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July 2013

MEDICARE OUTPATIENT THERAPY

Implementation of the 2012 Manual Medical Review Process

GAO-13-613

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GAO Highlights

Highlights of GAO-13-613, a report to congressional committees

Why GAO Did This Study

In 2011, Medicare paid about $5.7 billion to provide outpatient therapy services for 48 million beneficiaries. Rising Medicare spending for outpatient therapy services—physical therapy, occupational therapy, and speech-language pathology—has long been of concern. Congress established per person spending limits, or "therapy caps," for nonhospital outpatient therapy, which took effect in 1999. In response to concerns that some beneficiaries needing extensive services might be affected adversely, Congress imposed temporary moratoria on the caps several times until 2006, when it required CMS to implement an exceptions process. The Middle Class Tax Relief and Job Creation Act of 2012, in addition to extending the exceptions process, required CMS to conduct MMRs of requests for exceptions for outpatient services provided on or after October 1, 2012, over an annual threshold of $3,700. The act also mandated that GAO report on the implementation of the MMR process.

This report describes (1) CMS's implementation of the 2012 MMR process, and (2) the number of individuals and claims subject to MMRs and the outcomes of these reviews. GAO reviewed relevant statutes, CMS policies and guidance, and CMS data on these reviews. GAO also interviewed CMS staff and officials from three MACs that accounted for almost 50 percent of the MMR workload and that processed claims for states previously determined to be at a higher risk for outpatient therapy improper payments.

View GAO-13-613. For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

What GAO Found

The Centers for Medicare & Medicaid Services (CMS) implemented two types of manual medical reviews (MMR)—reviews of preapproval requests and reviews of claims submitted without preapproval—for all outpatient therapy services that were above a $3,700 per-beneficiary threshold provided during the last 3 months of 2012. However, CMS did not issue complete guidance on how to process preapproval requests before the implementation of the MMR process in October 2012, and the Medicare Administrative Contractors (MAC) that conducted the MMRs were unable to fully automate systems for tracking preapproval requests in the time allotted. CMS required the MACs to manually review preapproval requests within 10 business days of receipt of all supporting documentation to determine whether the services were medically necessary, and to automatically approve any requests they were unable to review within that time frame. CMS officials told GAO that the purpose of the preapproval process was to protect beneficiaries from being liable for payment for nonaffirmed services by giving the provider and beneficiary guidance as to whether Medicare would pay for the requested services. If a provider delivered services without submitting a preapproval request, the MACs were required to manually review submitted claims above the $3,700 threshold prior to payment within 60 days of receiving the needed documentation. The MACs faced particular challenges with implementing reviews of preapproval requests because CMS continued to issue new guidance on how to manage preapproval requests after the MMR process started. For example, CMS did not inform the MACs how to process incomplete requests or count the 10-day preapproval request review time frame until November 7, 2012, and the MACs initially handled requests differently. In addition, all three MACs GAO interviewed told GAO that MMRs of preapproval requests were especially challenging because they did not have time to fully automate systems for tracking and processing the requests before the start of the MMR process, although they adapted their systems to manage the requests in different ways.

CMS officials estimated that the MACs reviewed an estimated total of 167,000 preapproval requests and claims for outpatient therapy service above the $3,700 threshold provided from October 1, 2012, through December 31, 2012. Of these reviews, CMS estimated that 110,000 were for preapproval requests and 57,000 were for claims submitted without prior approval. However, due in part to the lack of automation, CMS officials reported that the total number of reviews should be considered estimates of the results of the MMR process at the time of this report. CMS estimated that the MACs affirmed about two-thirds of the preapproval requests and about one-third of the claims submitted without preapproval. Because providers can appeal denials of payment, the final outcome of the MMRs remains uncertain. CMS also estimated that by December 31, 2012, over 115,000 beneficiaries were affected by the reviews in 2012, a number that will rise as more claims subject to review are submitted throughout 2013.

In its comments on a draft of this report, HHS emphasized that CMS managed the 2012 MMR process without additional funding and within a short time frame. HHS noted that the MMR process was extended for 2013 and CMS transitioned the responsibility for these reviews to other contractors as of April 1, 2013.

Contents

Abbreviations

ABN	Advance Beneficiary Notice of Noncoverage
ADR	additional documentation request
BBA	Balanced Budget Act of 1997
CMS	Centers for Medicare & Medicaid Services
DRA	Deficit Reduction Act of 2005
HHS	Department of Health and Human Services
MAC	Medicare Administrative Contractor
MedPAC	Medicare Payment Advisory Commission
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MMR	manual medical review
OIG	Office of Inspector General
OT	occupational therapy
PT	physical therapy
RAC	recovery audit contractor
SLP	speech-language pathology

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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Congressional Committees

In 2011, Medicare, the federal health program insuring 48 million people who are age 65 and older or disabled, paid about $5.7 billion to provide three outpatient therapy services—physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP)—for 4.9 million beneficiaries.[1] Medicare's total spending was approximately $565 billion that year. Therapy services help treat a range of conditions from stroke recovery to the effects of Parkinson's disease, and are provided in a variety of settings including hospital outpatient departments, skilled nursing facilities, and outpatient rehabilitation facilities.[2] The Centers for Medicare & Medicaid Services (CMS)—the agency within the Department of Health and Human Services (HHS) that administers the Medicare program—applies financial limits, known as therapy caps, to help control growth in expenditures for and discourage medically unnecessary use of outpatient therapy services. According to CMS, between 1998 and 2008, Medicare expenditures for outpatient therapy increased at a rate of 10.1 percent per year while the number of Medicare beneficiaries receiving therapy services increased by 2.9 percent per year. In addition, we and the HHS Office of Inspector General (OIG) have previously

[1]Medicare also covers individuals with end stage renal disease. Outpatient therapy services are covered under Medicare Part B, which also covers physician, outpatient hospital, laboratory, and other services, and medical equipment and supplies. Unless otherwise specified, throughout this report the terms outpatient therapy and outpatient therapy services refer to all three therapy categories collectively: PT, OT, and SLP. PT includes services that restore and maintain physical function and treat or prevent impairments that result from disease or injury. OT services improve and compensate for a patient's ability to conduct activities of daily living, such as getting dressed after the loss of a limb. SLP services help patients with difficulties communicating as a result of disease, injury, or surgery.

