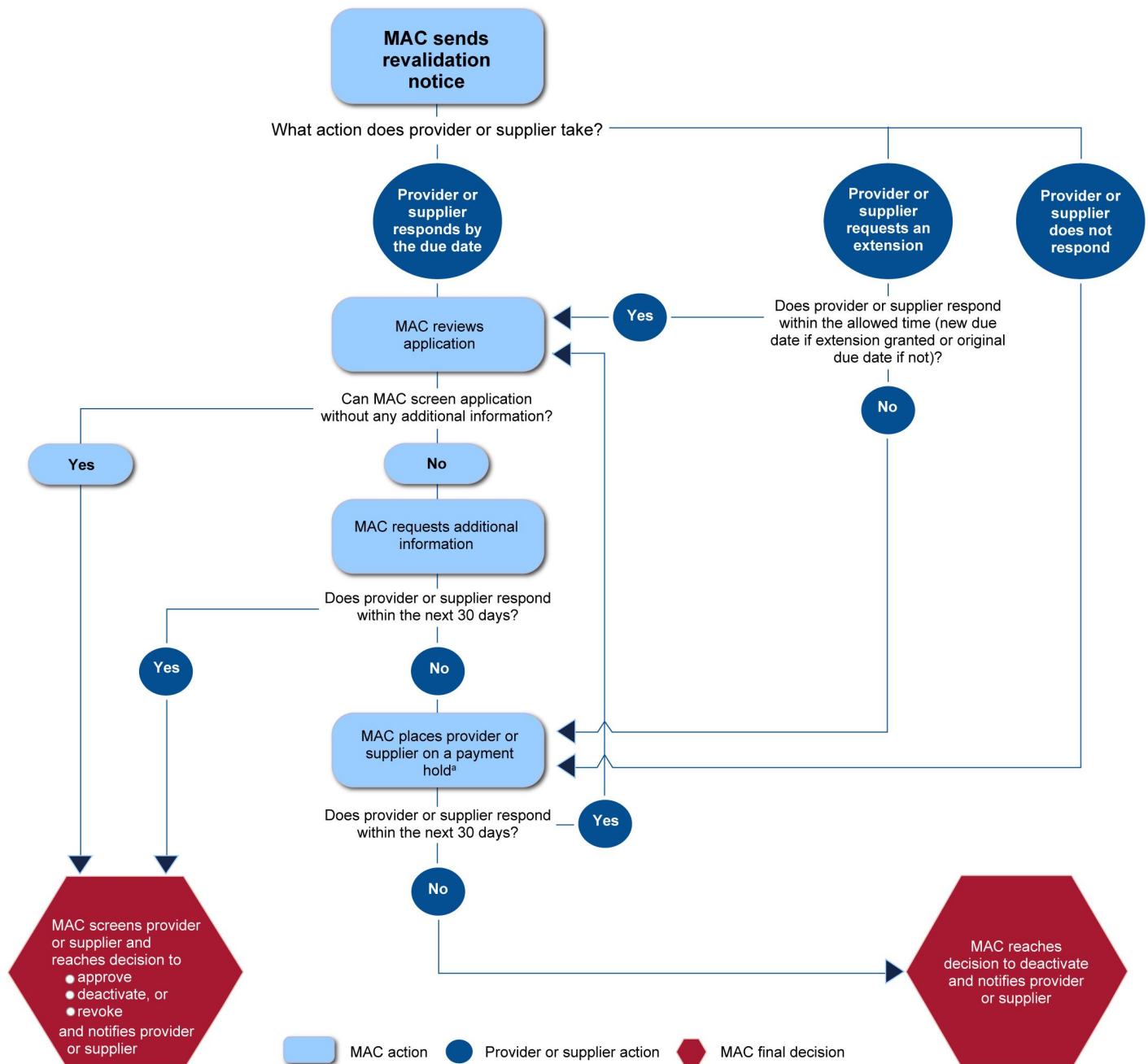
Providers and suppliers received revalidation notices during each phase:

- Providers and suppliers without an enrollment record in the Centers for Medicare & Medicaid Services' (CMS) centralized database for Medicare enrollment information;
 - Home health agencies, and
 - Independent diagnostic testing facilities.
- Moderate-risk providers and suppliers as designated by CMS;
 - High-risk providers and suppliers as designated by CMS; and,
 - Institutional providers (for example, hospitals, skilled nursing facilities, or other similar institutions which provide care to Medicare beneficiaries).
- All remaining providers and suppliers subject to revalidation.

Source: GAO analysis of CMS information. | GAO-17-42

Each notice sent by the MAC asks the provider or supplier to submit a newly completed enrollment application for revalidation, which the MAC then screens using the enrollment screening process to verify the information provided and determine whether the provider or supplier remains eligible to bill Medicare. A provider or supplier must respond by the due date or may request an extension to submit an application. If the provider or supplier does not respond within the allowed time, the provider or supplier is to be placed on a payment hold and is not to receive Medicare payment for services billed until a complete enrollment application has been submitted and approved by the MAC. Figure 3 illustrates the process MACs use to revalidate existing providers and suppliers.

Figure 3: Medicare Administrative Contractor (MAC) and Provider and Supplier Revalidation Process



Source: GAO analysis of CMS information. | GAO-17-42

^aIf the provider or supplier is a member of a large group practice, the MAC does not apply a payment hold, since this action would inappropriately affect the entire group.

CMS Applied the Revised Enrollment Screening Process to over 2.4 Million New Applications and Existing Records, and Estimated Avoiding \$2.4 Billion in Medicare Payments to Ineligible Providers and Suppliers

CMS Denied or Rejected over 23,000 New Applications and Deactivated or Revoked over 703,000 Existing Enrollment Records

According to our analysis of PECOS data, CMS applied its revised enrollment screening process to over 2.4 million unique new applications and existing enrollment records from March 25, 2011, through December 31, 2015.¹⁵ As a result, CMS took action to deny or reject new applications and to deactivate or revoke existing enrollment records that did not meet the revised screening requirements.

