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Report to Congressional Committees

December 2022

MEDICARE

CMS Needs to Address Risks Posed by Provider Enrollment Waivers and Flexibilities

GAO-23-105494

GAO Highlights

Highlights of GAO-23-105494, a report to congressional committees

December 2022

MEDICARE

CMS Needs to Address Risks Posed by Provider Enrollment Waivers and Flexibilities

Why GAO Did This Study

Medicare is on GAO's high-risk list due to its size, complexity, and vulnerability to improper payments, estimated at $47 billion in 2022. Medicare waivers and flexibilities during emergencies can help maintain access to Medicare services but also pose risks by removing program safeguards.

The CARES Act directs GAO to monitor the federal COVID-19 pandemic response. This report (1) describes Medicare waivers and flexibilities in response to the pandemic, (2) describes changes in Medicare provider enrollment after implementing waivers and flexibilities, and (3) examines CMS's oversight of waivers and flexibilities.

GAO reviewed relevant documents including CMS policies, such as waivers and flexibilities that it had issued. GAO analyzed Medicare provider enrollment data on the use of waivers and flexibilities from March 2020 through March 2022 and Medicare claims data from April 2020 through December 2021. GAO also interviewed officials from CMS and five Medicare contractors selected based on the geographic region where they operate, among other factors.

What GAO Recommends

GAO is making four recommendations to CMS including conducting fingerprint-based criminal background checks, increasing the pace of revalidating provider eligibility, and evaluating opportunities for improvement in planning for future emergencies. CMS concurred with GAO's recommendations.

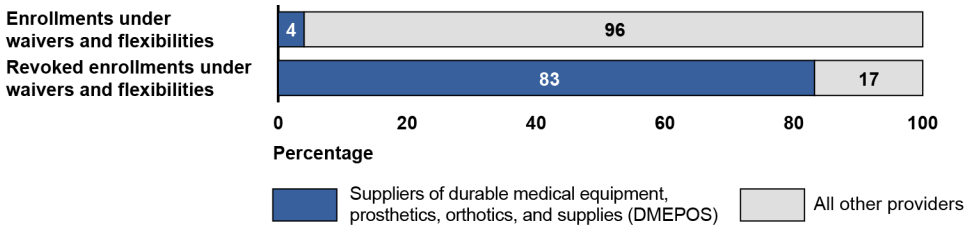
View GAO-23-105494. For more information, contact Leslie V. Gordon at (202) 512-7114 or gordonlv@gao.gov.

What GAO Found

GAO identified 47 waivers and flexibilities that the Centers for Medicare & Medicaid Services (CMS) issued to sustain Medicare's provider workforce capacity and beneficiary access to services during the COVID-19 pandemic. This included changes to provider enrollment screening, such as waiving about 7,300 fingerprint-based criminal background checks for provider types posing a high risk for fraud, waste, and abuse. It also included postponing site visits for high- and moderate-risk provider types, and postponing revalidating provider eligibility for all providers. In addition, CMS approved other waivers and flexibilities relating to clinicians' scope of practice and training, particularly for rural areas.

GAO found that about 220,000 providers enrolled under waivers and flexibilities from March 2020 through March 2022. Suppliers of durable medical equipment, prosthetics, orthotics, and supplies—a provider type CMS considers to pose a moderate or high risk for fraud, waste, and abuse—represented a small share (4 percent) of these enrollments. However, they were a large majority (83 percent) of the 208 enrollments CMS later revoked after finding they were ineligible. While this is not a large share of enrollments, even a small number of providers can cause significant financial harm if they commit fraud.

Percentage of Medicare Provider Enrollments and Revoked Enrollments under Waivers and Flexibilities, March 2020 through March 2022



Source: GAO analysis of data from the Centers for Medicare & Medicaid Services. | GAO-23-105494

CMS took steps to oversee providers who enrolled under waivers and flexibilities. Steps included monitoring providers' enrollment and billing information for potential fraud; conducting investigations; and applying safeguards, such as referring potential fraud to law enforcement. However, CMS has not fully addressed risks from provider enrollment waivers and flexibilities:

- **Fingerprint-based criminal background checks**: When waiving these checks, CMS officials intended to perform them later for providers enrolled under the waiver. However, CMS has not yet performed these checks.
- **Revalidating provider eligibility:** Without increasing pace and prioritization, CMS may not complete all 237,000 postponed revalidations of providers' eligibility before new revalidations are due, which occurs every 3 to 5 years.

There may be ways to improve the future use of provider enrollment waivers and flexibilities, according to CMS officials and contractor representatives. For example, maintaining requirements for providers posing a high risk of fraud may be appropriate. However, CMS has not planned an evaluation of these waivers and flexibilities, although the agency committed to do so in its *Pandemic Plan*.

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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 Contractors

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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Congressional Committees

Responding to the COVID-19 pandemic, the Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for overseeing Medicare and more than 2 million enrolled health care providers across all types, issued dozens of waivers and other flexibilities to change provider requirements.[1] CMS intended for these waivers and flexibilities to make it easier for certain providers to enroll in Medicare in order to sustain provider workforce capacity to meet beneficiaries' health care needs.[2] The COVID-19 pandemic increased beneficiaries' health care needs by disproportionately affecting seniors and other populations served by Medicare who rely on the program to pay for health care services. Specifically, by August 2022, individuals ages 65 and older represented 75 percent of COVID-19 deaths, even though that age group constituted about 17 percent of the U.S. population.[3]

Medicare providers affected by CMS's actions include physicians, nurse practitioners, and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) among others. CMS establishes the Medicare requirements providers must meet, such as upfront enrollment requirements, and ongoing requirements, such as annual training.[4] These

[1]CMS is an agency within the Department of Health and Human Services (HHS). Section 1135 of the Social Security Act (hereafter "Section 1135") authorizes the Secretary of Health and Human Services to temporarily waive or modify certain federal health care requirements, including in the Medicare program, to increase access to medical services when both a public health emergency and a disaster or emergency have been declared. See 42 U.S.C. § 1320b-5. For purposes of this report, we collectively refer to Section 1135 waivers and other changes to requirements made in response to COVID-19 as "waivers and flexibilities."

[2]For purposes of this report, providers include physicians and other clinicians or health care workers; DMEPOS suppliers; home health agencies; hospice organizations; and non-institutional providers such as ambulances or other free-standing facilities, such as clinical laboratories, unless otherwise specified.

[3]Centers for Disease Control and Prevention, "Demographic trends of COVID-19 cases and deaths in the US reported to the CDC," *COVID Data Tracker* (Aug. 29, 2022), accessed August 29, 2022, https://covid.cdc.gov/covid-data-tracker/#demographics.

[4]In addition to federal requirements, providers are also generally subject to state laws and regulations, such as those governing licensing and scope of practice.

requirements serve as program safeguards that promote program integrity by reducing risks of fraud and that help ensure patient safety.

GAO has designated Medicare a high-risk program, due in part to its size, complexity, and vulnerability to improper payments, including fraud, waste, and abuse.[5] Although the extent of fraud in Medicare is unknown, given the large size of the program, even a small percentage of fraud poses significant risks to the integrity of the program. In 2022, the Medicare program will spend an estimated $940 billion on health care services for 65 million beneficiaries, and estimated improper payments reported for the program were $47 billion.[6] In May 2021, we testified that careful monitoring and oversight is warranted to prevent potential fraud, waste, and abuse that can arise from waivers and flexibilities that CMS issued in response to the pandemic.[7]

Given the importance of maintaining provider workforce capacity and safeguarding the Medicare program, especially during public health emergencies, you asked us to review waivers and flexibilities that CMS issued to respond to COVID-19 and the effects of those waivers and flexibilities. In addition, the CARES Act includes a provision for GAO to report on its ongoing monitoring and oversight efforts related to the COVID-19 pandemic.[8] In this report, we

1. describe the Medicare waivers and flexibilities CMS issued to sustain provider workforce capacity in response to the COVID-19 pandemic;
2. describe changes in Medicare provider enrollment after the implementation of waivers and flexibilities; and
3. examine CMS's oversight of the waivers and flexibilities it issued.

[5]See GAO, *High-Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas*, GAO-21-119SP (Washington, D.C.: Mar. 2, 2021). Improper payments are those that should not have been made or were made in an incorrect amount, including overpayments and underpayments under statutory, contractual, administrative, or other legally applicable requirements.

[6]While not all improper payments are the result of fraud, all payments made as a result of fraudulent activities are considered to be improper payments. Improper payment estimates are not intended to measure fraud in a particular program.

[7]GAO, *Medicare and Medicaid: COVID-19 Program Flexibilities and Considerations for Their Continuation,* GAO-21-575T (Washington, D.C.: May 19, 2021).

[8]Pub. L. No. 116-136, § 19010(b), 134 Stat. 281, 580 (2020).

To describe the Medicare waivers and flexibilities issued to sustain provider workforce capacity, we reviewed CMS descriptions of Section 1135 waivers, CMS rulemaking from March 2020 through December 2021, and relevant guidance documents provided to us by CMS officials. We identified Medicare waivers and flexibilities to sustain provider workforce capacity, and confirmed the waivers and flexibilities we identified with agency officials to ensure their accuracy and completeness. We did not include waivers or flexibilities expanding the use of telehealth, which we have addressed in a separate report, or waivers or flexibilities that applied only to individual providers who requested waivers or flexibilities based on their specific circumstances.[9] We interviewed CMS officials and reviewed CMS's rulemaking and assessments of waivers and flexibilities to identify the factors the agency considered when making decisions to issue, end, or continue the waivers and flexibilities beyond the end of the COVID-19 public health emergency.

To describe Medicare provider enrollment after the implementation of selected waivers and flexibilities, we analyzed agency documentation and Medicare data on provider enrollment and Medicare fee-for-service claims, and we interviewed CMS officials. We reviewed the Department of Health and Human Services' (HHS) *Agency Financial Report* for fiscal years 2019 through 2021 to determine historical trends in the total number of provider enrollments that were active, across all provider types.[10] In addition, we analyzed CMS data on Medicare providers' enrollments under waivers and flexibilities from March 2020, when initial

[9]GAO, *Medicare Telehealth: Actions Needed to Strengthen Oversight and Help Providers Educate Patients on Privacy and Security Risks*, GAO-22-104454 (Washington, D.C.: Sept. 26, 2022).

[10]A provider enrollment represents a single Medicare enrollment for a provider. It might not represent a unique provider because a provider can have multiple enrollments. 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.

waivers and flexibilities were issued, through March 2022.[11] We analyzed Medicare fee-for-service claims data to identify expenditures associated with providers who enrolled under waivers and flexibilities.[12] We analyzed claims data from April 2020, the month after initial waivers and flexibilities were issued, through calendar year 2021, the most recent year of data available at the time of our review. In addition, we analyzed changes in the utilization of certain Medicare services or by certain Medicare providers associated with certain provider scope-of-practice waivers and flexibilities, selected based on the availability of relevant claims data to identify trends.[13]

We assessed the reliability of CMS data on Medicare providers who enrolled in the program under waivers or flexibilities by comparing these data with data on these provider enrollments in the Provider Enrollment, Chain, and Ownership System.[14] Medicare claims data are used by Medicare as a record of payments to health care providers and are closely monitored by both CMS and the Medicare contractors that process, review, and pay claims. On this basis, we determined that these data were sufficiently reliable for the purposes of our report.