[2]To receive outpatient therapy services, a beneficiary must be treated or referred by a physician or nonphysician practitioner. In addition, Medicare regulations and coverage rules require that the medical record of the beneficiary receiving outpatient therapy include a written treatment plan with information on the diagnosis and therapy goals.

reported that outpatient therapy is susceptible to improper payments and fraud.[3]

Although Medicare therapy caps, which originally took effect beginning in 1999 under the Balanced Budget Act of 1997 (BBA),[4] are set annually at a level exceeding that used by most beneficiaries receiving therapy services, concerns had been raised that patients with extensive need for outpatient therapy services might be affected adversely.[5] As a result, Congress imposed temporary moratoria on the caps several times from 1999 through 2006,[6] when it required the agency to implement an exceptions process to provide coverage for beneficiaries in need of services above the caps.[7] The Middle Class Tax Relief and Job Creation

[3]An improper payment is any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements. Fraud represents intentional acts of deception with knowledge that the action or representation could result in inappropriate gain. See GAO, *Medicare: Little Progress Made in Targeting Outpatient Therapy Payments to Beneficiaries' Needs,* GAO-06-59 (Washington, D.C.: Nov. 10, 2005), and Department of Health and Human Services, Office of Inspector General, *Questionable Billing for Medicare Outpatient Therapy Services*, OEI-04-09-00540 (Washington, D.C.: December 2010).

[4]See BBA, Pub. L. No. 105-33, § 4541, 111 Stat. 251, 454.

[5]BBA established one $1,500 therapy cap for OT and a combined cap of $1,500 for PT and SLP for calendar year 1999. The amount of the therapy caps is calculated annually to account for increases in the Medicare economic index, and has increased to $1,900 in 2013.

[6]See Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, App. F, § 221(a), 113 Stat. 1501, 1501A-351; Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, App. F., § 421(a), 114, Stat. 2763, 2763A-516; Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, 117 Stat. 2066, § 624(a), 117 Stat. 2066, 2317.

[7]The exceptions process was first required by the Deficit Reduction Act of 2005 (DRA) and has been extended by law numerous times through 2013. See DRA, Pub. L. No. 109-171, § 5107, 120 Stat. 4, 42 (2006); Tax Relief and Health Care Act of 2006, Pub. L. No. 109-432, § 201, 120 Stat. 2922, 2986; Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. No. 110-173, § 105, 121 Stat. 2492, 2496; Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 141, 122 Stat. 2494, 2542; Temporary Extension Act of 2010, Pub. L. No. 111-144, § 6, 124 Stat. 42, 46; Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3103, 124 Stat. 119, 417 (2010); Medicare and Medicaid Extenders Act of 2010, Pub. L. No. 111-309, § 104, 124 Stat. 3285, 3287; Temporary Payroll Tax Cut Continuation Act of 2011, Pub. L. No. 112-78, § 304, 125 Stat. 1280, 1284; Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. No. 112-96, § 3005, 126 Stat. 156, 187; American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 603(a), 126 Stat. 2313, 2347 (2013).

Act of 2012, enacted in February 2012, in addition to extending the exceptions process through December 31, 2012, made several changes affecting the processing of claims for outpatient therapy services. In particular, the act required CMS to conduct manual medical reviews (MMR) of requests for exceptions for therapy claims over an annual threshold of $3,700 for OT and $3,700 for a combination of PT/SLP for services provided on or after October 1, 2012.[8] The act also mandated that GAO report on the implementation of the 2012 MMR process. In this report, we discuss (1) CMS's implementation of the MMR process for outpatient therapy services conducted from October 1, 2012, through December 31, 2012, and (2) the number of individuals and claims subject to MMRs during the 3-month process and the outcomes of these reviews.

To describe CMS's implementation of the MMR process, we reviewed relevant statutes, including the Middle Class Tax Relief and Job Creation Act of 2012, the Deficit Reduction Act of 2005 (DRA), and the BBA; CMS policies and guidance for the MMR of Medicare outpatient therapy claims; and CMS data on MMRs for services provided during this 3-month period. We also interviewed CMS staff responsible for implementation and oversight of the mandated MMR process as well as staff from the Medicare Payment Advisory Commission (MedPAC) and representatives from three professional associations for providers of outpatient therapy. Further, we interviewed officials from three Medicare Administrative Contractors (MAC) selected from among the 15 MACs responsible for Medicare therapy claims processing in order to learn how they implemented and collected data on the MMR process. The three MACs interviewed accounted for nearly 50 percent of the MMR workload and processed claims for states previously determined by the HHS OIG to be at a higher risk for outpatient therapy improper payments and fraud. The information collected from these interviews is not generalizable to all MACs.

To report on the number of individuals and claims subject to MMRs during the last 3 months of 2012 and the outcomes of these reviews, we analyzed CMS's Therapy Cap Weekly Workload reports. These weekly reports were compiled by CMS with aggregate data from all 15 MACs implementing the mandated MMR process. We interviewed both CMS

[8]The $3,700 threshold applied to all outpatient therapy claims with dates of service provided during calendar year 2012. This threshold was chosen because it represented the spending level of the top 5 percent of outpatient therapy beneficiaries in 2011.

and MAC officials responsible for the collection of these data to learn about the data collection process and to assess the reliability of the data. Those officials acknowledged that data from the weekly reports provide an estimate of the number of individuals and claims subject to MMR, but are not an accurate and exact count. We believe that the data are sufficiently reliable to provide a reasonable estimate of the scope of the MMR process.

We conducted this performance audit from December 2012 to June 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Health care providers submit claims to the Medicare program in order to receive payment for services provided to beneficiaries. Financial limits known as therapy caps are one tool used to better manage spending on outpatient therapy services. Congress directed CMS, beginning in 2006, to establish an exceptions process for beneficiaries in need of services above the therapy caps.

Medicare Claims Payment Overview

Since the program was created in 1965, CMS has administered Medicare through private contractors, currently known as MACs.[9] The MACs are responsible for reviewing and paying claims in accordance with Medicare policy, and conducting provider outreach and education on correct billing practices. The MACs process more than 1.2 billion claims per year (the equivalent of 4.5 million claims per work day). The MACs use electronic payment systems, and they transfer any claims submitted on paper into electronic format for processing.

[9]The MMA consolidated Medicare contracting functions—such as claims payment and other administrative activities—in MACs. Pub. L. No. 108-173, § 911, 117, 2378. Entities that previously carried out these functions were known as fiscal intermediaries and carriers.

The computer systems that the MACs use for processing and paying claims execute automated prepayment "edits," which are instructions programmed into the system software to identify errors on individual claims and to prevent payment of incomplete or incorrect claims.[10] The system edits also help ensure that payments are made only for claims submitted by appropriate providers for medically necessary goods or services covered by Medicare for eligible individuals.[11] Edits may result in automatic rejection of claims due to missing information or data errors, or in payment denial for ineligible services. In addition to this automated process, the MACs may conduct MMRs when they are unable to determine whether the services provided were medically necessary on the basis of the information on the claim.[12] The MACs solicit documentation of medical necessity from the provider by issuing an additional documentation request (ADR) for the medical records associated with a service; providers are required to submit the records to the MACs within 45 days. Upon receipt, the MMRs are performed within 60 days by licensed health care professionals. Providers and beneficiaries may appeal denials of services that are based on these reviews.[13]

Manual reviews can be conducted either before or after a claim is paid and are referred to as prepayment or postpayment reviews, respectively. CMS reports that although the MACs have the authority to review any claim at any time, the volume of claims prohibits manual review of most

[10]Medicare claims include data such as beneficiary and provider identification numbers and demographic information, as well as codes assigned for every task and service a medical practitioner may provide to a beneficiary. These codes may require the use of modifiers to improve accuracy. Modifiers may include units of service, functional limitations, or discharge status.