CMS's screening of new enrollment applications resulted in actions against more than 23,000 new enrollment applications—CMS denied over 6,000 applications for ineligible providers and suppliers and rejected over 17,000 incomplete applications during the time period we reviewed.¹⁶ According to our analysis, the denials and rejections were disproportionately for providers and suppliers in the moderate- and high-risk categories. The most commonly recorded reason for a denial was

¹⁵We calculated this total by adding unique enrollment records for (1) the number of new enrollment application decisions made from March 25, 2011, through December 31, 2015, (2) the number of enrollment records with a change in enrollment status, such as deactivated or revoked, from March 25, 2011, through December 31, 2015, and (3) the number of approved enrollment records on March 25, 2011, that did not have an enrollment status change through December 31, 2015.

¹⁶Providers and suppliers with denied or rejected enrollment applications are not eligible to bill Medicare.

because Medicare provider or supplier type requirements were not met (over 42 percent of total denials). Officials from a MAC said this may occur, for example, if a provider does not hold a certification required for that provider type. See table 2 for the most commonly recorded reasons in PECOS for denial by risk category.

Table 2: Three Most Commonly Recorded Reasons for Denying Enrollment Applications Overall and within Each Risk Category from March 25, 2011, through December 31, 2015

Denial reason ^a	Risk category			
	Overall	Limited	Moderate	High
	Percentage of total (Rank ^b)	Percentage of total (Rank)	Percentage of total (Rank)	Percentage of total (Rank)
Provider/ supplier type requirements not met	43 (1)	56 (1)	35 (1)	19 (2)
Temporary moratorium ^c	14 (2)	N/A	N/A	38 (1)
Nonoperational	13 (3)	11 (2)	32 (2)	17 (3)
Not professionally licensed	N/A	8 (3)	N/A	N/A
Independent diagnostic testing facility standards not met	N/A	N/A	9 (3)	N/A

Source: GAO analysis of Provider Enrollment, Chain and Ownership System (PECOS) data. | GAO-17-42.

Notes: Centers for Medicare & Medicaid Services (CMS) officials reported that there could be multiple reasons to explain an enrollment status, for example, deactivated or revoked, recorded in PECOS, but due to PECOS system limitations, the contractors responsible for reviewing provider and supplier enrollment information can only record one reason in PECOS. In addition, the reasons to explain an enrollment status that can be recorded have changed between March 2011 and December 2015. N/A means that the reason was not one of the three most commonly recorded.

^aWe excluded the "Other" reason in PECOS from our list of most commonly recorded reasons because it is not a descriptive reason for denial.

^bIndicates whether the reason is the most, second-most, or third-most commonly recorded for denying an enrollment application overall and within each risk category.

^cCMS may impose temporary moratoria in 6 month increments on a particular provider or supplier type or a particular geographic area, or both, to prevent or combat fraud, waste, and abuse. During a temporary moratorium, CMS can deny an enrollment application from a provider or supplier with a particular provider or supplier type, or a new practice location of a particular type in a particular geographic area, where CMS has imposed the temporary moratorium.

The most commonly recorded reason in PECOS for a rejected enrollment application was a deleted enrollment application (about 25 percent of total rejections), which officials from a MAC said may occur when an enrollment application has been entered into PECOS in error, either by a provider or supplier, or by the MAC. See table 3 for the most commonly recorded reasons in PECOS for rejection by risk category.

Table 3: Three Most Commonly Recorded Reasons for Rejecting Enrollment Applications Overall and within Each Risk Category from March 25, 2011, through December 31, 2015

Rejection reason ^a	Risk category			
	Overall	Limited	Moderate	High
	Percentage of total (Rank ^b)	Percentage of total (Rank)	Percentage of total (Rank)	Percentage of total (Rank)
Deleted ^c	25 (1)	N/A	25 (1)	56 (1)
Duplicate application	21 (2)	26 (1)	17 (3)	9 (3)
Applicant unresponsive ^d	16 (3)	18 (3)	21 (2)	10 (2)
Applicant unresponsive: nonresponse to development ^e	N/A	19 (2)	N/A	N/A

Source: GAO analysis of Provider Enrollment, Chain and Ownership System (PECOS) data. | GAO-17-42.

Notes: Centers for Medicare & Medicaid Services (CMS) officials reported that there could be multiple reasons to explain an enrollment status, for example, deactivated or revoked, recorded in PECOS, but due to PECOS system limitations, the contractors responsible for reviewing provider and supplier enrollment information can only record one reason in PECOS. In addition, the reasons to explain an enrollment status that can be recorded have changed between March 2011 and December 2015. N/A means that the reason was not one of the three most commonly recorded.

^aWe excluded the "Other" reason in PECOS from our list of most commonly recorded reasons because it is not a descriptive reason for rejection.

^bIndicates whether the reason is the most, second-most, or third-most commonly recorded for rejecting an enrollment application overall and within each risk category.

^cOfficials from a Medicare Administrative Contractor (MAC) said a deleted enrollment application may occur when an enrollment application has been entered into PECOS in error, either by a provider or supplier, or by the MAC.

^dOfficials from a MAC said an unresponsive applicant may occur when a provider or supplier has not responded within the allotted timeframe to a request other than for more information. This includes situations in which a provider submits an enrollment application on web-based PECOS, but does not electronically sign it.

^eOfficials from a MAC said an unresponsive application for development may occur when a provider or supplier has not responded within the allotted timeframe to a request for more information in making an enrollment application decision.