To examine CMS's oversight of the types of waivers and flexibilities it issued, we reviewed relevant agency documentation and interviewed

[11]Data on Medicare provider enrollments under waivers and flexibilities describe all enrollments across all provider and supplier types that were new or were changed under certain waivers and flexibilities. For example, these data include enrollments under waivers of site visits for new enrollments or enrollments with new practice locations added. They also include new enrollments under waivers of fingerprint-based criminal background checks. These data do not include enrollments that only used waivers postponing provider enrollment revalidation or certain flexibilities applied to provider enrollment processing that had little effect on provider enrollment screening or claims payment. Not all provider enrollments that were new or changed during the time period covered by these data occurred under waivers and flexibilities.

[12]Specifically, we analyzed claims from CMS's carrier claims and durable medical equipment claims files.

[13]Providers' scope of practice defines the range of activities that different types of providers are permitted to perform. These activities can include which types of providers can order tests, make diagnoses, perform procedures, and prescribe medications. Selected waivers and flexibilities include allowing physician assistants, nurse practitioners, and clinical nurse specialists to begin home health certifications and allowing certain resident physicians to conduct more complex patient visits to evaluate and manage conditions.

[14]CMS's Provider Enrollment, Chain, and Ownership System is the agency's centralized database for Medicare enrollment information.

CMS officials and CMS contractor representatives. Specifically, we reviewed documentation of CMS's policies and activities to conduct oversight of Medicare provider enrollment, scope-of-practice, and other waivers and flexibilities. To examine these activities, we interviewed agency officials and representatives from selected Medicare Administrative Contractors (MAC) and unified program integrity contractors.[15] We selected three of the seven MACs and two of the three program integrity contractors to interview based on geographic variation and, in the case of MACs, variation in the types of providers they screen to ensure the selection covered all provider types. In addition, we reviewed CMS analyses of the number of Medicare providers who enrolled in the program under waivers or flexibilities and CMS's monitoring of these providers. We assessed CMS's oversight activities to protect Medicare from fraud, waste, and abuse, and act on opportunities to improve the agency's pandemic response against its *Pandemic Plan,* which provides a framework for CMS's response to pandemics.[16] In addition, we assessed the agency's activities against the risk assessment, information and communication, and monitoring components of federal internal control standards, including the underlying principle that management should identify, analyze, and respond to risks related to achieving the defined objectives.[17]

We conducted this performance audit from October 2021 to December 2022 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

[15]Seven MACs conduct provider enrollment screening and reach decisions on providers' applications for enrollment. One of these MACs also serves as the National Supplier Clearinghouse, which screens and enrolls DMEPOS suppliers. For the purposes of this report, MAC refers to both MACs and the National Supplier Clearinghouse unless otherwise noted. Three unified program integrity contractors—referred to as program integrity contractors for the purposes of this report—detect and investigate aberrant provider behavior and potential fraud in Medicare.

[16]Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Pandemic Plan*, V. 3.1. Public Release (updated Jan. 11, 2021).

[17]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: Sept. 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.

that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Medicare Provider Screening and Enrollment

Since 2011, CMS has used authorities granted by the Patient Protection and Affordable Care Act to screen new and certain existing providers to determine if they are eligible to enroll, or remain enrolled, in and bill Medicare for items or services provided to beneficiaries.[18] Enrollments can be either new, updated (for example, an existing enrollment that added a new practice location), or reactivated from an inactive enrollment. Providers face different enrollment requirements depending on the level of risk CMS has assigned to their provider type. CMS places all provider types into one of three risk categories: limited, moderate, or high.

CMS contracts with MACs to screen providers in all risk categories to verify that they meet Medicare requirements before enrolling providers and periodically after enrollment. For example, MACs are responsible for screening all providers, including ensuring they have current federal or state licenses or accreditation. For moderate- and high-risk provider types, Medicare regulations additionally require an onsite review, known as a site visit.[19] The site visit is to determine whether the reported practice locations are operational, meet requirements, and are appropriate for billed procedures. In addition, for high-risk provider types, all individuals who maintain a 5 percent or greater interest in the provider are required to undergo a fingerprint-based criminal background check to identify any criminal convictions for which the individual may or must be excluded from participation in Medicare.[20] For example, CMS may deny enrollment of a prospective provider (or revoke enrollment of an enrolled provider) with a felony conviction in the preceding 10 years that CMS has determined to be detrimental to the program and its beneficiaries, such as insurance fraud or assault.[21] (See table 1.)

[18]Pub. L. No. 111-148, § 6401(a), 124 Stat. 119, 747 (codified as amended at 42 U.S.C. § 1395cc(j)).

[19]42 C.F.R. §§ 424.518(b)(2)(ii) (moderate-risk), 424.518(c)(2)(i) (high-risk) (2022).

[20]42 C.F.R. § 424.518(d) (2022).

[21]See 42 C.F.R. §§ 424.530(a)(3) (denial), 424.535(a)(3) (revocation) (2022).

Table 1: Provider Risk Levels for Fraud, Waste, and Abuse as Defined by CMS and Examples of Provider Types and Provider Screening Activities

Risk level for fraud, waste, and abuse	Examples of provider types	Examples of provider screening activities
Limited	• Physician practitioners • Other clinicians, including nurse practitioners, physician assistants, and clinical nurse specialists	• Confirmation of practice location addresses • Licensure verifications • Federal database checks to ensure providers meet the enrollment criteria for their provider type
Moderate	• Hospice organizations • Independent clinical laboratories • Home health agencies revalidating enrollment[a] • Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) revalidating enrollment[a]	• All screening activities for limited-risk provider types • Provider site visits to verify the accuracy of enrollment information • Verification of required accreditation for DMEPOS suppliers[b]
High	• Prospective (newly enrolling) home health agencies • Prospective (newly enrolling) DMEPOS	• All screening activities for limited- and moderate-risk provider types • Fingerprint-based criminal background checks

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) guidance. | GAO-23-105494

Note: For purposes of this report, we use the term "providers" to include physicians and other clinicians or health care workers; DMEPOS suppliers; home health agencies; hospice organizations; and non-institutional providers such as ambulances or other free-standing facilities, such as clinical laboratories, unless otherwise specified.

[a]Most providers must revalidate their Medicare enrollment every 5 years, while DMEPOS suppliers must do so every 3 years. See 42 C.F.R. §§ 424.515, 424.57(g) (2022).

[b]Accreditation is generally required for all DMEPOS suppliers regardless of risk level. See 42 C.F.R. § 424.57(c)(22) (2022).

After enrolling in Medicare, providers must generally report changes to their enrollment information and, by law, periodically resubmit enrollment information for revalidation to maintain their billing privileges.[22] MACs use the enrollment screening process to revalidate provider enrollment information and ensure that provider enrollment information on file remains complete and up-to-date. Most providers must complete this revalidation process every 5 years, while DMEPOS suppliers must do so every 3 years under CMS regulations.[23]

Federal and State Scope of Practice Requirements

In general, Medicare providers must meet both federal and state scope-of-practice requirements. Federal laws and regulations specify the types of providers who may furnish and bill for covered Medicare items and services—such as ordering tests, performing procedures, and prescribing

[22]See 42 U.S.C. § 1395cc(j)(2)(D)(iv).

[23]See 42 C.F.R. §§ 424.515, 424.57(g) (2022).

medications—and the level of supervision required. For example, Medicare regulations address what services resident physicians, who are still completing their graduate medical education, can provide to Medicare beneficiaries and the type of supervision that is required from a teaching physician.

In addition, states commonly regulate health care providers by granting licenses to qualified providers. In granting these licenses, states can define minimum qualifications for each type of provider and regulate each type of provider's scope of practice. For example, some states permit nurse practitioners to prescribe medication, diagnose patients, and provide treatment without the presence of a physician. Other states require nurse practitioners to obtain a physician's authorization to prescribe medication.[24]

Medicare Waivers and Flexibilities to Address Public Health Emergencies

Under Section 1135 of the Social Security Act, the circumstances surrounding the COVID-19 pandemic in March 2020 triggered temporary authority for CMS to waive or modify Medicare requirements in response to the COVID-19 public health emergency.[25] In March 2020, CMS issued initial guidance waiving or modifying various Medicare requirements in response to COVID-19, including the need to sustain Medicare providers' workforce capacity. Further, CMS also used its non-emergency authorities to issue and amend Medicare regulations and sub-regulatory guidance throughout the COVID-19 public health emergency. As a result, some of the changes to Medicare requirements made during the COVID-19 public health emergency apply temporarily, while others are permanent, absent additional congressional or agency action. For purposes of this report, we refer to these waivers, regulatory amendments, and sub-regulatory changes as waivers and flexibilities.

[24]National Academies of Sciences, Engineering, and Medicine, *The Future of Nursing 2020-2030: Charting a Path to Achieve Health Equity*, (Washington, DC: The National Academies Press, 2021).

[25]On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency for the United States, retroactive to January 27. Subsequently, on March 13, 2020, the President declared COVID-19 a national emergency under the National Emergencies Act and a nationwide emergency under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act). See 50 U.S.C. § 1601 et seq. and 42 U.S.C. § 5121 et seq. These two actions triggered the availability of authority under Section 1135 for the Secretary of Health and Human Services to temporarily waive or modify Medicare program requirements, such as by issuing a blanket waiver. See 42 U.S.C. § 1320b-5. The Administrator of CMS typically implements Section 1135 waivers for Medicare.

CMS's *Pandemic Plan* describes the agency's policies for responding to pandemics, including Medicare oversight activities to protect the program and beneficiaries. These oversight activities include reviewing waivers and flexibilities to establish safeguards for fraud prevention, and evaluating CMS's pandemic response to identify areas for improvement.

CMS Issued 47 Waivers and Flexibilities Related to Provider Enrollment, Clinicians' Scope of Practice, and Training

We identified 47 Medicare waivers and flexibilities that CMS issued to sustain Medicare provider workforce capacity and thereby maintain beneficiary access to services during the COVID-19 public health emergency. These changed various Medicare requirements, including those related to provider enrollment, clinicians' scope of practice, and training.

CMS Issued Enrollment Waivers and Flexibilities for Providers across All Risk Levels to Maintain Beneficiary Access

Our review of agency documentation shows that in March 2020, CMS issued seven provider enrollment waivers affecting enrollments across all fraud risk levels. According to CMS's *Pandemic Plan,* CMS made these changes to expedite provider enrollment in Medicare so that more providers could deliver services and receive payments. (See table 2 for a list of provider enrollment waivers and flexibilities, and appendix I for a full list of CMS workforce capacity waivers and flexibilities.) According to representatives from three MACs, the provider enrollment waivers and flexibilities reduced application processing times. In addition, two of the three MACs said that these waivers and flexibilities expanded the provider workforce, such as enabling licensed providers in retirement to return to work to deliver services.

Table 2: Medicare Provider Enrollment Waivers or Flexibilities Issued to Sustain Workforce Capacity during the COVID-19 Public Health Emergency by CMS's Risk Categories for Fraud, Waste, and Abuse

Title of provider enrollment waiver or flexibility[a]			Provider risk category		
	Effective date	End date	High	Moderate	Limited
Waives fingerprint-based criminal background checks	March 1, 2020	October 31, 2021	✓	-	-
Postpones site visits	March 1, 2020	July 6, 2020	✓	✓	-
Postpones accreditation for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)[b]	March 1, 2020	July 6, 2020	✓	✓	-
Allows certain providers who opted out of Medicare to terminate their opt-out status early and enroll in Medicare[c]	March 1, 2020	End of public health emergency[d]	✓	-	✓
Postpones provider enrollment revalidation	March 1, 2020	October 31, 2021	✓	✓	✓
Waives application fee	March 1, 2020	October 2021	✓	✓	✓
Expedites review of any pending or new applications from providers	March 1, 2020	End of public health emergency[d]	✓	✓	✓

Legend:
✓ = provider enrollments in this risk category were subject to the waiver or flexibility.
- = provider enrollments in this risk category were not subject to the waiver or flexibility.