[11]CMS uses the terms providers and suppliers to differentiate between entities that provide health care services and entities that provide medical equipment to Medicare beneficiaries. In this report we use the term providers to refer collectively to providers and suppliers.

[12]The MACs and other Medicare contractors conduct manual reviews to determine whether the services provided meet medical necessity standards and are (1) reasonable and necessary; (2) for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member; and (3) not excluded under another requirement of the Medicare program.

[13]If a provider or beneficiary appeals a decision, the Medicare appeals process may take up to 2 years.

claims.[14] In general, CMS directs the MACs to focus their MMRs on program integrity efforts targeting payment errors for services and items that pose the greatest financial risk to the Medicare program.[15] We have previously reported that, overall, less than 1 percent of Medicare's claims are subject to medical record review by trained personnel.[16]

Medicare Outpatient Therapy Spending

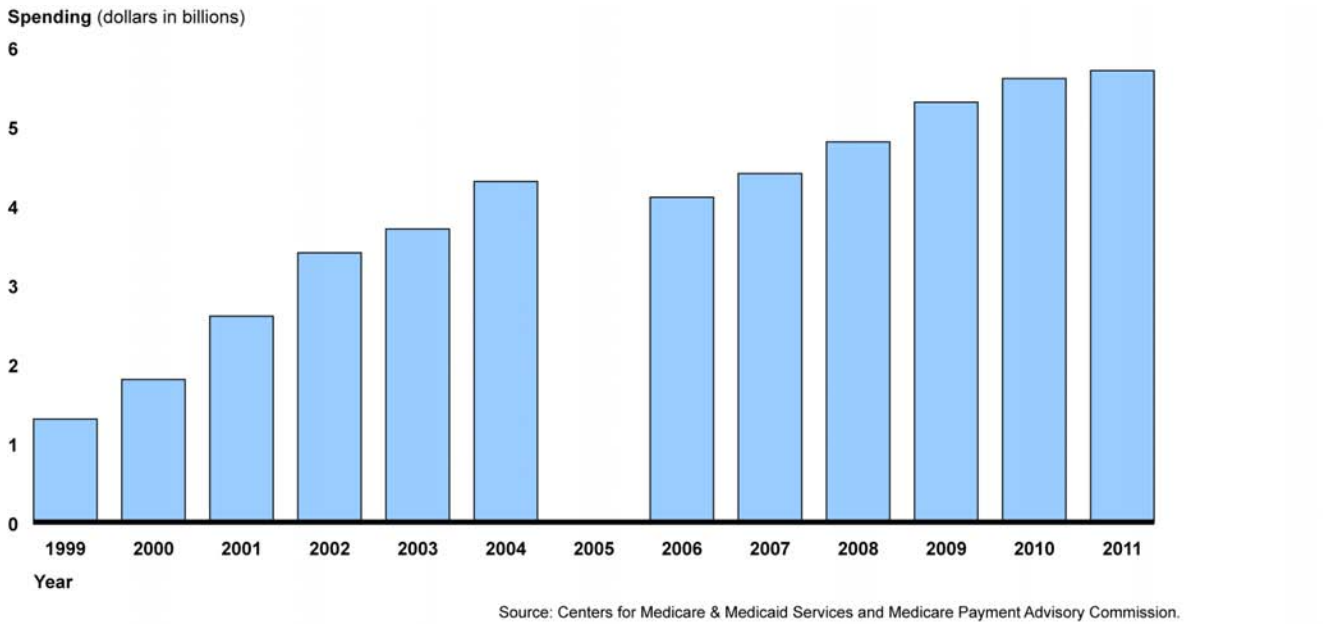
Medicare spending for outpatient therapy has increased from $1.3 billion in 1999 to $5.7 billion in 2011. (See fig. 1.) During this 12-year period, mean per user spending on outpatient therapy grew threefold from about $400 to almost $1,200. In 2011, about 80 percent of the 4.9 million Medicare beneficiaries who used OT and PT/SLP did not exceed the annual cap of $1,870. Twenty percent of the Medicare beneficiaries using outpatient therapy (about 980,000 individuals) exceeded the cap that year and spent, on average, $3,000 on outpatient therapy. Therapy provided in nursing homes and private practice offices accounted for over 70 percent of outpatient therapy services in 2011, with the remaining services being provided in hospital outpatient departments and outpatient rehabilitation centers, and by home health agencies.

[14]MACs typically select a small sample of claims for manual reviews from providers or suppliers who demonstrate aberrant billing or practice patterns. The MACs are responsible for developing, implementing, and monitoring annual error reduction plans.

[15]See also GAO, *Medicare: Improvements Needed to Address Improper Payments in Home Health*, GAO-09-185 (Washington, D.C.: Feb. 27, 2009); and *Medicare: Little Progress Made in Targeting Outpatient Therapy Payments to Beneficiaries' Needs,* GAO-06-59 (Washington, D.C.: Nov. 10, 2005).

[16]See GAO, *Improper Payments: Reported Medicare Estimates and Key Remediation Strategies*, GAO-11-842T (Washington, D.C.: July 28, 2011).

Figure 1: Medicare Part B Outpatient Therapy Spending 1999–2011



Source: Centers for Medicare & Medicaid Services and Medicare Payment Advisory Commission.

Note: Total outpatient therapy spending data are missing for 2005.

In addition, studies have found that utilization of outpatient therapy services is not evenly distributed across the country. For example, in 2010, the HHS OIG reported on 20 counties with spending per beneficiary 72 percent higher than the national average.[17] MedPAC's analysis of outpatient therapy claims data from 2011 showed that average per-beneficiary spending varied widely by county, ranging from $406 to $3,582.[18]

The Therapy Caps Exceptions Process

The therapy caps that were first imposed in 1999 to control spending growth raised concern that patients with extensive need of outpatient therapy services would be affected adversely, and the caps were only in effect in 1999 and for part of 2003 due to a series of temporary

[17]Department of Health and Human Services, Office of Inspector General, *Questionable Billing for Medicare Outpatient Therapy Services.*

[18]Medicare Payment Advisory Commission, *Mandated Report: Improving Medicare's Payment System for Outpatient Therapy Services* (Washington D.C.: Oct. 5, 2012).

congressional moratoria. As implemented in 2006, when the moratoria expired, Congress required CMS to implement a process to allow exceptions to the caps for certain medically necessary services.[19] This exceptions process allowed for two types of exceptions. The first was an automatic exception for certain conditions or complexities, such as hip and knee replacements. The second—called a manual exceptions process by CMS— was a preapproval process whereby a provider could submit a letter and supporting documentation requesting an exception—called a preapproval request—for up to 15 days of treatment above the annual cap, which would be manually reviewed by the MAC.[20] If the services qualified for either an automatic or a manual exception, CMS guidance instructed the provider to include a "KX" modifier on each line of the resulting claim that contained a service above the cap. This modifier represented the provider's attestation that the services rendered were medically necessary, and it triggered an exception in the Medicare claims processing system, which ensured payment for those outpatient therapy services above the cap.