Denied and rejected enrollment applications were relatively more common for moderate- and high-risk providers and suppliers and less common for limited-risk providers and suppliers. According to our analysis, while moderate- and high-risk providers and suppliers accounted for less than 10 percent of all new enrollment application decisions during the time period we reviewed, they accounted for over 30 percent of denials and over 22 percent of rejections. The disproportionate deactivations and rejections could be the result of the additional screening for moderate- and high-risk applicants or the underlying greater risk that these moderate- and high-risk providers and suppliers posed to Medicare.

CMS's screening of existing enrollment records resulted in actions against more than 703,000 provider and supplier enrollment records—CMS deactivated over 660,000 and revoked over 43,000 throughout this period.¹⁷ Providers and suppliers lose their ability to bill Medicare when CMS either deactivates or revokes their enrollment record. Providers and suppliers in the limited-risk category accounted for about 90 percent of deactivations and 84 percent of revocations.¹⁸ Enrollment records of limited-risk providers and suppliers represented about 90 percent of the 1.9 million approved enrollment records as of December 31, 2015.

The reasons for deactivations and revocations varied, according to our analysis. Many were the result of enrollment screening conducted during CMS's first revalidation cycle. For example, the most commonly recorded reason in PECOS for deactivations was not responding to a revalidation request (about 47 percent overall). See table 4 for the most commonly recorded reasons in PECOS for deactivation by risk category.

¹⁷Because an enrollment record could have been deactivated or revoked more than once, or both deactivated and revoked, during the time period we analyzed, there were fewer unique enrollment records deactivated and revoked than there were total enrollment records deactivated and revoked. Specifically, CMS deactivated over 17,000 enrollment records more than once and revoked over 400 enrollment records more than once.

¹⁸About 14 percent of deactivated enrollment records and 17 percent of revoked enrollment records did not have a risk category assigned in PECOS. According to a CMS official, an enrollment record may not have had a risk category assigned if no action had been taken on the enrollment record since the risk categories became effective in March 2011. For our analysis, we removed these records in calculating the percentages of enrollment records in each risk category.

Table 4: Three Most Commonly Recorded Reasons for Deactivating Enrollment Records Overall and within Each Risk Category from March 25, 2011, through December 31, 2015

Deactivation reason ^a	Risk category			
	Overall	Limited	Moderate	High
	Percentage of total (Rank ^b)	Percentage of total (Rank)	Percentage of total (Rank)	Percentage of total (Rank)
Nonresponse to revalidation	47 (1)	55 (1)	42 (1)	7 (3)
Voluntary withdrawal from Medicare program	29 (2)	28 (2)	35 (2)	27 (2)
No claims submitted within last 12 months	5 (3)	N/A	10 (3)	54 (1)
Voluntary withdrawal of ordering/referring status	N/A	3 (3)	N/A	N/A

Source: GAO analysis of Provider Enrollment, Chain and Ownership System (PECOS) data. | GAO-17-42.

Notes: Centers for Medicare & Medicaid Services (CMS) officials reported that there could be multiple reasons to explain an enrollment status, for example, deactivated or revoked, recorded in PECOS, but due to PECOS system limitations, the contractors responsible for reviewing provider and supplier enrollment information can only record one reason in PECOS. In addition, the reasons to explain an enrollment status that can be recorded have changed between March 2011 and December 2015. N/A means that the reason was not one of the three most commonly recorded.

^aWe excluded the "Other" reason in PECOS from our list of most commonly recorded reasons because it is not a descriptive reason for deactivation.

^bIndicates whether the reason is the most, second-most, or third-most commonly recorded for deactivating an enrollment application overall and within each risk category.

The most commonly recorded reason overall for revocations was not being professionally licensed (over 61 percent), but the most commonly recorded reasons differed between the limited-risk category and the moderate- and high-risk categories. See table 5 for the most commonly recorded reasons in PECOS for revocation by risk category.

Table 5: Three Most Commonly Recorded Reasons for Revoking Enrollment Records Overall and within Each Risk Category from March 25, 2011, through December 31, 2015

Revocation reason ^a	Risk category			
	Overall	Limited	Moderate	High
	Percentage of total (Rank ^b)	Percentage of total (Rank)	Percentage of total (Rank)	Percentage of total (Rank)
Not professionally license	61 (1)	74 (1)	N/A	N/A
CMS-approved revocation ^c	5 (2)	N/A	26 (1)	14 (3)
Provider/ supplier type requirements not met	4 (3)	4 (2)	N/A	N/A
Nonoperational	N/A	N/A	16 (3)	25 (1)
Durable medical equipment standards not met	N/A	N/A	20 (2)	21 (2)
Failure to comply with reporting requirements	N/A	4 (3)	N/A	N/A

Source: GAO analysis of Provider Enrollment, Chain and Ownership System (PECOS) data. | GAO-17-42.

Notes: Centers for Medicare & Medicaid Services (CMS) officials reported that there could be multiple reasons to explain an enrollment status, for example, deactivated or revoked, recorded in PECOS, but due to PECOS system limitations, the contractors responsible for reviewing provider and supplier enrollment information can only record one reason in PECOS. In addition, the reasons to explain an enrollment status that can be recorded have changed between March 2011 and December 2015. N/A means that the reason was not one of the three most commonly recorded.

^aWe excluded the "Other" reason in PECOS from our list of most commonly recorded reasons because it is not a descriptive reason for revocation.

^bIndicates whether the reason is the most, second-most, or third-most commonly recorded for revoking an enrollment application overall and within each risk category.

^cOfficials from a Medicare Administrative Contractor (MAC) said this reason includes any other revocation that does not fall under another available category but is within CMS direction, such as a provider having an adverse action taken against it and not disclosing it to the MAC within 30 days.

According to our analysis of PECOS data, there were about 500,000 more approved enrollment records nearly 5 years after CMS began applying its revised enrollment screening process. When the revised enrollment screening process took effect on March 25, 2011, there were about 1.4 million approved enrollment records in PECOS, which increased by more than 30 percent to about 1.9 million approved enrollment records by December 31, 2015.¹⁹ During roughly the same time frame, the number of Medicare beneficiaries increased by more than 13 percent, from 48.7 million in 2011 to 55.3 million in 2015.