Source: GAO analysis of information from the Centers for Medicare & Medicaid Services (CMS). | GAO-23-105494

[a]We use the term "providers" to include physicians and other clinicians or health care workers; DMEPOS suppliers; home health agencies; hospice organizations; and non-institutional providers such as ambulances or other free-standing facilities, such as clinical laboratories, unless otherwise specified.

[b]This accreditation waiver applies only to newly enrolling and expiring accreditations of current DMEPOS suppliers for 90 days. CMS considers these provider types to be either a high- or moderate-risk for fraud, waste, and abuse. In addition, CMS waived the requirements that DMEPOS suppliers maintain a physical facility, a primary business telephone, and be open to the public a minimum of 30 hours per week. CMS resumed these requirements effective July 6, 2020, consistent with when CMS resumed site visits.

[c]Providers may opt out of Medicare enrollment—generally for at least 2 years—to serve Medicare beneficiaries based on a private contract rather than terms established by the Medicare program.

[d]The Secretary of Health and Human Services first declared the COVID-19 public health emergency on January 31, 2020, and renewed this determination 11 times. The public health emergency was most recently renewed on October 13, 2022, and expires January 11, 2023. During the COVID-19 public health emergency, the Department of Health and Human Services made widespread use of authority under section 1135 of the Social Security Act to waive or modify certain Medicare requirements to maintain beneficiary access to care. See 42 U.S.C. § 1320b-5. For purposes of this report, we collectively refer to these waivers and other changes to requirements made in response to COVID-19 as "waivers and flexibilities."

As table 2 shows, CMS changed some provider enrollment requirements that only applied to high- or moderate-risk provider types.

- **Fingerprint-based criminal background checks.** CMS waived these checks of high-risk provider types for 18 months, from March 1,

2020, through October 31, 2021. CMS data show that during this period, about 7,300 high-risk provider types enrolled in Medicare.

- **Site visits at provider locations.** CMS postponed onsite review of a provider's location, for approximately 14,800 enrollments of high- and moderate-risk provider types for more than 4 months, from March 1, 2020, through July 6, 2020.[26] According to two MACs, changing this requirement reduced application processing times because site visits for new enrollments could normally take up to 15 days to complete.
- **Accreditation for DMEPOS suppliers.** CMS postponed accreditation requirements allowing about 800 DMEPOS suppliers, who it considers high- or moderate-risk, to enroll without accreditation from March 1, 2020, through July 6, 2020. Under normal circumstances, this accreditation certifies that suppliers meet certain DMEPOS quality standards set forth by law.[27] When CMS reinstated the DMEPOS accreditation requirement in July 2020, it required all DMEPOS suppliers that had enrolled without accreditation to obtain it.

In addition to changing some provider enrollment requirements for high- and moderate-risk provider types, CMS directed MACs to establish toll-free hotlines for certain providers, including physicians and other clinicians, to enroll and receive temporary Medicare billing privileges. According to agency documentation, these hotlines expedited the enrollment process, allowing certain providers to enroll the same day. These temporary enrollments will expire soon after the end of the public health emergency, unless renewed.[28]

When deciding to issue waivers soon after the public health emergency was declared in March 2020, CMS used past experience from previous emergencies, such as natural disasters, according to agency officials. Agency officials and documentation showed CMS also engaged subject

[26]As of April 2022, CMS had completed approximately 11,200 of the site visits that were postponed from March 1, 2020, through July 6, 2020.

[27]See 42 U.S.C. § 1395m(a)(20). CMS's DMEPOS quality standards contain two sets of requirements. The first, supplier business service requirements, contains standards for suppliers' administrative practices, including financial management and consumer services. The second section, supplier product-specific service requirements, includes requirements related to patient intake and assessment, equipment delivery and set up, and follow-up services. The standards also have requirements for specific items and services, such as respiratory equipment and manual wheelchairs.

[28]When the public health emergency ends, CMS will require providers with temporary enrollments to submit complete applications for enrollment. Providers will have 30 days to respond to the request for an application.

matter experts, including senior clinicians, and agency leadership to review and approve potential changes to Medicare requirements throughout the public health emergency. CMS officials said they considered the extent to which provider enrollment waivers and flexibilities might create risks to program integrity and whether such risks could be mitigated by other practices. For example, CMS monitored databases for criminal records among high-risk providers whose fingerprint-based criminal background checks were waived. Agency officials said they decided to end certain changes early, such as the waiver of in-person site visits, when declining COVID-19 risks enabled them to do so. They added that they continually reassessed the need for waivers or flexibilities.

CMS Issued Waivers and Flexibilities for Scope-of-Practice, Training, and Other Requirements, Particularly in Rural Areas

In addition to the provider enrollment waivers, CMS issued 40 other workforce capacity waivers and flexibilities during the COVID-19 public health emergency, including 17 changes related to providers' scope of practice, according to our review of agency documentation. Most of these waivers and flexibilities were effective March 1, 2020. The agency said these changes expanded the health care workforce by reducing burden on physicians, expanding the care other clinicians can provide, and postponing required training. In particular, the scope-of-practice waivers and flexibilities removed certain federal Medicare requirements and deferred to state requirements. For example, the agency allowed physicians in long-term care and certain related facilities to delegate required physician visits to nurse practitioners, among others, to the extent this was allowed by states. See table 3 for an overview of waivers and flexibilities related to scope-of-practice, training, and other requirements and appendix I for a full list of waivers and flexibilities CMS issued to sustain workforce capacity.

Table 3: Medicare Scope-of-Practice, Training, and Other Waivers and Flexibilities Issued to Sustain Workforce Capacity during the COVID-19 Public Health Emergency

Category of waivers and flexibilities	Number of waivers and flexibilities	Example of waiver or flexibility
Scope of practice: Supervision of clinicians or services performed by clinicians	11	Anesthesia services at hospitals, critical access hospitals, and ambulatory surgical centers: Waives federal requirements that a certified registered nurse anesthetist be under the supervision of a physician.
Scope of practice: Delegation of duties from one type of clinician, such as a physician, to another, such as a nurse practitioner	5	Physician visits for long-term care facilities and skilled nursing facilities: Permits physicians in long-term care and certain related facilities to delegate any required physician visit to certain other clinicians.
Scope of practice: Expansion of duties	1	Modification to Medicare rules and Medicaid concerning certification and provision of home health services: Modifies which providers are allowed to certify the need for home health services and order services.[a]
Training for clinicians or other personnel providing patient care	10	12-hour annual in-service training requirement for home health aides: Postpones the deadline for requirement that each home health aide receives 12 hours of in-service training in a 12-month period.
Other	13	Physician services at hospitals, psychiatric hospitals, and critical access hospitals: Waives the requirement that Medicare patients be under the care of a physician.

Source: GAO analysis of information from the Centers for Medicare & Medicaid Services. | GAO-23-105494

Note: The Secretary of Health and Human Services first declared the COVID-19 public health emergency on January 31, 2020, and renewed this determination 11 times. The public health emergency was most recently renewed on October 13, 2022, and expires January 11, 2023. During the COVID-19 public health emergency, the Department of Health and Human Services made widespread use of authority under section 1135 of the Social Security Act to waive or modify certain Medicare requirements to maintain beneficiary access to care. See 42 U.S.C. § 1320b-5. For purposes of this report, we collectively refer to these waivers and other changes to requirements made in response to COVID-19 as "waivers and flexibilities." Many waivers and flexibilities were effective March 1, 2020 and end when the public health emergency ends. See appendix I for a full list of Medicare workforce capacity waivers and flexibilities and information on when they are scheduled to end.

[a]Absent additional action, this change will continue indefinitely after the end of the public health emergency under CMS regulations promulgated during the public health emergency. See 85 Fed. Reg. 27,550, 27,551 (May 8, 2020) (codified as amended at 42 C.F.R. § 409.42(b) (physician or allowed practitioner)).

Seven of CMS's workforce capacity waivers and flexibilities applied specifically to rural areas. (See appendix I.) For example, CMS waived the requirement that a nurse practitioner, physician assistant, or certified midwife be available at least 50 percent of the time in rural health clinics, to increase staffing flexibility. In addition, the agency made two changes related to residency training and supervision in rural areas that apply indefinitely after the public health emergency ends:

- Allowed teaching physicians to supervise residents virtually, rather than in-person, for certain services.
- Expanded the type of services residents can perform without in-person supervision.

The agency stated that the need to improve rural access to care and training opportunities for physician residents overshadowed its concerns about physicians' ability to adequately supervise residents virtually. According to CMS documentation, permitting the virtual presence of teaching physicians could expand training opportunities for residents in rural settings, which have historically been in limited supply. CMS also determined that more data would be needed to determine whether to expand or terminate this regulatory change and said it may conduct further study.[29]

Waivers and Flexibilities Helped Increase Provider Enrollments, Including High-Risk Enrollments That CMS Later Revoked

Active Provider Enrollments Increased while Waivers and Flexibilities Were in Effect

The total number of provider enrollments that were active in the Medicare program increased during the COVID-19 public health emergency. There were 2.3 million enrollments across all provider types in fiscal year 2019—before the public health emergency—and 2.6 million enrollments in fiscal year 2021—after the waivers and flexibilities were implemented, according to HHS. This represents a 13 percent increase in active enrollments over the 2-year period.[30] Both enrollment increases from new providers and the continued active status of current providers—which was maintained in part by decreases in disenrollment, such as deactivated

[29]See 85 Fed. Reg. 84,472, 84,579-82 (Dec. 28, 2020).

[30]A provider enrollment represents a single Medicare enrollment for a provider. It might not represent a unique provider because a provider can have multiple enrollments. 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.

and revoked provider enrollments—contributed to the overall increase in active enrollments.[31]

Types of Physicians, Other Clinicians, and Specialties That Enrolled under Waivers and Flexibilities

Individual providers, such as physicians and nurse practitioners, accounted for 69 percent of enrollments that occurred under waivers and flexibilities. The individual provider population was split almost evenly between physicians and other clinicians. For physicians that were enrolled under waivers and flexibilities, the top specialties were internal medicine (17 percent), family medicine (12 percent), and emergency medicine (8 percent). For other clinicians, the top provider types were nurse practitioners (39 percent), physician assistants (20 percent), and physical therapists in private practice (12 percent). See appendix II for a list of physicians, other clinicians, and specialties of enrollments under waivers and flexibilities.

Source: GAO analysis of data from the Centers for Medicare & Medicaid Services. | GAO-23-105494

About 222,000 enrollments occurred under the waivers and flexibilities between March 2020 and March 2022, not including enrollments with postponed revalidation requirements (see sidebar for enrollments by type of provider). Of these enrollments,

- 64 percent were new enrollments,
- 31 percent were updated enrollments,[32] and
- 5 percent were reactivated enrollments that had previously been deactivated or revoked.