An automatic exceptions process for claims with a KX modifier was extended through 2012 for claims over the annual cap of $1,880, with manual reviews required for claims above the threshold of $3,700.[21] The American Taxpayer Relief Act of 2012 extended the Medicare therapy caps exceptions process, including the requirement for the manual review of claims over $3,700, through December 31, 2013.[22]

According to CMS, in 2012, claims for services above the $1,880 cap without a KX modifier or above the $3,700 threshold were considered a benefit category denial, making the beneficiary liable for payment. To protect beneficiaries from unexpected liability for payment of denied

[19]DRA, Pub. L. No. 109-171, § 5107, 120 Stat. 42 (2005). As previously noted, an exceptions process has remained in effect since then.

[20]CMS required the MACs to conduct MMRs of these preapproval requests within 10 business days and determine whether treatment above the cap was medically necessary.

[21]See Pub. L. No. 112-96, § 3005(a), 126 Stat. 187.

[22]Pub. L. No. 112-240, § 603, 126 Stat. 2347. As of April 1, 2013, the responsibility for conducting prepayment MMRs in 11 states for claims above the $3,700 threshold was transitioned from the MACs to CMS's Recovery Audit Contractors (RAC) as part of the agency's Prepayment Review Demonstration. The RACs will conduct postpayment MMRs in the states that are not part of the demonstration.

claims above the threshold, CMS gave providers the option to send beneficiaries an Advance Beneficiary Notice of Noncoverage (ABN) informing them that Medicare might not pay for an item or service and that they might be liable for payment. An ABN enables the beneficiary to make an informed decision about whether to get services and accept financial responsibility for those services if Medicare does not pay.

CMS Implemented Two Types of MMRs, but the Process Lacked Timely Guidance and Fully Automated Systems

CMS implemented two types of MMRs during the last 3 months of 2012—reviews of preapproval requests and reviews of claims submitted without preapproval. CMS did not issue complete guidance at the start of the MMR process, causing implementation challenges for the MACs, and the MACs were unable to fully automate systems for tracking the reviews of preapproval requests in the time allotted.

CMS Implemented MMRs of Preapproval Requests and of Claims Submitted without Preapproval

CMS implemented two types of MMRs during the last 3 months of 2012—reviews of preapproval requests and reviews of claims submitted without preapproval. First, CMS directed the MACs to manually review preapproval requests for outpatient therapy services above the $3,700 threshold—one for OT and one for PT/SLP combined—before the services were provided. Providers were permitted to request up to 20 days of treatment up to 15 days before providing medically necessary outpatient therapy services above $3,700. In contrast to the MMR process as implemented in 2006, CMS guidance did not allow any automatic exceptions for certain conditions; the MACs had to manually review preapproval requests for any services above $3,700. CMS officials told us that they included the preapproval request process in 2012 in order to help protect beneficiaries from being held liable for payment of claims not affirmed by the MMR, as the process would give the provider and beneficiary guidance as to whether the MACs would affirm or not affirm payment for the requested outpatient therapy services.[23]

In order to manage the expected volume of preapproval requests submitted to MACs at the start of the MMR process, CMS divided all

[23]CMS used the terms affirmed and nonaffirmed to indicate whether outpatient therapy services were approved or denied as part of the MMR process.

outpatient therapy providers among three phases, based primarily on their past billing practices.[24] Providers were instructed to submit preapproval requests during their assigned phase.[25] CMS assigned providers with the highest average billing per patient for outpatient therapy services in 2011 to the first phase, which began on October 1, 2012. According to CMS, these high billers accounted for approximately 25 percent of all outpatient therapy providers and were subject to MMR for the full 3 months of the MMR process during 2012. The second phase began on November 1 and included providers with the next highest billing (also about 25 percent of the total number of providers). The third phase, which included the remaining 50 percent of outpatient therapy providers, generally the lowest billers, began on December 1.[26] CMS officials explained that providers with historically low billing were less likely to have patients who would reach the threshold. CMS also included providers identified by law enforcement or the HHS OIG as being involved in active fraud investigations in the third phase. CMS officials stated that they did not include these providers until the third phase to avoid conflicts with ongoing investigations. As of December 1, all outpatient therapy providers were included in the MMR process.

CMS notified providers about the preapproval request process and assignment of phases by letter and provided further information through three conference calls and additional agency communications. CMS instructed providers to submit preapproval requests by mail or fax, including key information such as provider and beneficiary identification numbers as well as supporting documentation including treatment notes and progress reports.[27] CMS also instructed the MACs to post guidelines on their websites to educate providers about these requirements. In

[24]Approximately 91,000 outpatient therapy providers were divided into these phases. CMS officials noted that they implemented the MMR process in phases because they did not want to overwhelm the MACs with a large volume of preapproval requests at the beginning of the process, as occurred during the preapproval process in 2006.

[25]CMS instructed the MACs to review requests no sooner than 15 days in advance of the phase to which providers were assigned.

[26]CMS officials stated that they also included new outpatient therapy providers and those who had not billed Medicare for outpatient therapy in 2011 in the third phase. CMS made additional adjustments to the assignment of providers to each phase in order to accommodate MACs whose contracts were in transition due to the consolidation of contractors resulting from Medicare contracting reform.

[27]Providers did not have an option to submit requests electronically.

addition, CMS sent letters in mid-September 2012 to all Medicare beneficiaries who had received therapy services totaling over $1,700 by that date informing them that they might have to pay for services over the cap should the MACs determine that the services were not medically necessary.