¹⁹This total does not include providers and suppliers that were eligible to bill Medicare, but did not have an enrollment record(s) in PECOS as of March 25, 2011. If a provider or supplier had not reported a change to enrollment information since 2003, there would not have been an enrollment record in PECOS as of 2011 when CMS began revalidation.

CMS Estimates It Avoided \$2.4 Billion in Medicare Payments to Ineligible Providers and Suppliers from Enrollment Screening Process, Among Other Benefits

CMS estimates the revised enrollment screening process avoided \$2.4 billion in Medicare payments to ineligible providers and suppliers from March 2011 to May 2015, and CMS and MAC officials report additional benefits. According to CMS officials, the estimate is based on Medicare payments providers and suppliers with revoked enrollment records would have received had they not been revoked. To make its estimate, CMS used the provider's or supplier's past billing history and a formula it has developed for estimating Medicare payments avoided from other Medicare program integrity efforts. In addition to Medicare payments avoided, CMS and MAC officials report other benefits from the revised enrollment screening process, including the following:

- More accurate and complete data in PECOS. For example, the MACs deactivated providers and suppliers that were no longer billing Medicare, and created new PECOS enrollment records during the first program-wide revalidation effort for providers and suppliers that were in the Medicare claims system but not in PECOS.²⁰
- Providers and suppliers more knowledgeable about their responsibilities to keep enrollment information up to date. MAC officials said providers and suppliers are now more frequently providing them with changes of information, which according to CMS and MAC officials may result in fewer deactivated enrollment records during the second program-wide revalidation effort that began in March 2016.
- Identified provider and supplier enrollment records that needed increased scrutiny. CMS reported in September 2016 that it identified about 1,700 such cases and raised the provider's or supplier's risk category from limited or moderate risk to high risk.

While CMS and MAC officials reported benefits from the revised enrollment screening process, they also reported challenges. For example, MAC officials said that there were challenges revalidating enrollment information for providers and suppliers with multiple billing locations during the first program-wide revalidation effort, which led to deactivations of some otherwise eligible providers and suppliers. According to officials at one MAC we interviewed, this could have

²⁰For some providers or suppliers enrolled in Medicare, an enrollment record may not have existed in PECOS when CMS began the first program-wide revalidation effort. If a provider or supplier had not submitted an enrollment application to report a change to enrollment information since 2003, there would not have been an enrollment record in PECOS as of 2011 when CMS began revalidation.

occurred, for example, if the provider's or supplier's address information in PECOS was not accurate and a revalidation letter was not sent to each billing location or if the revalidation notice did not reach the correct office personnel handling the requests for enrollment information for revalidation.

We and the HHS Office of the Inspector General have also found some issues with PECOS data since the revised process took effect. In June 2015, we reported that a review of PECOS data as of early 2013 found that an estimated 23,400 of 105,234 practice location addresses in PECOS were potentially ineligible, for example because they were vacant addresses.²¹ CMS concurred with our recommendations to incorporate flags into its software to help identify potentially questionable practice location addresses and to collect additional license information.²² In January 2016, CMS replaced the current PECOS address verification software used during the enrollment screening process for new applications with software that, according to CMS, will better detect potentially ineligible addresses. In April 2016, the HHS Office of the Inspector General reported that PECOS did not contain the reasons for enrollment application submissions—for example, whether a new enrollment application or an application submitted in response to a revalidation request—for 54,903 of 479,115 applications submitted from March 25, 2012, through March 24, 2013.²³ The reason for submission determines the screening level for certain providers and suppliers—for example, newly enrolling home health agencies are screened in the high-risk category while home health agencies being revalidated are screened in the moderate-risk category—and therefore some providers and suppliers may not have received appropriate screening. CMS concurred with the HHS Office of the Inspector General's recommendations.

²¹See GAO, *Medicare Program: Additional Actions Needed to Improve Eligibility Verification of Providers and Suppliers*, [GAO-15-448](#) (Washington, D.C.: June 2015). Addresses that generally would be considered ineligible include vacant addresses, post office boxes, and those associated with a certain type of Commercial Mail Receiving Agency, such as a United Parcel Service store. Post office boxes and drop boxes are not acceptable except in some cases where the provider is located in rural areas.

²²In June 2015, CMS did not agree with our recommendation to revise its 2014 guidance for verifying practice locations. However, in October 2016, HHS reported that it concurs with the recommendation and is actively working to implement it.

²³See HHS Office of the Inspector General, *Enhanced Enrollment Screening of Medicare Providers: Early Implementation Results*, OEI-03-13-00050 (Washington, D.C.: April 2016).

CMS Modified Elements of the Revised Enrollment Screening Process and Plans to Implement Further Modifications in the Future

Since 2011, CMS has modified some of the methods it uses to screen providers and suppliers trying to enroll or maintain eligibility to bill Medicare. For example, CMS officials said that screening modifications include the addition of a licensure continuous monitoring report, beginning in November 2013, and a criminal continuous monitoring report, beginning July 2015. CMS officials stated that the MACs now use these reports to help ensure that providers and suppliers continue to meet CMS's enrollment requirements after they have been enrolled. The MACs do so by identifying those providers and suppliers that no longer meet licensure requirements or that now have certain criminal convictions, and deactivating or revoking their enrollment records. Before implementing the reports, MACs did not receive routine reporting to use for checking licensure and criminal convictions of enrolled providers and suppliers, and CMS officials said they did not know whether the MACs were conducting such reviews regularly. CMS officials reported the agency made these screening modifications in part to meet PPACA requirements for provider and supplier enrollment. Table 6 includes examples of modifications CMS has made to methods used to screen providers and suppliers under the revised enrollment screening process put into effect in 2011.