In addition to waivers that affected requirements for providers' initial enrollment, the waiver postponing provider enrollment revalidations likely contributed to the overall increase in total active enrollments during the public health emergency. During revalidation, MACs are required to review enrolled providers for eligibility. If providers do not pass the revalidation review, the providers can be deactivated or have their enrollment revoked, which decreases the number of enrollments. About 237,000 revalidations were postponed between March 2020 and October 2021. This coincided with fewer deactivated and revoked enrollments. According to HHS, deactivations declined from about 151,000 to 123,000 from fiscal years 2019 to 2021, while revoked enrollments declined from about 2,600 to 2,300.

High-Risk DMEPOS Supplier Types That Enrolled under Waivers and Flexibilities Accounted for a Majority of Revocations

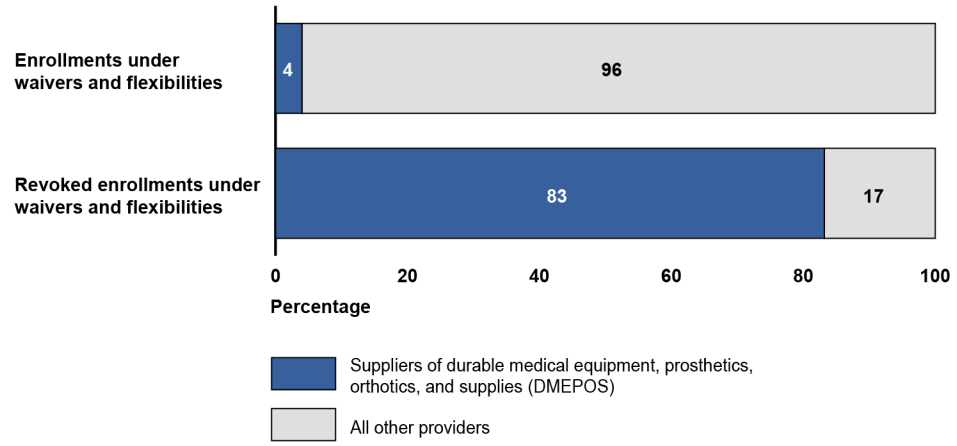
Of the 220,000 enrollments that occurred from March 2020 through March 2022, 208 enrollments were revoked as of March 2022. Most of the revocations were for DMEPOS suppliers, particularly newly enrolling suppliers CMS considers to pose a high risk of fraud, waste, and abuse. Although all DMEPOS suppliers made up only 4 percent of the 220,000 provider enrollments under waivers and flexibilities, they accounted for 83 percent of the 208 enrollments that were later revoked. (See figure 1.) A provider enrollment can be revoked for multiple reasons, including if a provider fails to meet eligibility requirements, such as if they are convicted

[31]A deactivation can occur when a provider fails to submit required information, for example. A revocation can occur, for example, if a provider fails to meet eligibility requirements, such as if they are convicted of a felony CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries. See 42 C.F.R. §§ 424.540, 424.535 (2022).

[32]An existing enrollment can be updated when a change occurs. For example, an existing enrollment that added a new practice location would be an updated enrollment.

of a felony CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

Figure 1: Percentage of Provider Enrollments and Revoked Enrollments under Waivers and Flexibilities, March 2020 through March 2022



Source: GAO analysis of data from the Centers for Medicare & Medicaid Services. | GAO-23-105494

Note: We identified 47 Medicare waivers and flexibilities CMS issued to sustain Medicare workforce capacity during the COVID-19 public health emergency. During the COVID-19 public health emergency, the Department of Health and Human Services made widespread use of authority under section 1135 of the Social Security Act to waive or modify certain Medicare requirements to maintain beneficiary access to care. See 42 U.S.C. § 1320b-5. For purposes of this report, we collectively refer to these waivers and other changes to requirements made in response to COVID-19 as "waivers and flexibilities." We use the term "providers" in this figure to include all types of Medicare providers and suppliers.

Newly enrolled DMEPOS suppliers had the highest percentage of revoked enrollments, compared to other providers. Specifically, from March 2020 through March 2022, about 2.6 percent of the approximately 6,000 DMEPOS suppliers with new enrollments under waivers and flexibilities had their enrollments later revoked. This percentage is dramatically higher than the less than 0.1 percent of all other providers who later had their enrollments revoked.

From March 2020 through March 2022, the percent of enrollments under waivers and flexibilities that were later revoked was particularly high for certain waivers and flexibilities and in certain states. This may indicate certain waivers or geographic areas that posed heightened risk. For example, DMEPOS suppliers that enrolled under the accreditation waiver had a higher percentage of revoked enrollments (7.3 percent) than DMEPOS enrollments without the accreditation waiver (1.4 percent) but

with another waiver or flexibility.[33] Similarly, the percentage of these DMEPOS supplier enrollments revoked varied by state. For example, the three states with the largest number of DMEPOS supplier enrollments under waivers and flexibilities that were revoked—Florida, California, and Texas—ranged from 8.4 percent (Florida) to 1.9 percent (Texas) of DMEPOS supplier enrollments under waivers and flexibilities that were later revoked.

Agency officials said CMS monitored all new providers who enrolled under waivers and flexibilities, but applied additional scrutiny to DMEPOS supplier enrollments. For example, according to agency officials, program integrity contractors took steps to verify ownership information for 2,425 new DMEPOS supplier enrollments under waivers and flexibilities, leading to 1.6 percent of them being revoked. Agency officials said these suppliers have posed a high risk of fraud, so CMS allocated resources to identify ineligible DMEPOS enrollments. Both the high risk associated with these suppliers and CMS's additional scrutiny of them could contribute to the high percentage of revoked DMEPOS supplier enrollments.

While the total number of enrollments under waivers and flexibilities that were revoked is small, even a limited number of providers could cause significant financial harm if they engage in fraud. For example, in June 2022, a nurse practitioner pleaded guilty to conspiring in a DMEPOS fraud scheme that defrauded Medicare of almost $15 million, and in July 2022, the Department of Justice announced criminal charges against 36 defendants for more than $1.2 billion in alleged fraud that included DMEPOS fraud schemes.[34]

[33]DMEPOS enrollments granted an accreditation exemption may have also used other waivers or flexibilities.

[34]Department of Justice, "Nurse Practitioner Pleads Guilty To Conspiracy In $15 Million Durable Medical Equipment Scheme," (June 30, 2022), accessed August 4, 2022, https://www.justice.gov/usao-wdnc/pr/nurse-practitioner-pleads-guilty-conspiracy-15-million-durable-medical-equipment-scheme; "Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud," (July 20, 2022), accessed August 4, 2022 https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud.

Providers Who Enrolled under Waivers and Flexibilities Accounted for 8 Percent of Medicare Expenditures

Providers who enrolled under waivers and flexibilities from March 2020 through March 2022 accounted for about $19 billion in expenditures, according to our analysis of CMS claims data for the period April 2020 through December 2021.[35] During this time, these providers represented about 8 percent of providers billing Medicare and about 8 percent of total expenditures for Medicare fee-for-service claims, according to our analysis of CMS's carrier claims and durable medical equipment supplier claims files.

CMS data show that specialty categories for ambulance providers, DMEPOS suppliers, and testing providers who enrolled under waivers and flexibilities accounted for a greater share of Medicare expenditures than other providers in various specialties. See table 4.

Table 4: Medicare Specialty Categories of Providers Who Enrolled under Waivers and Flexibilities and Associated Expenditures, April 2020 through December 2021

Specialty category	Percentage of providers in specialty category	Percentage of expenditures in specialty category	Expenditures associated with providers enrolled under waivers and flexibilities ($ millions)
Ambulance	8%	21%	1,928
Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)	12%	18%	3,386
Testing[a]	9%	16%	3,686
Other[b]	10%	12%	1,307
Other clinician[c]	10%	9%	1,571
Behavioral health	7%	7%	295
Therapy[d]	7%	6%	474
Medical[e]	7%	4%	6,293
All specialties	**8%**	**8%**	**18,938**

Source: GAO analysis of data from the Centers for Medicare & Medicaid Services on provider enrollment as well as carrier claims and durable medical equipment claims files. | GAO-23-105494

Notes: During the COVID-19 public health emergency, the Department of Health and Human Services made widespread use of authority under section 1135 of the Social Security Act to waive or modify certain Medicare requirements to maintain beneficiary access to care. See 42 U.S.C. § 1320b-5. For purposes of this report, we collectively refer to these waivers and other changes to requirements made in response to COVID-19 as "waivers and flexibilities." In addition, we use the term "providers" in this table to include all types of Medicare providers and suppliers.

Table includes provider enrollments under waivers and flexibilities that occurred from March 2020 to March 2022 and associated claims data for the period April 2020 through December 2021, the most recently available calendar year of claims data at the time of our study.

[a]Testing specialties include diagnostic radiology and clinical laboratories, for example.

[35]This was the most recently available calendar year of claims data at the time of our study.

[b]Other provider specialties include mass immunization providers and ambulatory surgical centers, for example.

[c]Other clinicians include nurse practitioners and physician assistants, for example.

[d]Therapy specialties include physical therapists and occupational therapists, for example.

[e]Medical specialties include emergency medicine, primary care, and surgical specialties, for example.

Providers' use of scope-of-practice waivers and flexibilities also varied. Allowing physician assistants, nurse practitioners, and clinical nurse specialists to begin home health certifications in May 2020 resulted in these clinicians conducting 10 percent of certifications by the end of 2021. In contrast, we found a less than 1 percent increase associated with a change allowing certain resident physicians to conduct more complex patient visits to evaluate and manage conditions.[36]

CMS Oversight Has Not Fully Addressed Risks Posed by Provider Enrollment Waivers and Flexibilities

CMS has taken steps to assess and mitigate risks posed by provider enrollment waivers and flexibilities. However, CMS has not fully addressed risks related to waiving fingerprint-based criminal background checks and postponing revalidations. In addition, CMS has not developed a plan to evaluate waivers and flexibilities to improve its response to future emergencies.

CMS Assessed Risks Posed by Waivers and Flexibilities and Took Steps to Address Them