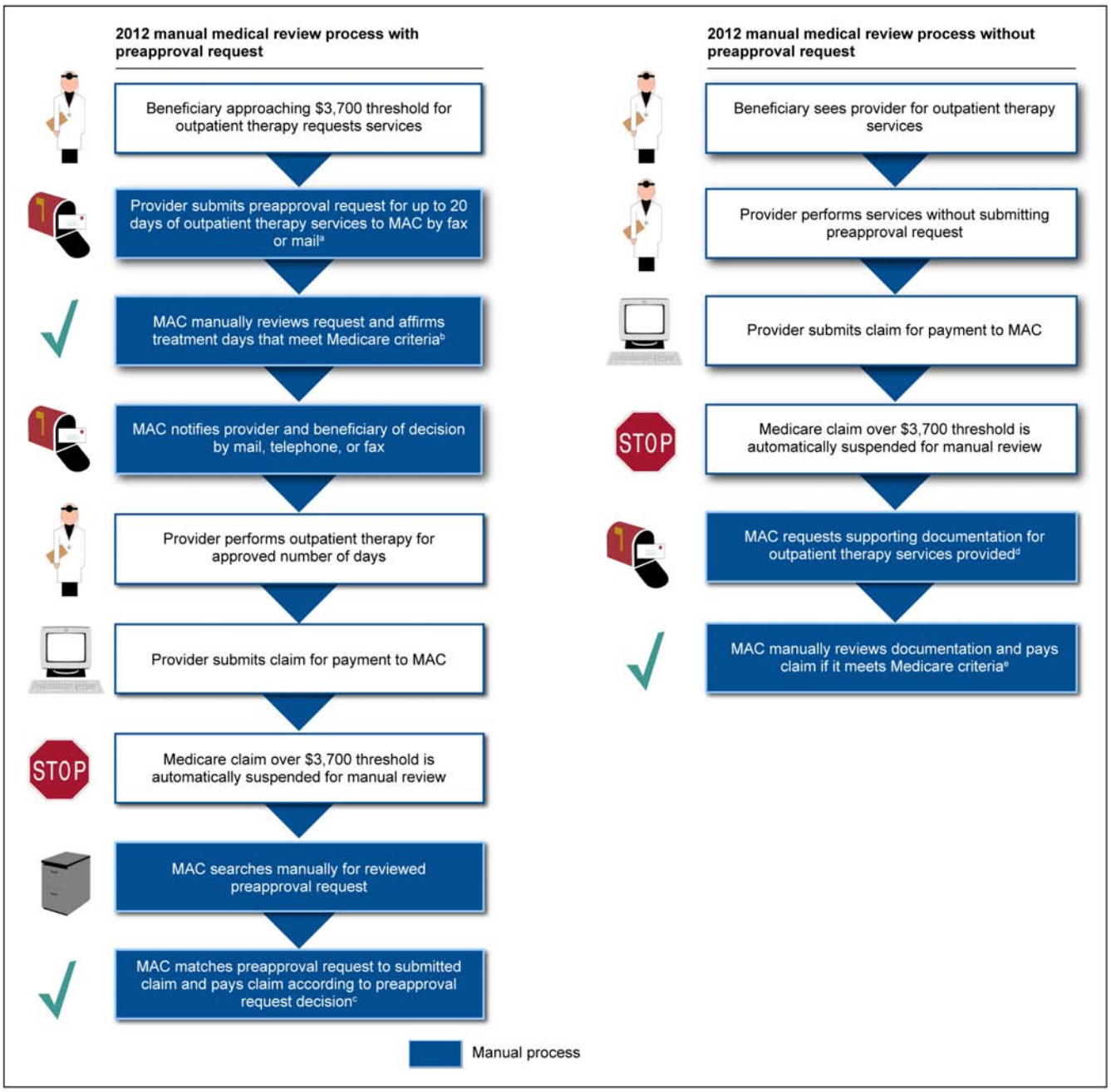
To expedite the preapproval process, CMS instructed the MACs to review preapproval requests within 10 business days of receipt of all requested documentation to determine whether the services were medically necessary.[28] After reviewing the requests, the MACs were required to notify providers and beneficiaries of the number of treatment days affirmed or provide detailed reasons for not affirming a request.[29] In addition, CMS instructed the MACs to automatically approve any requests they were unable to review within 10 business days.[30] The MACs had to inform providers of their decisions by telephone, fax, or letter, and postmark all letters by the 10th day after receipt of all requested documentation. Providers were allowed to resubmit nonaffirmed requests with additional documentation for consideration by the MAC, at which point the MAC would have another 10 days within which to review the new request. (See fig. 2.)

[28]CMS instructed the MACs to review preapproval requests in accordance with Medicare coverage and payment policies, including applicable local coverage policies. The relevant coverage and payment policies are contained in Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual*, CMS Pub. 100-02, section 220 (June 8, 2012).

[29]Beneficiaries could elect to receive services even if a preapproval request was not affirmed. If they did so, the beneficiaries would be liable for payment for those services. In addition, providers could submit a claim for nonpreapproved services after providing the services. According to CMS instructions, the claim would then be denied in accordance with the preapproval decision. At that point, the provider or beneficiary could file an appeal seeking Medicare payment for the services.

[30]In a CMS Open Door Forum on October 22, 2012, providers noted that they sometimes waited more than 10 business days to receive a response, and were concerned that they had to delay needed services as a result.

Figure 2: Outpatient Therapy Manual Medical Reviews (MMR), October–December 2012



Sources: GAO analysis of CMS data; Art Explosion (images).

[a]Providers could submit preapproval requests up to 15 days before the intended dates of service.

[b]Centers for Medicare & Medicaid Services (CMS) required the Medicare Administrative Contractors (MAC) to review preapproval requests within 10 business days of receipt of all requested documentation and automatically affirm requests they were unable to review within that time frame.

[c]If the submitted claim did not match the related preapproval request, the MAC would request additional supporting documentation and conduct further review before determining how to pay the claim, as it would for claims submitted without a preapproval request.

[d]Providers had to submit requested documentation within 45 days.

[e]The MACs had to review all supporting documentation within 60 days. If the MAC requested additional documentation, the review time frames would reset. Providers and beneficiaries could appeal denied claims.

Second, CMS instructed the MACs to develop a mechanism for tracking preapproval requests in order to match the requests with submitted claims. Because preapproval requests were received by fax or mail, not through the automated claims payment systems, the MACs had to manually match the claim with the corresponding preapproval request. If the services included on the claim matched those affirmed during the preapproval process, the MAC would pay the claim; if not, the MAC would issue an ADR for the medical records associated with the services and conduct further manual review, which could extend the review process more than 3 months.

The MACs were also required to manually review submitted claims before providing payment for therapy services provided above $3,700 without a preapproval request.[31] Effective for dates of service on or after October 1, 2012, CMS required the MACs to implement an edit in part of the claims processing system to stop claims that reached the $3,700 threshold and to trigger MMRs by the MACs.[32] To manually review claims without preapprovals, the MACs requested and reviewed supporting documentation from providers to determine whether the services were medically necessary. As with typical prepayment manual reviews, providers had 45 days to provide documentation of medical necessity, and the MACs had 60 days to review the supporting materials and notify providers and beneficiaries of their decisions. (See fig. 2.) If a MAC requested additional documentation, the review time frames would begin again. In contrast to preapproval request decisions, the MACs' claims

[31]Providers were advised, but not required, to submit preapproval requests.