Table 6: Examples of Modifications to the Methods Used to Screen Medicare Providers and Suppliers Under the Revised Enrollment Screening Process

Modification	Description	Implementation Date
Licensure continuous monitoring reports	The Licensure Continuous Monitoring Reports are utilized by Medicare contractors to validate licensure eligibility requirements and to take administrative action against providers and suppliers that do not meet those requirements.	November 2013
Fingerprint-based criminal background checks	Upon application for enrollment, fingerprint-based criminal background checks are conducted for categorical high-risk providers. ^a	August 2014
Criminal continuous monitoring reports	The Criminal Continuous Monitoring reports are utilized by the Centers for Medicare & Medicaid Services (CMS) to monitor provider and supplier criminal convictions. Contractors then take administrative action against providers and suppliers that do not meet those eligibility requirements.	July 2015
Increased site visits	In addition to the mandatory site visits to moderate- and high-risk providers, CMS has the authority, when deemed necessary, to perform onsite reviews of a limited-risk provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Under this authority, CMS has increased site visits for certain limited-risk providers and suppliers.	December 2015
Monthly monitoring of potentially invalid addresses	CMS has started to continuously monitor and identify addresses that may have become vacant or nonoperational after initial enrollment. This monitoring is done through monthly data analysis that validates provider and supplier enrollment practice location addresses against the U.S. Postal Service address verification database.	January 2016

Modification	Description	Implementation Date
Enhanced address verification	CMS recently replaced the Provider Enrollment, Chain, and Ownership System (PECOS) address verification software with new software that includes Delivery Point Verification in addition to the functionality that previously existed. ^b This new Delivery Point Verification functionality flags addresses that may be vacant, commercial mail reporting agencies, or invalid addresses. These verifications take place during the application submission process and may trigger additional ad hoc site visits.	January 2016

Source: GAO analysis of CMS information and interviews. | GAO-17-42.

^aCMS places all provider and supplier types into risk categories—limited, moderate, or high—based on CMS’s assessments of the potential risk of fraud, waste, and abuse each provider and supplier type poses to Medicare program integrity and designates specific screening activities for each risk category.

^bPECOS is CMS’s centralized database for Medicare enrollment information.

CMS has also made a number of operational modifications to the enrollment screening process used to revalidate existing providers and suppliers since 2011. These modifications include some that CMS officials said are intended to encourage providers to be more responsive to revalidation requests, such as establishing revalidation due dates that are posted online 6 months in advance and eliminating automatic approvals of provider and supplier requests for deadline extensions. Others are modifications that help the MACs better manage and streamline their operations, CMS officials said, such as eliminating the requirement for MACs to send CMS bi-monthly revalidation data, as MAC officials told us that CMS can pull that data directly from PECOS. CMS also began giving the MACs the lists of providers to contact for revalidation further in advance of the required mailing date than CMS did during the first program-wide revalidation cycle. CMS officials said these changes resulted from work groups that included CMS and MAC officials that were set up to identify and plan operational modifications to improve and streamline revalidation. See appendix II for examples of operational modifications CMS has made to the enrollment screening process used to revalidate existing providers and suppliers.

CMS plans to implement additional modifications using a detailed work plan, but has not yet determined these modifications. In March 2016, CMS officials said they plan to continue to work with the MACs to generate modifications as in the past, allowing each of the four MAC work groups, which according to CMS officials include CMS points-of-contact, to keep track of its own notes and individually manage its activities as it works to generate ideas and proposals for modifications that each work group then submits to CMS for consideration. While CMS did not use a detailed work plan to make operational modifications to the enrollment screening process in preparation for the second program-wide

revalidation effort, CMS officials said that the agency intends to develop a detailed work plan for the modifications they select for implementation, but have not yet set a time frame for developing such a plan. CMS officials stated that they have not yet determined future modifications and are waiting to see the results of the previous modifications before modifying the enrollment process further.

CMS Monitors Elements of Its Screening Process but Monitoring Is Limited by a Lack of Objectives and Performance Measures

CMS monitoring includes reviewing certain results of enrollment screening, examining the efficiency of the enrollment screening process, and evaluating the performance of contractors.

- CMS officials said that the agency reviews, at least monthly, information such as the number of deactivations and revocations, including the reasons for deactivations and revocations, the number of deactivations and revocations that result from fingerprint checks and site visits, and the number of provider and supplier revocations that are overturned upon appeal.
- CMS and MAC officials said they meet periodically to examine operational efficiency. For example, CMS officials met with the MACs to examine the efficiency of the first program-wide revalidation effort and reviewed operations to identify potential efficiency improvements. According to CMS and MAC officials, those meetings resulted in changes to operations, such as CMS giving MACs the lists of providers to contact for revalidation further in advance of the required mailing date. CMS and MAC officials said they convened work groups based on those meetings and are continuing to use those work groups to identify future operational modifications, as we noted earlier in this report.
- We found that CMS also annually evaluates contractor performance by comparing performance against specific measures for the MACs and other contractors that assist with enrollment screening, such as the site visit contractor. For example, CMS developed the Performance Assessment Program for the MACs, which includes three evaluative reviews—the Quality Control Plan review, the Quality Assurance Surveillance Plan review, and the Award Fee Plan review. The Quality Assurance Surveillance Plan review includes, and the Award Fee Plan review may include, contractor performance measures for provider enrollment. The contractor performance measures relate to MAC processing of provider enrollment

applications and are designed to assess elements such as timeliness and accuracy.²⁴

Despite these efforts, we found that CMS's monitoring of enrollment screening, including screening conducted as part of revalidation, lacks objectives and performance measures for assessing progress toward achieving its goals. In November 2015, CMS officials stated that the goals for the enrollment screening process are to (1) place providers and suppliers into proper risk categories and (2) effectively screen the providers in each category. According to CMS officials, the agency also set goals for its revalidation effort to (1) implement provisions of PPACA, (2) keep provider and supplier information up to date, (3) reduce improper payments, and (4) ensure program integrity. However, CMS officials said they have not established objectives and performance measures to use in monitoring progress toward achieving these goals. Federal internal control standards specify that management should define objectives in specific and measurable terms, establish appropriate performance measures for the defined objectives, and conduct ongoing monitoring so that progress toward achieving desired goals can be assessed.²⁵ In addition, leading practices call for performance measures to monitor and gauge results.