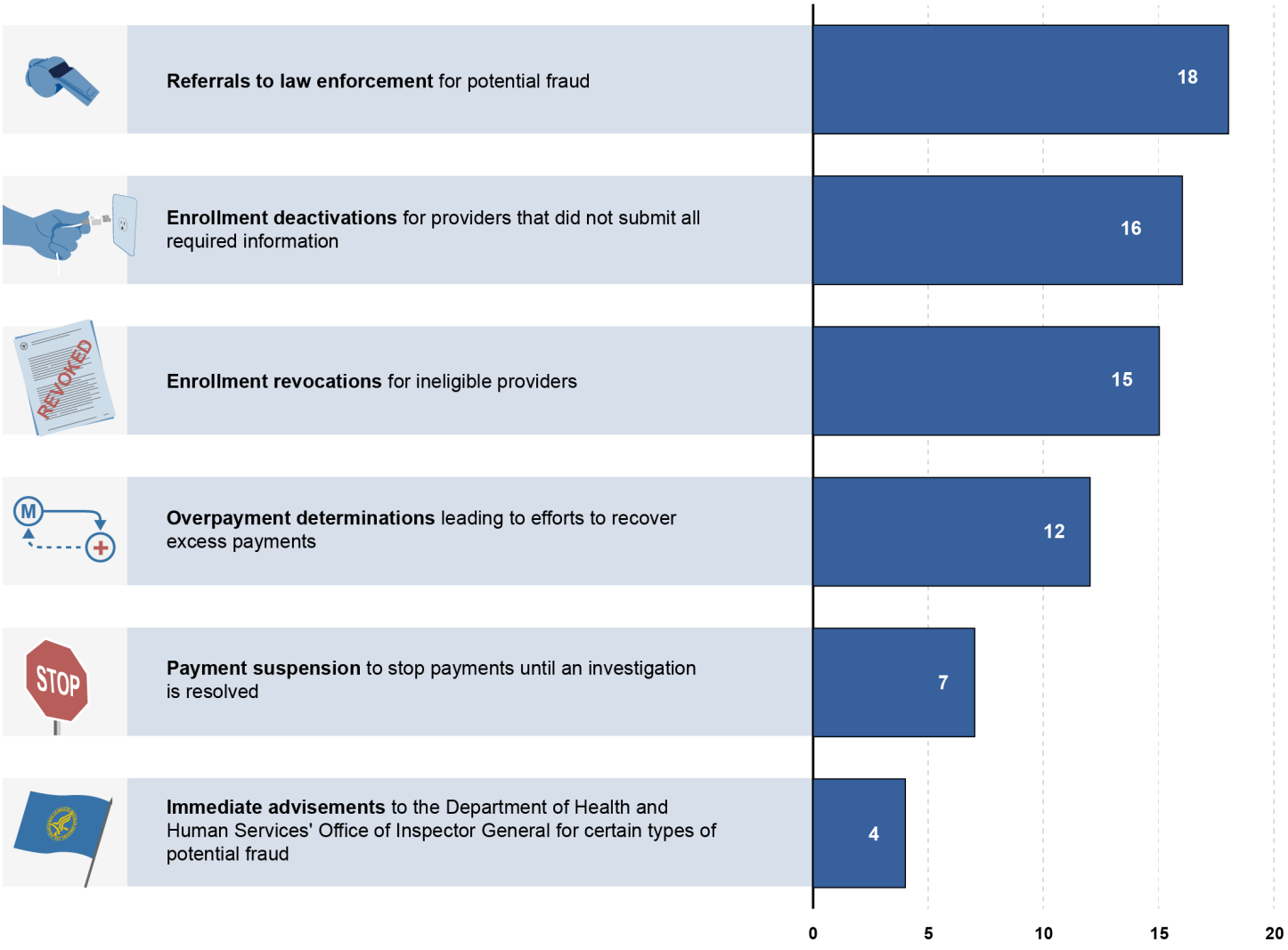
CMS's Center for Program Integrity identified program integrity vulnerabilities associated with provider screening and scope-of-practice waivers and flexibilities and conducted oversight activities to mitigate associated risks, according to our review of agency documentation. CMS inventoried waivers and flexibilities after it had implemented them, and identified associated program integrity vulnerabilities. It then determined the vulnerabilities' associated risks by analyzing the amount of payments associated with vulnerabilities, the likelihood of improper payments, and the vulnerabilities' likely effect on patient safety.

[36]During the COVID-19 public health emergency, CMS allows resident physicians in certain primary care facilities to provide all levels of evaluation and management services in outpatient or office settings while under direct virtual or in-person supervision of the teaching physician. See 42 C.F.R. § 415.172(a) (2022). From April 2020 through December 2020, these resident physicians performed 38 percent fewer evaluation and management services across all levels of complexity than they had during those months the previous year, and they performed less than 1 percent of the more complex level 4 and 5 services performed by all physicians.

CMS identified a medium-risk vulnerability for provider enrollment waivers and flexibilities generally. Further, the agency identified three high-risk vulnerabilities related to DMEPOS supplier enrollment. For scope-of-practice waivers and flexibilities, CMS identified a medium-risk vulnerability related to home-health services. It also monitored provider enrollment and billing information across provider types to help mitigate identified risks, according to agency documentation and officials. CMS continued its ongoing monitoring of providers' enrollment information and associations with other individuals that may indicate potential fraud. In addition, it continued its ongoing monitoring of billing information for indicators of potential fraud, waste, and abuse, such as providers who are outliers in terms of the home health services ordered.

CMS also identified provider enrollments warranting further investigation. For example, CMS's oversight of newly enrolled providers from March 2020 through January 2022 resulted in 94 leads for further investigation that led to actions to protect Medicare program integrity. These actions included referrals to law enforcement for potential fraud or revoking enrollments for providers found ineligible. (See fig. 2.)

Figure 2: Outcomes of CMS Monitoring of Newly Enrolled Medicare Providers during the COVID-19 Public Health Emergency, March 2020 through January 2022



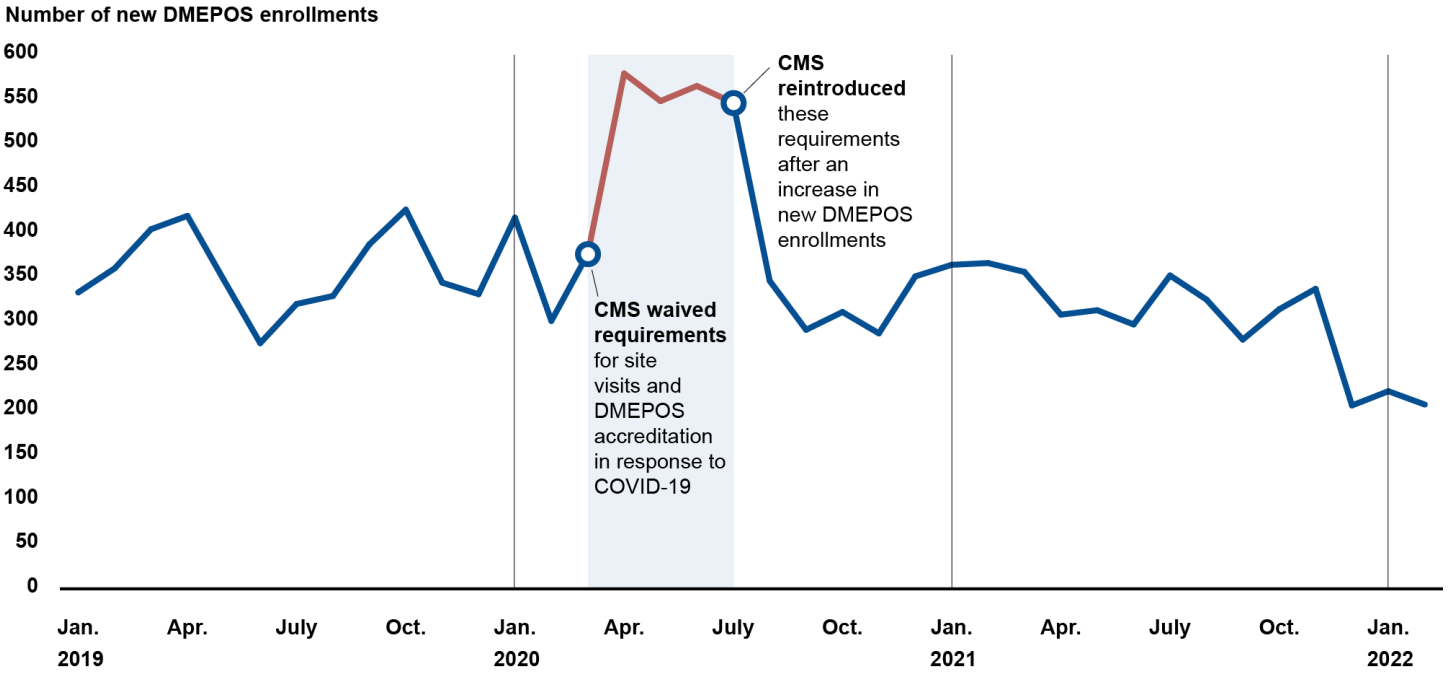
Source: GAO analysis of information provided by the Centers for Medicare & Medicaid Services (CMS). | GAO-23-105494

Note: Multiple outcomes, including outcomes not listed, can apply to a single investigation. We use the term "providers" in this figure to include all types of Medicare providers and suppliers that CMS monitored, which agency officials said included suppliers of durable medical equipment, laboratories, Federally Qualified Health Centers, hospitals, hospices, skilled nursing facilities, home health agencies, and immunization centers.

CMS identified an increase in DMEPOS enrollments after waivers and flexibilities began in March 2020, and reintroduced requirements for site visits and DMEPOS accreditation in July 2020. The rate of new DMEPOS enrollments fell soon after. (See fig. 3.) In addition, CMS directed program

integrity contractors to validate information about who owns DMEPOS supplier organizations that enrolled under waivers and flexibilities. The contractors did so using information collected by third parties, such as information on businesses from states' Secretary of State, to identify any discrepancies.

Figure 3: New Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Medicare Enrollments and Changes in Enrollment Requirements by Month, January 2019 to February 2022



Source: GAO analysis of data provided by the Centers for Medicare & Medicaid Services (CMS). | GAO-23-105494

CMS continued to monitor patient safety metrics for long-term care residents, although it did not analyze the effects of waivers and flexibilities on patient safety.[37] For example, CMS collected data on nursing home staffing during most of the public health emergency, but did not analyze the potential effects of waiving required training and certification of nursing aides employed by skilled nursing facilities on patient safety

[37]CMS took additional steps related to infection control in long-term care facilities. See GAO, *COVID-19 in Nursing Homes: CMS Needs to Continue to Strengthen Oversight of Infection Prevention and Control*, GAO-22-105133 (Washington, D.C.: Sept. 14, 2022). CMS's *Pandemic Plan* outlining its policies for responding to a pandemic establishes that the agency will monitor the efficacy of the waivers CMS implements.

metrics. CMS officials said it was not possible to measure the unique effects of waivers and flexibilities, given other changes affecting long-term care residents such as staffing absences due to COVID-19. Both CMS and GAO found that performance on certain metrics fell, such as long-term care residents experiencing increased pressure ulcers, weight loss, and depression during the COVID-19 public health emergency.[38] CMS stated that certain waivers and flexibilities—among other factors—might have contributed to declines in patient safety metrics for long-term care residents. To address this potential risk to patient safety, CMS reintroduced certain minimum training and scope-of-practice requirements when the agency found related waivers were no longer needed, making the requirements effective May 2022 or June 2022.[39]

In addition to monitoring providers and patient safety of long-term care residents, CMS monitored MACs' implementation of provider enrollment waivers and flexibilities. During the COVID-19 public health emergency, the agency continued its review of measures of the accuracy and timeliness of MACs' performance, such as the accuracy and timeliness of provider enrollment application processing. Through this monitoring, CMS was able to determine that one MAC did not always screen enrollments that used waivers and flexibilities against lists of entities excluded from receiving federal contracts, as required. The agency addressed this deficiency in writing with the MAC and issued guidance advising other MACs to continue performing this screening.

CMS Has Not Fully Addressed Risks from Provider Enrollment Waivers and Flexibilities

Since ending the waiver of fingerprint-based criminal background checks, CMS has not conducted these checks on providers who had them waived. Instead, it has relied on its monitoring of criminal records associated with providers based on the providers' names rather than fingerprints, even though it previously indicated fingerprints were more accurate and appropriate. In addition, CMS has begun conducting provider enrollment revalidations that the agency postponed through a

[38]See CMS, Center for Clinical Standards and Quality/Quality, Safety & Oversight Group, *Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers*, QSO-22-15-NH & NLTC & LSC (Baltimore, M.D., April 7, 2022), and, GAO-22-105133, 10-15.

[39]Specifically, CMS ended Section 1135 blanket waivers related to (1) required training for feeding assistants in long-term care facilities, (2) required in-service training for nursing aides in skilled nursing facilities and nursing homes, (3) required training and certification of nursing aides employed by skilled nursing facilities and nursing homes, (4) physician delegation of tasks in skilled nursing facilities, and (5) required physician visits in skilled nursing facilities and nursing homes.

waiver, but CMS may not complete all revalidations within established time frames.