[32]A MAC could choose to conduct MMRs of outpatient therapy claims for services above the 2012 annual cap of $1,880 and below the mandatory review threshold of $3,700 if it was concerned about potential fraud or aberrant billing patterns by a provider.

payment systems automatically send letters notifying providers and beneficiaries of payment determinations.

MACs Did Not Receive Timely Guidance from CMS and Could Not Fully Automate Systems for Processing Preapproval Requests

The MACs did not receive complete CMS guidance before the start of the 3-month MMR process regarding how the MACs should manage incomplete preapproval requests, how they should count the 10-day review time frame, and how they should handle preapproval requests received in the wrong phase. In addition, the MACs did not have enough time to fully automate systems for tracking and processing preapproval requests before the start of the MMR process.

Lack of Timely CMS Guidance

CMS did not issue complete guidance at the start of the MMR effort and changed the process throughout the 3-month period, which created implementation challenges. CMS provided instruction to the MACs through various forms of written guidance, as well as twice-weekly conference calls beginning in August 2012.[33] However, CMS did not issue instructions on how the MACs should conduct MMRs of preapproval requests until August 31, 2012.[34] The MACs we interviewed stated that receiving this guidance 1 month before the October 1st start of the MMR process made it difficult for them to adequately prepare and establish systems for reviews of preapproval requests. For example, one MAC said that because of the short turnaround time for implementation, it was not prepared for the high volume of preapproval requests received in the early weeks of the process, which caused it to approve requests without reviewing them. Another stated that it could have better managed the volume of preapproval requests received if it had more time to develop needed support systems. This late guidance also made it difficult for the MACs to train temporary staff assigned to the MMR process in a timely way; two MACs noted that they were still training temporary staff in October, after the start of the process, and one added that this made it

[33]CMS issues guidance in the form of change requests and technical direction letters, among other things. CMS issues a change request when the agency wants an addition or alteration to the agreed-upon deliverables for a project carried out by a contractor. Technical direction letters provide supplementary guidance to contractors regarding tasks contained in their statements of work or change requests.

[34]CMS began conducting conference calls with the MACs in early August to help them prepare for the process. According to CMS, the MACs are not allowed to devote resources to a new project, including hiring new or temporary staff, until a change request is issued.

difficult to manage the volume of preapproval requests received in October.

Further, CMS did not provide guidance on how the MACs should process incomplete preapproval requests, which accounted for approximately 23 percent of the total requests submitted, until November 7, 2012. CMS officials told us they did not initially issue such guidance because they did not anticipate receiving a high volume of incomplete submissions. As a result, the MACs handled incomplete requests in different ways. For example, one MAC held incomplete requests—as many as several thousand—as pending without making a determination or providing a response to providers and beneficiaries within 10 business days. Another initially determined that incomplete requests would be rejected and returned to the provider for additional information.

In addition, CMS did not initially issue clear instruction about how the MACs were to count the 10-day time frame for provider and beneficiary notification, which may have caused notification delays. CMS initially instructed the MACs to make decisions on preapproval requests and inform providers and beneficiaries of their decisions within 10 business days of receipt of all requested documentation, and to automatically approve requests they were unable to review within 10 days. The MACs stated that they were unclear, however, about how to count the 10-day time frame. On November 7, 2012, CMS clarified that the count was to begin on the day the MAC received the preapproval request in its mailroom, not in its MMR department. The MACs we interviewed stated that they received a large volume of requests per day—at times several hundred. In addition, two noted that providers often sent in additional supporting documentation for prior requests, which added to the volume of paper files the MACs had to manage and may have created a further lag between when the complete requests were received and when the paperwork was given to MMR staff for review. Before CMS issued this clarifying guidance, providers and beneficiaries may have experienced a longer wait time than expected if a MAC counted the 10 days beginning when the MMR department, rather than the mailroom, received the completed requests.

Finally, CMS did not initially provide the MACs with instructions about how to handle preapproval requests and claims submitted in the wrong phase. In its written guidance issued on August 31, 2012, CMS instructed the MACs that they should not review preapproval requests any sooner than 15 days before the start of each phase for providers within that phase, but did not clarify whether requests received out of phase should

be rejected and returned to providers, not affirmed, or held as pending until the start of the phase. As a result, one of the MACs we spoke with stated that it initially held requests received out of phase to be processed in the correct phase, but later in the process began rejecting such requests.

Lack of Fully Automated Systems for Processing Preapproval Requests

CMS and the three MACs we interviewed reported challenges with processing preapproval requests because they were not able to fully automate systems to receive and track them in the time allotted. MACs typically conduct either prepayment or postpayment reviews after claims have been submitted; they do not typically receive or conduct MMRs of preapproval requests before the provision of services. All three MACs interviewed told us that MMRs of preapproval requests were more time-consuming and cumbersome because they had to process them outside of their claims processing systems. In addition, all three MACs told us they suspended some of their other medical review efforts in order to implement the mandated outpatient therapy MMRs. For example, the MACs we interviewed explained that they typically use automated edits in their claims processing systems to flag claims for prepayment review in areas identified to be at higher risk for improper payments, such as certain billing codes or service areas, but told us they turned off some other outpatient therapy edits while conducting the mandated MMRs.

All three MACs interviewed said that it was difficult to develop fully automated systems for processing preapproval requests at the start of the 3-month process. Two noted that they would have required several months to develop the type of automated systems that, integrated with their regular claims processing systems, would have enhanced the efficiency and accuracy of their MMR efforts. However, CMS did not issue written guidance until August 31, 2012, instructing the MACs to develop processes for receiving and tracking preapproval requests.

The MACs we interviewed adapted their systems to manage the preapproval process in different ways with varying degrees of automation. Two of the MACs received requests by fax, scanned the requests and supporting documents, and saved them electronically by date or other identification numbers for tracking. One of these MACs also developed a database in which it manually entered and tracked its MMR decisions, which MAC staff then manually searched to match with submitted claims. The other, however, stated that it did not have time to establish such a database, and conducted reviews without any automation. A third MAC received all requests by mail and developed a database in which it entered its preapproval decisions. This MAC also developed an electronic

edit in its claims processing system that tracked incoming therapy claims so they could be processed according to the preapproval decision. Though this MAC was able to automate this step in the preapproval process, staff explained that they were still in the process of testing the edit after the start of the MMR process, and continued to address system errors until December.

CMS Estimates That Preapproval Requests and Claims for over 115,000 Beneficiaries Were Subject to MMRs, but the Final Outcomes of These Reviews Remain Uncertain

CMS officials estimate that preapproval requests and claims for over 115,000 Medicare beneficiaries were subject to approximately 167,000 MMRs conducted by the MACs as of March 1, 2013. Delays in claim submissions and pending appeals create uncertainty about the final outcomes of the 2012 MMR process.