In March 2016, CMS officials said that the agency does not plan to develop any objectives or performance measures for enrollment screening, including screening conducted as part of revalidation, which is contrary to federal internal control standards and leading practices for managing programs. Performance measures focus on whether a program has achieved measurable standards. They allow agencies to monitor and report program accomplishments on an ongoing basis.²⁶ CMS officials stated that while they want to assess the screening process, they are uncertain of what performance measures to establish in part because they are concerned that some measures would be inappropriate. For

²⁴In other work we have examined CMS's evaluations of the MACs, including the Performance Assessment Program. For more information, see GAO, *Medicare Contracting Reform: Agency Has Made Progress with Implementation, but Contractors Have Not Met All Performance Standards*, [GAO-10-71](#) (Washington, D.C.: March 2010) and GAO, *Medicare Administrative Contractors: CMS Should Consider Whether Alternative Approaches Could Enhance Contractor Performance*, [GAO-15-372](#) (Washington, D.C.: April 2015).

²⁵See [GAO/AIMD-00-21.3.1](#) and [GAO-14-704G](#).

²⁶See [GAO-11-646SP](#).

example, CMS officials stated that while they review the number of deactivations and revocations, it would not be appropriate to have targets for deactivating or revoking a predetermined number of providers or suppliers. This is consistent with our previous work in which CMS officials stated that setting such targets could create incentives that could potentially jeopardize the quality of contractors' work.²⁷ We also previously reported that it is important that agencies avoid the appearance of striving to achieve certain numerical quotas regardless of quality.²⁸

However, without developing objectives and performance measures to use in ongoing monitoring, the agency will be unable to measure the progress it has made toward achieving its goals for the screening process and for revalidating provider and supplier enrollment information. We have previously reported that performance measurement gives managers crucial information to identify gaps in program performance and plan any needed improvements.²⁹ While there may be challenges in developing such objectives and performance measures, there are opportunities to do so that would allow CMS to better monitor the enrollment screening process without setting specific targets for the number of deactivations or revocations. For example, CMS could focus on developing objectives and performance measures related to its goals for enrollment screening, such as keeping enrollment information up to date. CMS officials have said that since the revised screening process took effect, providers and suppliers are more aware of their responsibilities to keep information up to date, and MAC officials have stated that providers and suppliers are more frequently providing MACs with changes of information. According to CMS officials, this may result in fewer deactivated enrollment records during the second program-wide revalidation effort. CMS officials said they regularly review the number of deactivated enrollment records, and the agency has information on the reasons for deactivation. Some of those reasons may be associated with failing to keep information up to date, such as nonresponse to requests for updated enrollment

²⁷See GAO, *Medicare Program Integrity: Contractors Reported Generating Savings, but CMS Could Improve Its Oversight*, [GAO-14-111](#) (Washington, D.C.: October 2013).

²⁸See GAO, *Intellectual Property: Federal Enforcement Has Generally Increased, but Assessing Performance Could Strengthen Law Enforcement Efforts*, [GAO-08-157](#) (Washington, D.C.: March 2008).

²⁹See GAO, *Managing for Results: Enhancing Agency Use of Performance Information for Management Decision Making*, [GAO-05-927](#) (Washington, D.C.: Sept. 9, 2005).

information. However, CMS has no objectives and performance measures for the reasons for deactivation to use in measuring progress toward its goal of keeping enrollment information up to date.

Conclusions

Effective provider and supplier enrollment screening is critical to ensuring program integrity and preventing improper payments. With its revised enrollment screening process, CMS has implemented a preventive risk-based strategy for achieving program integrity where increased scrutiny and greater resources are dedicated to providers and suppliers that present a higher potential risk of fraud, waste, and abuse. CMS has subsequently modified some elements and conducted monitoring of the process. However, CMS has not taken certain important steps that could help ensure the effectiveness of these actions. As CMS considers future modifications to the enrollment screening process and undertakes its second program-wide revalidation effort, opportunities exist to address limitations in its current monitoring of the process. By establishing specific objectives and performance measures for the enrollment screening process and periodically assessing the progress, the agency could better ensure the effectiveness of the screening process as a means of maintaining program integrity and limiting improper payments in Medicare.

Recommendation for Executive Action

To improve the efficiency and effectiveness of the agency's enrollment screening process, we recommend that the Administrator of CMS establish objectives and performance measures for assessing progress toward achieving its goals.

Agency Comments

We provided a draft of this report to HHS for comment, and its comments are reprinted in appendix III. HHS also provided technical comments, which we incorporated as appropriate.

In commenting on this report, HHS agreed with our recommendation. HHS stated that it will review the goals of the enrollment screening process and determine if there are appropriate objectives and performance measures for the program that the agency can establish.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health

and Human Services, the Administrator of the Centers for Medicare & Medicaid Services, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report are listed in appendix IV.

Sincerely yours,

A handwritten signature in black ink that reads "Kathleen M. King". The signature is written in a cursive, flowing style.