Waivers and Flexibilities Precluded Fingerprint-Based Criminal Background Checks for High-Risk Providers

When CMS waived fingerprint-based criminal background checks from March 2020 through October 2021, the agency intended to postpone checks and conduct them after resuming this requirement, according to officials. However, CMS officials said that because the agency only has statutory authority to conduct these checks at enrollment, the agency was precluded from conducting these checks later.[40] Although CMS regulations authorize these checks for certain providers when CMS revalidates provider information for re-enrollment, which occurs every 3 years for DMEPOS suppliers and every 5 years for other providers, CMS officials indicated that only providers who have been elevated to the high-risk screening level would be subject to the fingerprinting requirement at revalidation.[41]

As of August 2022, CMS has not taken steps to conduct the fingerprint-based criminal background checks that it intended to postpone. Not conducting fingerprint-based criminal background checks is counter to CMS's *Pandemic Plan*. This plan states that the agency will act to protect its programs and beneficiaries from fraud, waste, and abuse, as well as review policy changes to establish safeguards for fraud prevention. Without fingerprint-based criminal background checks, CMS lacks assurance that about 7,000 enrollments of high-risk provider types who had these checks waived—including enrollments for home health agencies and DMEPOS suppliers—did not include providers who would be ineligible due to felony convictions. Conducting fingerprint-based criminal background checks would offer greater assurance that CMS is preventing ineligible providers from enrolling and billing for Medicare services.

[40]Section 1866 of the Social Security Act authorizes HHS to establish Medicare provider enrollment and revalidation procedures including criminal background checks as the Secretary determines appropriate based on the risk of fraud, waste, and abuse with respect to the category of provider. See 42 U.S.C. § 1395cc(j).

[41]HHS regulations generally require individuals with a 5 percent or greater interest in a high-risk provider to submit to a fingerprint-based criminal history record check, among other screening requirements, upon initial application and—for providers elevated to the high-risk screening level—revalidation. See 42 C.F.R. § 424.518(c)(2) (2022). According to CMS officials, providers at a moderate- or limited-risk screening level at the time of revalidation are not subject to fingerprinting, even if the provider was high-risk at initial enrollment and the applicable fingerprinting requirement was waived.

CMS officials said that the agency mitigated risks by regularly monitoring for criminal records that match enrolled providers' names and thus conducting fingerprint based criminal background checks would offer no benefit while potentially adding provider burden.[42] This is inconsistent with previous CMS statements on the benefits fingerprint-based criminal background checks provide over name-based checks. Further, it is contrary to the need for additional scrutiny of high-risk provider types, as CMS explained in the preamble to rulemaking that implemented procedures to screen Medicare providers.[43] CMS's regular monitoring for criminal records based on providers' names could help with ongoing oversight. However, it does not address the risk of providers avoiding detection by falsifying their name, which CMS previously explained could be reduced by conducting fingerprint-based criminal background checks.

CMS officials confirmed the agency had commonly approved waivers and flexibilities for fingerprint-based criminal background check requirements for previous natural disasters or public health emergencies and could do so again.[44] Officials told us that using these waivers and flexibilities during future emergencies could again result in the agency not conducting these checks after the emergency ended. However, despite commonly waiving these checks, CMS did not have plans to develop policies and procedures to postpone rather than waive fingerprint-based criminal background checks during future emergencies, as of August 2022. This is inconsistent with CMS's Pandemic Plan, which commits to reviewing policy changes to establish safeguards for fraud prevention. Developing policies and procedures to postpone rather than waive these checks will

[42]According to CMS officials, the agency's advanced provider screening system monitors felonies in the last 10 years and uses the same database used for fingerprint-based criminal background checks.

[43]CMS cited reasons that fingerprint-based background checks are more accurate than name-based checks, including that people (1) lie about their names, (2) obtain names from false documents, (3) change their names, (4) have the same name, (5) misspell names, (6) use different versions of their names, and (7) use aliases. Further, CMS stated that provider types it considers high risk had not undergone sufficient scrutiny prior to the implementation of fingerprint-based criminal background check. See 76 Fed. Reg. 5,862, 5,876 (Feb. 2, 2011).

[44]Between the COVID-19 public health emergency declaration and September 2022, CMS has allowed providers to request Section 1135 waivers for at least five additional public health emergencies declared in response to hurricanes, wildfires, and severe weather. In addition, a national public health emergency was declared due to the monkeypox virus in August 2022.

enable CMS to maintain important safeguards against fraud during future emergencies.

Postponed Provider Enrollment Revalidations May Not Be Completed Within Established Time Frames

In January 2022, CMS resumed provider enrollment revalidations that the agency postponed from March 2020 through October 2021, but the agency may not complete these revalidations within the established 3- to 5-year time frames. As of August 2022, about 16,000 of the 237,000 postponed revalidations were completed, according to CMS officials. At the current rate, it would take until 2029—more than 9 years after CMS issued related waivers and flexibilities—or later to catch up on the revalidations that CMS postponed.

CMS has prioritized catching up on postponed revalidations for providers who received accelerated or advanced payments in accordance with the CARES Act, according to agency officials.[45] However, CMS has not prioritized revalidations for provider types it considers moderate- or high-risk of fraud, waste, and abuse—including DMEPOS suppliers, who we also found to have higher rates of revoked enrollments under waivers and flexibilities than other provider types.

CMS officials acknowledged that at the current rate it could take years to complete these revalidations. As of August 2022, they said they did not have a plan with target dates for completing revalidations as they are still considering resource needs and time frames for completing these revalidations. If CMS does not prioritize and complete postponed revalidations within the established 5-year or—for DMEPOS suppliers—3-year period since enrollment or the previous revalidation, CMS will have effectively waived one or more cycles of revalidations. As CMS noted in establishing such time frames, revalidations are intended to ensure providers' continued compliance with Medicare requirements, including

[45]Accelerated and advance payments provide eligible providers with necessary funds in certain circumstances, such as due to a disruption in the submission or processing of claims for payment, or to accelerate cash flow to affected providers during a national emergency or disaster. The CARES Act expanded the existing program providing these payments to give additional flexibilities during the COVID-19 public health emergency. See Pub. L. No. 116-136, div. A, tit. III, pt. IV, subtit. D, § 3719, 134 Stat. 281, 426 (2020) (codified as amended at 42 U.S.C. § 1395g(f)).

that Medicare beneficiaries are receiving services furnished only by legitimate providers.[46]

Not developing and implementing a plan for conducting postponed provider enrollment revalidations in a timely manner, including prioritizing moderate- and high-risk provider types, is inconsistent with federal internal control standards, which call for agencies to identify, analyze, and respond to risks related to achieving the defined objectives.[47] In the absence of such a plan and implementation activities, CMS might not identify providers who do not continue to comply with program requirements.

CMS Has Not Planned an Evaluation of Waivers and Flexibilities Related to Provider Enrollment

According to CMS's *Pandemic Plan,* following a return to normal operations after a pandemic, the agency should conduct appropriate post-pandemic activities, including evaluations of the agency's performance to identify areas for improvement.[48] Further, all opportunities for improvement should be captured and synthesized into a continuity corrective action plan.

However, CMS has not planned an evaluation of the agency's performance with respect to waivers and flexibilities for provider enrollment, and CMS has not incorporated opportunities for improvement in a corrective action plan as of August 2022. CMS officials told us they were exploring options to evaluate waivers and flexibilities related to provider enrollment, but did not provide documentation of planned evaluation activities. Absent an evaluation, CMS will likely miss opportunities to improve its response to future natural disasters and public health emergencies. These missed opportunities likely include improvements that address and limit risks to program integrity and patient safety. For example, CMS officials and representatives from MACs and program integrity contractors we spoke with identified potential opportunities to improve future oversight of waivers and flexibilities for provider enrollment:

- **Targeting waivers and flexibilities.** CMS officials said that they may be able to better target waivers and flexibilities for provider enrollment

[46]See, e.g., 77 Fed. Reg. 20,754, 20,758 (Apr. 21, 2006) (establishing provider revalidation requirements currently codified, as amended, at 42 C.F.R. §§ 424.515, 424.57(g)).

[47]GAO-14-704G.

[48]CMS's *Pandemic Plan* does not set a deadline for this evaluation.

during future emergencies. Representatives from one program integrity contractor we spoke with identified provider enrollment waivers and flexibilities for DMEPOS suppliers as an area for improvement, explaining that issuing waivers and flexibilities for all DMEPOS suppliers offered minimal benefits in responding to COVID-19 and introduced program integrity risks that were potentially very high. CMS officials explained that some DMEPOS suppliers may have enrolled under provider enrollment waivers and flexibilities to deliver important supplies, such as oxygen tanks.

- **Preparing for revalidation backlogs.** Representatives from each of the three MACs we spoke with identified challenges or potential improvements related to revalidation waivers and flexibilities. For example, representatives from one MAC suggested that CMS could have requested providers revalidate their enrollment on a voluntary basis while waivers and flexibilities are in place, and representatives from another MAC suggested more preparation before resuming revalidations to mitigate the backlog of postponed revalidations.
- **Tracking and communicating waivers and flexibilities.** Each of the MACs and program integrity contractors we spoke with said that access to additional detail about the specific waivers and flexibilities under which enrollment occurred would have helped their oversight efforts. For example, representatives from one program integrity contractor explained that additional detail could help them identify which DMEPOS suppliers enrolled without accreditation requirements and better monitor whether these suppliers delivered supplies they were not qualified to offer. CMS took steps to track provider enrollments that occurred under waivers and flexibilities and communicate that to MACs and program integrity contractors, but this did not include information on which waivers and flexibilities each provider enrolled under, and CMS officials had not identified how contractors' inability to track that information limited contractors' oversight activities. CMS officials also noted that an information system redesign is underway that would enhance CMS's ability to provide this information.[49]

Conclusions

In response to the COVID-19 public health emergency and the need to maintain beneficiary access to Medicare services, CMS acted quickly to issue waivers and flexibilities related to provider enrollment, clinicians' scope of practice, and training. These actions also helped sustain provider workforce capacity to deliver services. As CMS transitions back

[49]Specifically, CMS officials said they were in the process of developing the Provider Enrollment, Chain, and Ownership System 2.0.

to normal operations, additional actions could help reduce risks of fraud, waste, and abuse, and risks to patient safety. Fingerprint-based criminal background checks for high-risk providers who enrolled without them would help identify providers who may have falsified their enrollment application. In addition, timely revalidations of provider enrollments, particularly for provider types who the agency considers a high-risk or moderate-risk, would help identify providers who are no longer eligible to deliver Medicare services. Further, without plans to evaluate waivers and flexibilities or related challenges, the agency will not have identified important areas for improvement. Absent plans for improvement, CMS may not avoid repeating mistakes it made responding to COVID-19 nor tailor its actions to better safeguard the Medicare program and its beneficiaries in future emergencies.

Recommendations

We are making the following four recommendations to CMS.