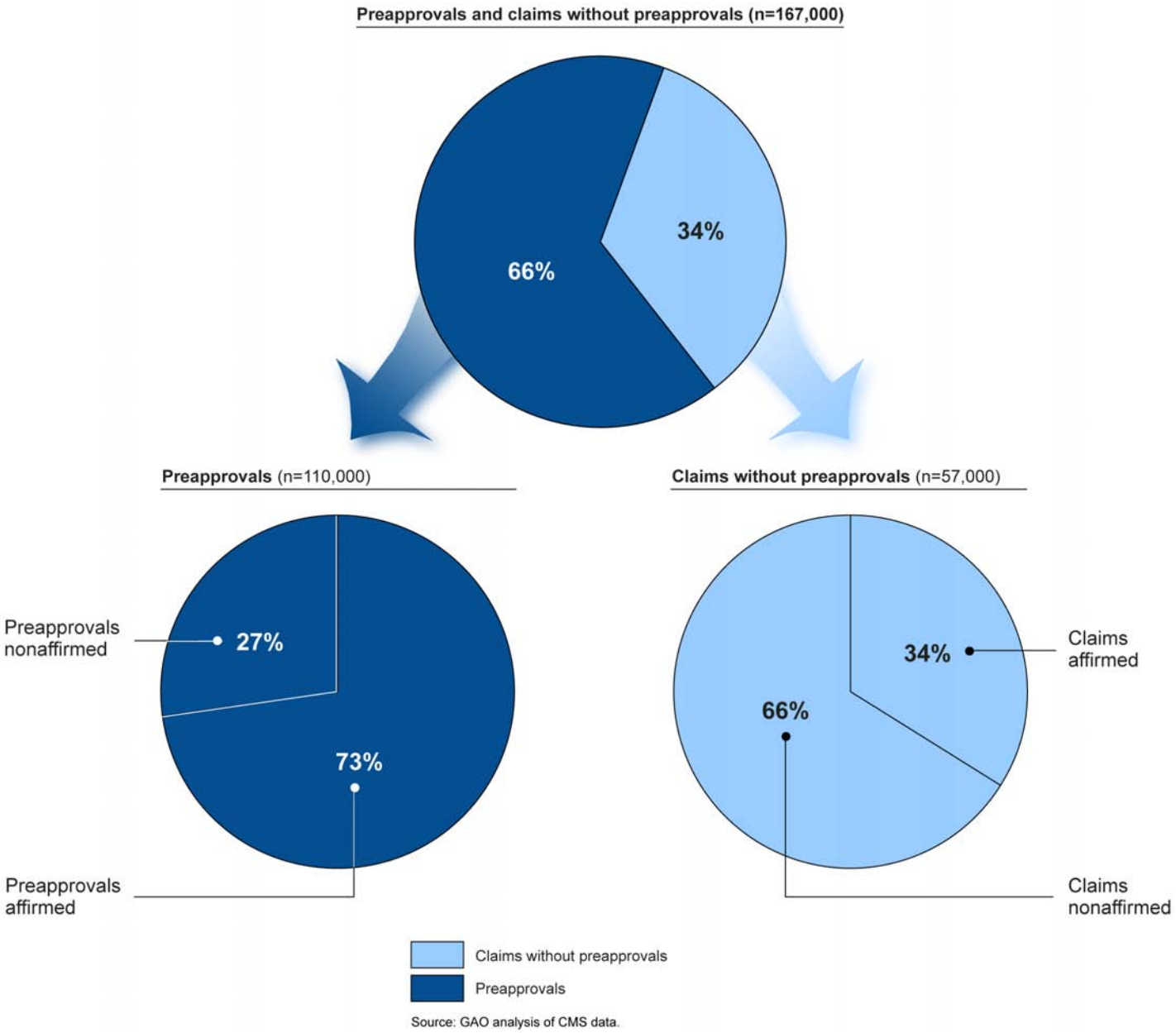
MACs Reviewed an Estimated 167,000 Preapproval Requests and Claims and Affirmed 60 Percent

CMS staff estimated that the MACs manually reviewed more than 167,000 preapproval requests and claims without preapprovals for outpatient therapy from October 1, 2012, through December 31, 2012, affecting more than 115,000 Medicare beneficiaries. Of these MMRs, an estimated 110,000 were for preapproval requests[35] and 57,000 were for claims for services that were not preapproved. Of the estimated 110,000 preapproval requests reviewed, the MACs affirmed 80,500 (73 percent) and did not affirm 29,500 (27 percent). As of March 1, 2013, providers who did not request preapprovals submitted an estimated 57,000 claims for outpatient therapy services provided during the last quarter of 2012. The results of the MMRs of claims without preapprovals resulted in 19,500 (34 percent) claims affirmed for payment and 37,000 claims (66 percent) not affirmed for payment. These estimates indicate that MMRs of both preapproval requests and claims resulted in a number of

[35]The total of 110,000 preapproval requests included the requests either affirmed or nonaffirmed.

nonaffirmed outpatient therapy services during the last quarter of 2012 (see fig. 3).

Figure 3: Estimated Total Manual Medical Reviews (MMR) Conducted for Outpatient Therapy Services Provided October 1, 2012–December 31, 2012



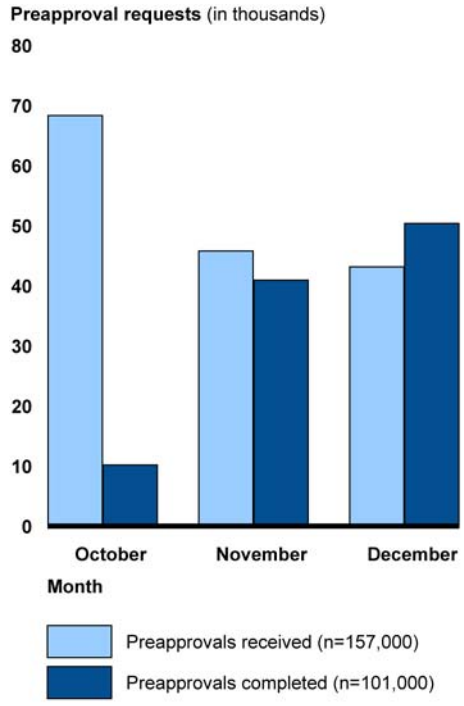
Note: In total, of the 167,000 preapprovals requests and claims without preapprovals reviewed by the Medicare Administrative Contractors (MAC) as of March 1, 2013, 60 percent were affirmed and 40 percent were not affirmed. The Centers for Medicare & Medicaid Services (CMS) and the MACs acknowledge that the estimates are not exact counts.