Kathleen M. King
Director, Health Care

Appendix I: Scope and Methodology for the Provider Enrollment, Chain and Ownership System Data Analysis

To examine the results of the revised enrollment screening process put into place in 2011, we analyzed data from provider and supplier enrollment records in the Provider Enrollment, Chain and Ownership System (PECOS), the Centers for Medicare & Medicaid Services' (CMS) centralized database for Medicare enrollment information. We analyzed PECOS data from March 25, 2011 (the date the new screening process went into effect) through December 31, 2015 (the most current data available at the time of our analysis) to determine (1) the number enrollment records and enrollment applications to which CMS applied the revised screening process, (2) the number of approved, denied, and rejected new enrollment applications, (3) the number of deactivated or revoked existing enrollment records, and (4) the number of enrollment records associated with providers and suppliers eligible to bill Medicare. We did not independently verify the accuracy of the PECOS data; however, we checked the PECOS data for obvious errors and omissions, compared analysis results to CMS publicly reported information on screening process outcomes, and interviewed CMS officials to resolve any identified discrepancies. On the basis of this review, we determined that the PECOS data were sufficiently reliable for the purposes of this report, and we accounted for any limitation in these data during our analyses, such as removing certain outcomes from our analysis of initial enrollment applications and removing enrollment records that did not have a risk category assigned in PECOS from our analysis of the percentages of deactivated and revoked enrollment records in each risk category.

To determine the number of enrollment records and enrollment applications to which CMS applied the revised enrollment screening process during the time period we reviewed, we analyzed PECOS data to identify which one of three distinct groups each enrollment record belonged. Specifically, we identified (1) the number of new enrollment application decisions made, (2) the number of enrollment records with a change in enrollment status, for example, from approved to deactivated, and (3) the number of approved enrollment records as of March 25, 2011, that did not have an enrollment status change during the time period. Each enrollment record could only fall in to a single group and we excluded from our analysis deactivated or revoked enrollment records that did not have an enrollment status change during the time period since CMS would not have applied the enrollment screening process to these enrollment records.

To determine the number of approved, denied, and rejected new enrollment applications during the time period we reviewed, we analyzed

PECOS data to calculate the number of enrollment applications by outcome. For the denied and rejected new enrollment applications, we analyzed the PECOS recorded reasons for the denial or rejection and calculated the number of denials and rejections by recorded reason and by provider and supplier risk category during that time period. CMS officials reported that there could be multiple reasons for a denial or rejection, but due to PECOS system limitations, the Medicare Administrative Contractors (MAC) responsible for enrolling providers and suppliers can only record one reason. In addition, the reason codes that can be recorded in PECOS changed during the time frame covered by our analysis.

To determine the number of existing enrollment records deactivated or revoked during the time period we reviewed, we analyzed PECOS data to identify enrollment record statuses that changed to deactivated or revoked during the time period. We identified both the total number of status changes, as well as the number of unique enrollment records deactivated or revoked. The total number of deactivations or revocations is greater than the number of unique enrollment records deactivated or revoked because a provider's or supplier's enrollment record could have been deactivated or revoked more than once during that time. For enrollment records with deactivated or revoked statuses, we analyzed the PECOS recorded reason for the deactivation or revocation and calculated the number of deactivations and revocations by recorded reason and by provider and supplier risk category during that time period. As with new enrollment application decisions, the reason codes that can be recorded in PECOS for existing enrollment records changed during the time period of our analysis.

To determine the number of enrollment records associated with providers and suppliers eligible to bill Medicare during the time period we reviewed, we analyzed PECOS data to calculate the total number of approved enrollment records on March 25, 2011, and on December 31, 2015.

Appendix II: Examples of Operational Modifications to Revalidation

The Centers for Medicare & Medicaid Services (CMS) has made operational modifications to revalidation since 2011. For example, in September 2014, CMS modified its guidelines so that the Medicare Administrative Contractors (MAC) need not obtain data missing from a provider's or supplier's application elsewhere if the information is disclosed in another place on the application or in the supporting documentation in the enrollment application submitted for revalidation. In addition, CMS made several modifications in preparation for the second program-wide enrollment record revalidation effort which began March 2016. Table 7 provides examples of these operational modifications, as described in CMS instructions to the MACs.

Table 7: Examples of Operational Modifications to the Revalidation of Medicare Providers and Suppliers Implemented in February 2016

Modification	Description
Distribution of revalidation notices	The Centers for Medicare & Medicaid Services (CMS) provides Medicare Administrative Contractors (MACs) with 12 months' worth of revalidation due dates at a time. The MACs have the opportunity to review and alter a provider's or supplier's due date month based on staffing levels and workload.
Fixed revalidation dates	CMS takes the confirmed lists of revalidation due dates that the MACs provide and generates a final list that captures a fixed revalidation date for each enrollment.
Posted revalidation dates	CMS will post a list of all currently enrolled providers and suppliers, along with their established revalidation due date, to https://data.cms.gov . The revalidation due date will be posted up to 6 months in advance of the date to provide sufficient notice and time for the provider or supplier to comply. A crosswalk to the organizations that the individual providers and suppliers reassign benefits to will also be available.
Standardization of revalidation letters	The MACs are required to send a revalidation notice between 75 to 90 days prior to the revalidation due date posted to the CMS website, using a sample revalidation letter provided by CMS as the template.
Emailed notices of revalidation	The MACs are allowed to send revalidation notices via email if this option is in line with the contractor's security requirements and capabilities.
Return of unsolicited revalidation applications	The MACs are required to return all revalidation applications received more than 6 months prior to the provider's or supplier's established due date using a "return letter" template provided by CMS. The MACs must accept and process revalidation applications submitted within 6 months of their due date.
Identification of reassignment associations	When issuing revalidation notices to individual group members, the MACs must identify on the revalidation notice the name of the organization(s) that the provider reassigns benefits to in lieu of including the provider's Provider Transaction Access Number (PTAN). This modification was made in part because individual group members may be more familiar with the legal business name or Doing Business As name of the organizations they are associated with than with their PTANs.
Elimination of required contractor follow-up phone calls	The MACs may continue to contact providers and suppliers via telephone or email to communicate nonreceipt of revalidation applications, but these contacts are no longer required.
Elimination of automatic approval of extension requests	Eliminates the approval of extension requests except in extenuating circumstances. The MACs must contact CMS for review and approval if any requests for an extension are received.
Single development requests	The MACs are required to develop for all information missing from a revalidation application (i.e., missing application fee, signatures, etc.) in one development request.