The Administrator of CMS should conduct fingerprint-based criminal background checks for high-risk provider types who enrolled during the COVID-19 public health emergency, such as when CMS revalidates these providers' information. (Recommendation 1)

The Administrator of CMS should develop policies and procedures to postpone rather than waive fingerprint-based criminal background checks during future emergencies. (Recommendation 2)

The Administrator of CMS should develop and implement a plan for conducting provider enrollment revalidations to ensure providers are revalidated prior to the end of their 3- to 5-year revalidation cycles, prioritizing moderate- and high-risk provider types. (Recommendation 3)

The Administrator of CMS should evaluate waivers and flexibilities for provider enrollment, including related oversight challenges, and address any opportunities for improvement. This evaluation could consider targeting provider enrollment waivers and flexibilities to maintain requirements for provider types CMS considers high risk—including DMEPOS suppliers—and opportunities to track and communicate to program integrity contractors information about each waiver and flexibility providers enrolled under. (Recommendation 4)

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review and comment. In its written comments, printed in appendix III, CMS agreed with our recommendations. HHS and CMS also provided technical comments, which we incorporated as appropriate.

Regarding our first recommendation—to conduct fingerprint-based criminal background checks for high-risk provider types who enrolled during the COVID-19 public health emergency—CMS agreed to conduct these checks for providers who have been elevated to the high-risk category. CMS also agreed to explore options for provider types who were high-risk at the time of enrollment, when these checks were waived, but are subsequently considered a moderate risk, while noting this would require notice and comment rulemaking. We maintain that conducting these checks would offer greater assurance that CMS is preventing ineligible providers from enrolling and billing for Medicare services.

Regarding our second recommendation—to develop policies and procedures to postpone rather than waive fingerprint-based criminal background checks during future emergencies—CMS agreed to explore ways to effectively postpone these checks while noting that doing so would require notice and comment rulemaking. We maintain that developing these policies and procedures will enable CMS to sustain important safeguards against fraud during future emergencies.

Regarding our third recommendation—to develop and implement a plan for conducting provider enrollment revalidations to ensure providers are revalidated prior to the end of their 3- to 5-year revalidation cycles, prioritizing moderate- and high-risk provider types—CMS agreed to develop and implement a plan for conducting these revalidations and prioritizing higher risk provider types. CMS said that conducting these revalidations requires additional resources and CMS is assessing the resources needed to conduct them all within 1 to 3 years. We maintain that conducting these revalidations in a timely manner that prioritizes higher risk provider types would help identify providers who do not continue to comply with program requirements.

Regarding our fourth recommendation—to evaluate waivers and flexibilities for provider enrollment, including related oversight challenges, and address any opportunities for improvement—CMS agreed with the importance of such an evaluation. CMS said that it is undertaking an agency-wide initiative to assess the lessons learned from the waivers issued during the COVID-19 pandemic to inform decision making for future emergencies.

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

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

Leslie V. Gordon
Acting Director, Health Care

List of Committees

The Honorable Patrick Leahy
Chairman
The Honorable Richard Shelby
Vice Chairman
Committee on Appropriations
United States Senate

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Patty Murray
Chair
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Gary C. Peters
Chairman
The Honorable Rob Portman
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Rosa L. DeLauro
Chair
The Honorable Kay Granger
Ranking Member
Committee on Appropriations
House of Representatives

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Bennie G. Thompson
Chairman
The Honorable John Katko
Ranking Member
Committee on Homeland Security
House of Representatives

The Honorable Carolyn B. Maloney
Chairwoman
The Honorable James Comer
Ranking Member
Committee on Oversight and Reform
House of Representatives

The Honorable Richard E. Neal
Chairman
The Honorable Kevin Brady
Republican Leader
Committee on Ways and Means
House of Representatives

Appendix I: Summary of Medicare Waivers and Flexibilities CMS Issued to Sustain Workforce Capacity

Table 5: Medicare Waivers and Flexibilities to Sustain Provider Workforce Capacity during the COVID-19 Public Health Emergency (PHE) Implemented from March 2020 through December 2021

Category of waiver or flexibility	Title of waiver or flexibility	Source of waiver or flexibility	End date	Change targets rural areas
Provider enrollment	Waive criminal background checks associated with fingerprint-based criminal background check	Section 1135 blanket waiver guidance	10/31/2021	-
	Postpone all revalidation actions	Section 1135 blanket waiver guidance	10/31/2021	-
	Waive site visits	Section 1135 blanket waiver guidance	7/6/2022	-
	Accreditation for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)	Section 1135 blanket waiver guidance	7/6/2022	-
	Waive application fee	Section 1135 blanket waiver guidance	October 2021	-
	Allow opted-out physicians and other practitioners to terminate their opt-out status early and enroll in Medicare	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Expedites review of any pending or new applications from providers	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
Scope of practice – delegation of duties	Physician delegation of tasks in skilled nursing facilities	Section 1135 blanket waiver guidance	5/7/2022	-
	Physician visits for long-term care facilities	Section 1135 blanket waiver guidance	5/7/2022	-
	Allow occupational therapists, physical therapists, and speech language pathologists to perform initial and comprehensive assessment for all patients	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Modify requirements for ordering COVID-19 diagnostic laboratory tests	85 Fed. Reg. 27550 (May 8, 2020) 85 Fed. Reg. 54820 (Sep. 2, 2020)	End of the COVID-19 PHE declaration	-
	Therapy—therapy assistants furnishing maintenance therapy	85 Fed. Reg. 27550 (May 8, 2020) 85 Fed. Reg. 84472 (Dec. 28, 2020)	Not applicable; no end date specified	-
Scope of practice – expansion of duties	Modification to Medicare rules and Medicaid concerning certification and provision of home health services	85 Fed. Reg. 27550 (May 8, 2020)	Not applicable; no end date specified	-
Scope of practice – supervision	Waive onsite visits for home health agency aide supervision	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-

Category of waiver or flexibility	Title of waiver or flexibility	Source of waiver or flexibility	End date	Change targets rural areas
	Anesthesia services at hospitals, critical access hospitals, and ambulatory surgical centers	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Responsibilities of physicians in critical access hospitals	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	✓
	Physician supervision of nurse practitioners in rural health clinics and federally qualified health centers	Section 1135 blanket waiver guidance	End of the calendar year in which the PHE ends	✓
	Waive onsite visits for hospice aide supervision	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Revisions to teaching physician regulations (evaluation and management services)	85 Fed. Reg. 19230 (Apr. 6, 2020) 85 Fed. Reg. 84472 (Dec. 28, 2020)	End of the COVID-19 PHE declaration[a]	✓
	Revisions to teaching physician regulations (interpretation of diagnostics)	85 Fed. Reg. 19230 (Apr. 6, 2020)	End of the COVID-19 PHE declaration	-
	Direct supervision by interactive telecommunications technology	85 Fed. Reg. 19230 (Apr. 6, 2020) 85 Fed. Reg. 84472 (Dec. 28, 2020) 85 Fed. Reg. 85866 (Dec. 29, 2020)	End of the calendar year in which the PHE ends[a]	✓
	Requirements for consultations or services furnished by or with the supervision of a particular medical practitioner or specialist	85 Fed. Reg. 19230 (Apr. 6, 2020)	End of the COVID-19 PHE declaration	-
	Physician supervision flexibility for outpatient hospitals—outpatient hospital therapeutic services assigned to the non-surgical extended duration therapeutic services level of supervision	85 Fed. Reg. 19230 (Apr. 6, 2020) 85 Fed. Reg. 85866 (Dec. 29, 2020)	Not applicable; no end date specified	-
	Supervision of diagnostic tests by certain practitioners	85 Fed. Reg. 27550 (May 8, 2020) 85 Fed. Reg. 84472 (Dec. 28, 2020)	Not applicable; no end date specified	-
Training	Training and certification of nurse aides	Section 1135 blanket waiver guidance	6/6/2022	-
	In-service training for long-term care facilities and skilled nursing facilities and/or nursing facilities	Section 1135 blanket waiver guidance	6/6/2022	-
	Paid feeding assistants for long-term care facilities and skilled nursing facilities and/or nursing facilities	Section 1135 blanket waiver guidance	6/6/2022	-

Category of waiver or flexibility	Title of waiver or flexibility	Source of waiver or flexibility	End date	Change targets rural areas
	12-hour annual in-service training requirement for home health aides	Section 1135 blanket waiver guidance	End of the first full quarter after the PHE concludes	-
	Hospice aide competency testing allow use of pseudo patients	Section 1135 blanket waiver guidance 86 Fed. Reg. 42528 (Aug. 4, 2020)	Not applicable; no end date specified	-
	12-hour annual in-service training requirement for hospice aides	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Hospice annual training	Section 1135 blanket waiver guidance	End of the first full quarter after the PHE concludes	-
	Emergency preparedness for end-stage renal dialysis facilities	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Director of food and nutrition services	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Home Health Agencies and Hospice Training and Assessment of Aides	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
Other	Critical access hospital staff licensure	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	✓
	Dialysis patient care technician certification	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Medical staff for hospitals, psychiatric hospitals, and critical access hospitals	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Practitioner locations	Section 1135 blanket waiver guidance	Not applicable; no end date specified	-
	Critical access hospital personnel qualifications	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	✓
	Transferability of physician credentialing	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Certain staffing requirements for rural health clinics and federally qualified health centers	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	✓
	Medical staff for ambulatory surgical centers	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Physician services at hospitals, psychiatric hospitals, and critical access hospitals	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	✓
	Nursing services for ambulatory surgical centers	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-
	Waive requirement for hospices to use volunteers	Section 1135 blanket waiver guidance	End of the COVID-19 PHE declaration	-

Category of waiver or flexibility	Title of waiver or flexibility	Source of waiver or flexibility	End date	Change targets rural areas
	Revisions to moonlighting regulations	85 Fed. Reg. 19230 (Apr. 6, 2020) 85 Fed. Reg. 84472 (Dec. 28, 2020)	Not applicable; no end date specified	-
	Modification of 60-day limit for substitute billing arrangements	Section 1135 blanket waiver guidance	No more than 60 days after the COVID-19 PHE ends	-

Legend:

✓ = All or a portion of this flexibility applies specifically to providers in rural areas.

- = This flexibility does not apply specifically to providers in rural areas.

Source: GAO analysis of information from Centers for Medicare & Medicaid Services. | GAO-23-105494

Note: During the COVID-19 public health emergency, the Department of Health and Human Services made widespread use of authority under section 1135 of the Social Security Act to waive or modify certain Medicare requirements to maintain beneficiary access to care. See 42 U.S.C. § 1320b-5. For purposes of this report, we collectively refer to these waivers and other changes to requirements made in response to COVID-19 as "waivers and flexibilities." In addition, we use the term "providers" to include physicians and other clinicians or health care workers; DMEPOS suppliers; home health agencies; hospice organizations; and non-institutional providers such as ambulances or other free-standing facilities, such as clinical laboratories, unless otherwise specified. The Secretary of Health and Human Services first declared the COVID-19 public health emergency on January 31, 2020, and renewed this determination 11 times. The public health emergency was most recently renewed on October 13, 2022, and expires January 11, 2023. Many of the waivers and flexibilities have an effective date of March 1, 2020. Section 1135 blanket waiver guidance includes CMS, COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers (Baltimore, M.D., March 30, 2020) and CMS, Durable Medical Equipment, Prosthetics, Orthotics and Supplies: CMS Flexibilities to Fight COVID-19 (Baltimore, M.D.).

[a]This change was updated to keep portions of the change in place indefinitely.