Both CMS officials and MAC staff acknowledged that the MACs were not able to process all the preapprovals submitted in a timely manner. The MACs do not usually conduct preapprovals of services, and the MACs stated that the high volume of preapproval requests outpaced the capacity of the MACs to review them. For example, the MACs we interviewed reported receiving thousands of preapproval requests by mail or fax prior to the start of the MMRs. By mid-October 2012, the MACs estimated they had received 46,000 preapproval requests for outpatient therapy services above the $3,700 threshold. In addition, the MACs rejected about 23 percent of all preapproval requests because they were incomplete. Incomplete requests could be resubmitted. In November 2012, on average more than 24,000 preapproval requests were categorized as having not been reviewed at the end of each of the 4 weeks.[36] Overall, the MACs estimated they completed MMRs for about 52 percent of the total preapproval requests received within the 10 days required by CMS.[37] (See fig. 4.)

[36]CMS categorized requests that were not completed in a given week as pending review.

[37]CMS advised but did not require the MACs to expedite the outpatient therapy prepayment reviews.

Figure 4: Estimated Outpatient Therapy Requests Received and Completed by Month, October–December, 2012



Source: GAO analysis of CMS data.

Note: CMS guidance did not include information on how the MACs should count "completed reviews" so the total number of requests completed does not equal the number of preapproval requests the MACs affirmed plus those not affirmed. The total number of preapprovals received included some rejected, duplicate, or resubmitted claims.

By the end of December 2012, the MACs had conducted MMRs on about 15,000 claims submitted without preapproval requests. However, the MACs were not under the same time constraints when reviewing claims because, unlike the preapproval requests, CMS guidance permits the MACs 2 months to conduct MMRs after they receive the supporting documentation. In addition, claims for therapy provided during the last quarter of 2012 were submitted incrementally, increasing from about 15,000 at the end of December to almost 57,000 by March 1, 2013. As a result, the MMRs of these claims are staggered over time. CMS officials indicated that the number of claims submitted and beneficiaries affected by these prepayment MMRs would continue to increase in 2013.

Final Outcomes of MMRs Remain Uncertain Due to Data Limitations and Timing

Although CMS was able to estimate the results of the MMRs conducted, the final outcomes of the 2012 MMRs remain uncertain due to inconsistencies among the MACs in how the data were collected, and errors in the calculation of the number of preapproval requests received and the MMR decisions made. In addition, the time lag for submitting claims and finalizing the appeals process means that the final outcome of the MMR process will not be known for months. CMS officials told us that MACs did the "best they could" and that the final numbers provided in the MMR weekly workload report were obtained outside the MACs' computerized systems and should be considered approximate or an estimate of the results of the reviews at the time of this report.

The manual processes CMS and the MACs used to complete the weekly MMR workload reports resulted in inconsistencies in the data. Both the CMS and MAC officials interviewed acknowledged that human error may have contributed to discrepancies in the reported numbers because the reports were assembled manually. In addition, due to the timing of CMS guidance throughout the MMR, the MACs reported collecting key data elements differently. For example, one MAC included the number of requests rejected in the total number of requests completed while two others did not. CMS officials also reported that they identified gaps or errors in MACs' weekly workload reports, but the agency did not require the MACs to go back to revise prior weeks' data. As a result, the running totals included errors from prior weeks and the final numbers do not total correctly. For example, the total number of treatment days that CMS estimates were requested (2.4 million) is significantly greater than the estimated total number of treatment days affirmed plus days nonaffirmed (1.9 million).

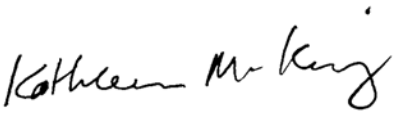
The combination of potential delays in billing, the prepayment review of claims, and the appeals process also creates uncertainty about the final outcomes of the mandated MMRs associated with outpatient therapy services provided in 2012. Because claims for services provided from October 1, 2012, through December 31, 2012, may be submitted to the MACs as late as December 31, 2013, the total number of claims reviewed will not be known until 2014. In addition, CMS officials, some MAC staff, and outpatient therapy provider association representatives reported the filing of appeals for denials of payment for therapy provided during this period. The appeals process—which may involve five levels of review—could take more than 2 years to reach a conclusion, and any reversals of prior therapy coverage denials will affect the final outcomes of the 2012 MMR process.

Agency Comments

HHS provided written comments on a draft of this report. HHS highlighted CMS's 2012 efforts to review the medical records associated with requests for exceptions for outpatient therapy services in excess of the annual $3,700 threshold. The department noted that CMS managed the new workload without additional funding and within a short time frame, and that the MACs shifted staff from other responsibilities to the MMR process. Outpatient therapy manual reviews were extended for 2013 and, according to HHS, CMS streamlined the MMRs of therapy services by transitioning the responsibility for these reviews from the MACs to the agency's RACs as of April 1, 2013. The RACs are conducting prepayment review of claims at the $3,700 threshold in California, Florida, Illinois, Louisiana, Michigan, Missouri, New York, North Carolina, Ohio, Pennsylvania, and Texas, and are conducting immediate postpayment reviews in all other states. HHS's comments are printed in appendix I.

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

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



Kathleen M. King
Director, Health Care

List of Committees

The Honorable Max Baucus
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
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The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Camp
Chairman
The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Appendix I: 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

JUN 25 2013

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

Dear Ms. King:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Medicare Outpatient Therapy: Implementation of the 2012 Manual Medical Review Process" (GAO-13-613).

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

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "MEDICARE OUTPATIENT THERAPY: IMPLEMENTATION OF THE 2012 MANUAL MEDICAL REVIEW PROCESS (GAO-13-613)

The Department appreciates the opportunity to review and comment on this draft report.

The Manual Medical Review (MMR) process requires that Centers for Medicare & Medicaid Services (CMS) review the medical record associated with a request and exception for therapy services exceeding an annual threshold of $3,700 for a beneficiary to determine whether the exception should be granted or whether the claim should be paid. However, we note that there were significant budgetary issues associated with this substantial new workload. The law provided a short timeframe for implementation of the MMR process without additional funding for the MMR process. Therefore, CMS had to find resources to implement this new requirement. Our Medicare Administrative Contractors (MACs) had to shift staff from their other responsibilities to do this task.

The MMR process for therapy services has been extended for 2013. The responsibility for this process is being handled by the Recovery Auditors as of April 1, 2013. We believe this will expedite and streamline these MMRs of therapy services. The Recovery Auditors will conduct two types of MMR of therapy services: prepayment and post-payment review. In the following states: Florida, California, Michigan, Texas, New York, Louisiana, Illinois, Pennsylvania, Ohio, North Carolina and Missouri, the Recovery Auditors will conduct prepayment review for claims over the $3,700 threshold . In the remaining States, the Recovery Auditors will conduct immediate post-payment review.

CMS is managing this work as efficiently and effectively as possible, given the budget constraints, and is working to better educate providers regarding outpatient therapy services.

1

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Kathleen M. King, (202) 512-7114 or kingk@gao.gov

Staff Acknowledgments

In addition to the contact named above, Martin T. Gahart, Assistant Director; George Bogart; Anne Hopewell; and Sara Rudow made key contributions to this report.