**Appendix II: Examples of Operational
Modifications to Revalidation**

Modification	Description
Deactivation for nonresponse to development	The MACs are required to deactivate the provider or supplier within 25 days after the development due date if the missing information identified in a development request is not received within 30 days, and to notify the provider or supplier using a “stopping billing privileges” letter template provided by CMS.
Reduction in the duration of payment hold	The MACs are required to continue to apply a payment hold in the Provider Enrollment, Chain and Ownership System (PECOS) enrollment database if the provider or supplier fails to respond to the revalidation request. The MACs are required to perform this action within 25 days after the revalidation due date and may, but are not required to, notify the provider or supplier of the payment hold.
Changes to the consequences of deactivation	The MACs are required to deactivate a provider or supplier enrollment record for failure to respond to a revalidation request between days 60-75 after the revalidation due date and to notify the provider or supplier using a “stopping billing privileges” letter template provided by CMS. While the provider or supplier shall maintain their original PTAN, the MACs will reflect a gap in coverage between the deactivation and reactivation of billing privileges on that existing PTAN. The provider or supplier will not be able to bill for dates of service in which they were not in compliance with Medicare requirements.
Elimination of the bi-monthly contractor report	The MACs are no longer required to submit certain previously required reports on the 5th and 20th of each month, but will maintain internally the method of delivery for the provider and supplier revalidation notices and the date the email or letter was sent.
Systematic deactivations for nonbilling	CMS will conduct routine analysis of providers and suppliers that have not billed for the previous 13 consecutive months. The nonbilling PTANs will be deactivated systematically by CMS.

Source: GAO analysis of CMS instructions for process modifications. | GAO-17-42.

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

OCT 31 2016

Kathleen King
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. King:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Medicare: Initial Results of Revised Process to Screen Providers and Suppliers, and Need for Objectives and Performance Measures*" (GAO-17-42).

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

Sincerely,

A handwritten signature in dark ink, reading "Jim R. Esquea", is positioned above the printed name and title.

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO'S) DRAFT REPORT ENTITLED: MEDICARE: INITIAL RESULTS OF REVISED PROCESS TO SCREEN PROVIDERS AND SUPPLIERS, AND NEED FOR OBJECTIVES AND PERFORMANCE MEASURES (GAO-17-42)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on GAO's draft report. HHS is strongly committed to robust program integrity efforts in Medicare and is continuously working to enhance the provider enrollment and screening process.

In February 2011, HHS finalized regulations to implement categorical risk-based screening of newly enrolling Medicare providers and suppliers and to revalidate all current Medicare providers and suppliers under new requirements established by the Affordable Care Act. Limited risk providers and suppliers undergo verification of licensure, verification of compliance with federal regulations and state requirements, and checks against various databases. Moderate and high risk providers and suppliers undergo additional screening, including unannounced site visits. Additionally, individuals with a five percent or greater direct or indirect ownership interest in a high risk provider or supplier must consent to criminal background checks, including fingerprinting.

HHS screened over 2.4 million new applications and existing records under categorical risk-based screening and avoided \$2.4 billion in Medicare payments to ineligible providers and suppliers from March 2011 to May 2015. HHS has also taken actions to deactivate billing privileges for more than 543,000 providers and suppliers as a result of revalidation and other screening efforts and more than 34,000 providers and supplier enrollments have been revoked. All existing Medicare providers and suppliers enrolled prior to the new screening requirements becoming effective were sent revalidation notices by March 23, 2015.

HHS was also able to identify provider and supplier enrollment records that warranted increased scrutiny and improve the accuracy and completeness of data in the Provider Enrollment, Chain and Ownership System (PECOS), HHS' provider enrollment database. In addition, HHS has performed nearly 250,000 site visits on Medicare providers and suppliers. HHS uses site visits to verify that a provider's or supplier's practice location meets Medicare requirements, which helps prevent questionable providers and suppliers from enrolling or maintaining enrollment in the Medicare program.

In April 2014, HHS partnered with an automated screening contractor to screen all providers and suppliers to identify any criminal background histories or licensure issues that would prevent them from being enrolled in Medicare. HHS has since screened more than 1.6 million active providers and suppliers through this process and regularly screens newly enrolled providers and suppliers in addition to re-screening currently enrolled providers and suppliers. The automatic screening process flags necessary application information for further review and verification.

In February 2016, HHS proposed new provider enrollment regulations to help make certain that entities and individuals who pose risks to the Medicare program and beneficiaries are kept out of or removed from Medicare for extended periods. These proposed enhancements would allow HHS to take action to remove or prevent the enrollment of health care providers and suppliers that attempt to circumvent Medicare's enrollment requirements through name and identity changes as well as through elaborate, inter-provider relationships.

GAO's recommendations and HHS' responses are below.

GAO Recommendation

To improve the efficiency and effectiveness of the agency's enrollment screening process, we recommend that the Administrator of CMS establish objectives and performance measures for assessing progress towards achieving its goals.

HHS Response

HHS concurs with GAO's recommendation. HHS will review the goals of the enrollment screening process and determine if there are appropriate objectives and performance measures for the program that HHS can establish.

HHS thanks GAO for their efforts on this issue and looks forward to working with GAO on this and other issues in the future.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, Karen Doran (Assistant Director), Peter Mangano (Analyst-in-Charge), Cathy Hamann, Colbie Holderness, Sylvia Diaz Jones, and Daniel Ries made key contributions to this report. Also contributing were Muriel Brown, Christine Davis, and Jennifer Whitworth.

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