Appendix II: Summary of Physicians and Other Clinicians Who Enrolled in Medicare under Waivers and Flexibilities

Table 6: Medicare Physician Enrollments by Specialty, March 2020 through March 2022

Specialty	Number of enrollments
Internal medicine	13,196
Family medicine	9,510
Emergency medicine	6,555
Pediatric medicine	3,766
Anesthesiology	3,750
Diagnostic radiology	3,710
Psychiatry	3,114
Obstetrics/gynecology	2,787
General surgery	2,522
Hospitalist	2,296
Chiropractic	1,973
Optometry	1,921
Neurology	1,863
Orthopedic surgery	1,863
Cardiovascular disease (cardiology)	1,223
Dentist	1,197
All other specialties	16,376
Total	**77,622**

Source: GAO analysis of information from Centers for Medicare & Medicaid Services. | GAO-23-105494

Table 7: Medicare Enrollment for Clinicians Other than Physicians by Specialty, March 2020 through March 2022

Clinician specialty	Number of enrollments
Nurse practitioner	29,378
Physician assistant	14,921
Physical therapist in private practice	9,291
Clinical social worker	7,306
Certified registered nurse anesthetist	5,266
Clinical psychologist	2,604
Occupational therapist in private practice	2,223
Qualified speech language pathologist	1,346
Registered dietitian or nutrition professional	1,181
Qualified audiologist	601
All other clinicians	1,127
Total	**75,244**

Source: GAO analysis of information from Centers for Medicare & Medicaid Services. | GAO-23-105494

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

November 23, 2022

Leslie V. Gordon
Acting Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Gordon:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"MEDICARE: CMS Needs to Address Risks Posed by Provider Enrollment Waivers and Flexibilities" (GAO-23-105494).**

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

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT TITLED: MEDICARE: CMS NEEDS TO ADDRESS RISKS POSED BY PROVIDER ENROLLMENT WAIVERS AND FLEXIBILITIES (GAO-23-105494)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report. HHS thanks GAO for their efforts on this issue and looks forward to working with GAO on this and other issues in the future.

Throughout the COVID-19 public health emergency (PHE), the Centers for Medicare & Medicaid Services (CMS) has worked hard to make sure beneficiaries and enrollees could safely access the health care services they need while avoiding COVID-19. CMS built efforts around the crucial feedback we received from stakeholders across the industry, including providers, plan issuers, patients, pharmacies, and partners across state, local, and federal governments.

Under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123), the Families First Coronavirus Response Act (P.L. 116-127), and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136), CMS has been able to provide additional waivers and flexibilities to respond to the evolving needs of providers and patients throughout the COVID-19 PHE.

On January 31, 2020, the Secretary of Health and Human Services issued a determination that a PHE pursuant to section 319 of the Public Health Service Act existed nationwide as a result of COVID-19. On March 13, 2020, the President declared the rapidly evolving COVID-19 situation a national emergency pursuant to the National Emergencies Act. When both of these actions occur, section 1135 of the Social Security Act (Act) authorizes the Secretary to waive certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) program requirements. Since that time, CMS has used this authority to issue blanket and individual waivers to help ensure that patients have access to the health care items and services they need throughout the COVID-19 PHE.

Generally, these waivers became available March 1, 2020, and will continue through the end of the COVID-19 PHE, although CMS has already ended several. Pursuant to the statutory authority under section 1135 of the Act, CMS issues blanket waivers to assure that health care providers that furnish items and services in good faith—but are unable to comply with one or more requirements as a result of the COVID-19 pandemic—can be paid for such items and services and exempted from sanctions or penalties for noncompliance, absent any determination of fraud, abuse or health and safety infractions that create a serious risk for injury, harm, impairment or death. To support this work, CMS established a rapid response team to review requests for waivers, and issue additional blanket waivers when appropriate, in order to address developing provider needs. CMS has reviewed over 250,000 individual and blanket waiver requests since 2020. These waivers and flexibilities have helped increase hospital capacity, rapidly expand the health care workforce, reduce administrative burden, and expand access to care during the COVID-19 PHE.

In an effort to maintain provider workforce capacity and beneficiary access to care during the COVID-19 PHE, CMS waived a number of provider enrollment requirements, including

temporarily waiving the requirement for fingerprint-based criminal background checks for five percent or greater owners of newly enrolling high-risk categories of providers and suppliers, such as newly-enrolling Home Health Agencies and suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). To mitigate the risks of this waiver, CMS maintained continuous monitoring of criminal alerts produced by the Advanced Provider Screening system. This system is an interactive screening, monitoring and alerting tool for licensure information and criminal history that provides federal, state and local criminal alerts for any felony in the last ten years. In addition, CMS continuously monitors all Medicare enrollments with associations to providers[1] with current or past revocations and payment suspensions.

CMS recognizes the importance of analyzing the impact of these changes, and, as such, has continuously reviewed the waivers and flexibilities issued to determine the potential for fraud, waste, and abuse in the Medicare program. This process included identifying program integrity risks and vulnerabilities associated with the waivers and flexibilities; prioritizing those with the largest potential for financial loss, beneficiary harm and/or likelihood of occurrence; and creating mitigations that addressed these program integrity risks and vulnerabilities. When CMS identifies a flexibility that is no longer necessary during this phase of the COVID-19 PHE, we issue updated regulations and program guidance, and we work with providers to ensure they receive adequate notice and direction before these changes take place.

CMS has already resumed certain provider enrollment activities in advance of the end of the COVID-19 PHE, including revalidation, fingerprint-based criminal background checks, site visits, application fees and accreditation. This decision was based on the state of the COVID-19 PHE at the time and the provider community's ability to comply with these activities. CMS provided 60 days advanced notice to the provider community prior to resuming these activities. CMS also released fact sheets summarizing the current status of Medicare blanket waivers and flexibilities by provider type to help providers transition to operations once the COVID-19 PHE ends.[2]

CMS is continuing to use the updated CMS Pandemic Plan as a guidebook for evaluating all existing flexibilities, while developing a comprehensive long-term approach for the health care system based on recovery and resiliency. CMS's strategic plan includes a cross-cutting initiative to address the COVID-19 PHE and apply lessons learned from the flexibilities provided to ensure that CMS has a roadmap to support a health care system that is more resilient and better prepared to adapt to future disasters.

GAO's recommendations and HHS' responses are below.

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[1] In the Medicare program, the term "provider" includes hospitals, critical access hospitals, SNFs, comprehensive outpatient rehabilitation facilities, home health agencies, hospices, community mental health centers that only furnish partial hospitalization services, and clinics, rehabilitation agencies, or public health agencies that only furnish outpatient physical therapy or speech pathology services. The term "supplier" includes a physician or other practitioner, or any entity that is eligible to enroll and furnish health care services under Medicare other than a provider (e.g., a durable medical equipment company). *See* 42 C.F.R. § 400.202. For the ease of the reader, this report will use the term "provider" to refer to both Medicare providers and suppliers unless otherwise noted.

[2] CMS, Creating a Roadmap for the End of the COVID-19 Public Health Emergency. August, 18, 2022. Accessed at https://www.cms.gov/blog/creating-roadmap-end-covid-19-public-health-emergency

GAO Recommendation 1
The Administrator of CMS should conduct fingerprint-based criminal background checks for high-risk provider types who enrolled during the COVID-19 public health emergency, such as when CMS revalidates these providers' information for re-enrollment.

HHS Response
CMS concurs with GAO's recommendation. In an effort to maintain provider workforce capacity and beneficiary access to care during the COVID-19 PHE, CMS temporarily waived the requirement for fingerprint-based criminal background checks for five percent or greater owners of newly enrolling high-risk categories of providers and suppliers. To mitigate the risks of the waiver, CMS maintained continuous monitoring of criminal alerts produced by the Advanced Provider Screening system. This system provides continuous monitoring of individuals against federal, state and local databases for felony alerts.

In addition, providers who temporarily enrolled via the Medicare Provider Enrollment Hotline are required to fully enroll once the COVID-19 PHE expires. The fingerprint-based criminal background check will be required if the provider is in the high-risk category. Providers who submitted an online or paper enrollment application during the COVID-19 PHE, and had fingerprints waived, can only be fingerprinted at revalidation if they are elevated to high-risk consistent with 42 C.F.R. § 424.518(c)(3). CMS is exploring ways of revalidating moderate risk providers and suppliers that were in a high-risk category at the time of initial enrollment where a PHE waived the applicable fingerprinting requirement. However, CMS notes this would require notice and comment rulemaking.

GAO Recommendation 2
The Administrator of CMS should develop policies and procedures to postpone rather than waive fingerprint-based criminal background checks during future emergencies.

HHS Response
CMS concurs with GAO's recommendation. CMS is evaluating options available to require fingerprint-based criminal background checks post initial enrollment that could be used during future emergencies. CMS notes that all of the providers that had their fingerprint-based criminal background checks waived during the COVID-19 PHE have continued to be monitored through the Advance Provider Screening system. This system provides continuous monitoring of individuals against federal, state and local databases for felony alerts. Further, CMS is exploring ways of revalidating moderate risk providers and suppliers that were in a high-risk category at the time of initial enrollment where a PHE waived the applicable fingerprinting requirement. This revalidation approach would effectively operate like a postponement of the fingerprint requirement. However, CMS notes this would require notice and comment rulemaking.

GAO Recommendation 3
The Administrator of CMS should develop and implement a plan for conducting provider enrollment revalidations to ensure providers are revalidated prior to the end of their 3- to 5-year revalidation cycles, prioritizing moderate- and high-risk provider types.

HHS Response
CMS concurs with GAO's recommendation. CMS postponed provider enrollment revalidations from March 2020 through October 2021 and has resumed a phased-in approach to revalidation activities since October 31, 2021. CMS is actively working to address the postponed revalidations while continuing to maintain the standard revalidation workload. Given that the increased revalidation workload is up to four times above the Medicare Administrative Contractors' standard workload, the effort requires additional staffing resources and funding. CMS is currently working with the Medicare Administrative Contractors to assess the level of effort involved in completing the postponed revalidations in a one-, two-, or three-year timeframe, while maintaining their ongoing revalidation workload. Contingent on available funding, CMS will develop and implement a plan for conducting provider enrollment revalidations, prioritizing higher risk provider types while taking into consideration provider burden.

GAO Recommendation 4
The Administrator of CMS should evaluate waivers and flexibilities for provider enrollment, including related oversight challenges, and address any opportunities for improvement. This evaluation could consider targeting provider enrollment waivers and flexibilities to maintain requirements for provider types CMS considers high risk—including DMEPOS suppliers—and opportunities to track and communicate to program integrity contractors information about each waiver and flexibility providers enrolled under.

HHS Response
CMS concurs with GAO's recommendation. CMS recognizes the importance of evaluating waivers and flexibilities for provider enrollment, and, as such, has continuously reviewed those issued to determine the potential for fraud, waste, and abuse in the Medicare program. This process included identifying program integrity risks and vulnerabilities associated with the waivers and flexibilities; prioritizing those with the largest potential for financial loss, beneficiary harm and/or likelihood of occurrence; and creating mitigations that addressed these program integrity risks and vulnerabilities. The COVID-19 PHE is still in effect, and CMS is undertaking an agency-wide initiative to assess the lessons learned from the waivers issued during the pandemic to inform decision making for future emergencies.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Leslie V. Gordon, (202) 512-7114 or GordonLV@gao.gov

Staff Acknowledgments

In addition to the contact named above, Iola D'Souza (Assistant Director), Russell Voth (Analyst in Charge), Gabrielle Crossnoe, Jack Knauer, and Dan Ries made key contributions to this report. Also contributing were Sam Amrhein, Sandra George, Jennifer Rudisill, and Ethiene Salgado-Rodriguez.