The MEDIC Produced Some Positive Results but More Could be Done to Enhance its Effectiveness

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What OIG Found

While the Medicare Drug Integrity Contractor's (MEDIC's) reported recoveries resulted in a positive return on investment ($3 in recoveries for every $1 invested in 2017), the Centers for Medicare & Medicaid Services (CMS) has no measures that specifically assess the MEDIC's effectiveness. Without specific measures, it is unclear how CMS assesses the MEDIC's effectiveness in fighting fraud. The Office of Inspector General's (OIG's) analysis of MEDIC activities and responses from MEDIC staff provided insights into MEDIC operations that could lead to both enhanced MEDIC effectiveness and improved measures to gauge this effectiveness.

CMS directed the MEDIC to devote more resources to proactive data analysis and administrative actions in 2014 and 2015, which led to a sharp increase in proactive data analysis, but a decrease in the MEDIC resources available to follow up on the results of these analyses. As a result, there have been fewer MEDIC investigations and referrals to law enforcement agencies, including OIG. The direction did lead to an initial upswing in administrative actions (revocations and exclusions); however, those declined precipitously in 2017 due to other procedural changes. Through its increased proactive analyses, the MEDIC was able to identify thousands of high-risk leads involving drugs, including opioids, from 2014 through 2017. The impact of these activities, however, cannot be measured as plan sponsors are not required to report to CMS the actions taken in response to these leads.

In addition, MEDIC staff described numerous barriers that limit the MEDIC's overall impact. These barriers include the MEDIC's lack of access to complete Part C encounter data; its inability to recommend certain administrative actions, such as revocation of billing privileges, against Part C and Part D providers and pharmacies not enrolled in Medicare; and its inability to obtain all requested medical records from pharmacies, providers, and pharmacy benefit managers.

What OIG Recommends

We recommend that CMS (1) require plan sponsors to report fraud and abuse incidents and the actions taken to address them; (2) provide the MEDIC with centralized access to all Part C encounter data; (3) require that Part C and Part D providers/pharmacies enroll in Medicare; (4) clarify the MEDIC's authority to require records from pharmacies, pharmacy benefit managers, and other entities under contract with Part C and Part D plan sponsors; (5) ensure that the MEDIC has the ability to require medical records from prescribers of Part D drugs not under contract with plan sponsors, obtaining legislative authority, if necessary; and (6) establish measures to assess the MEDIC's effectiveness. CMS did not concur with the third and fifth recommendations.

Full report can be found at oig.hhs.gov/oei/reports/oei-03-17-00310.asp

Why OIG Did This Review

The MEDIC is CMS's benefit integrity contractor tasked with detecting and preventing fraud, waste, and abuse in Medicare Part C and Part D. These programs involve billions of dollars in expenditures and cover millions of beneficiaries. Therefore, effective, proactive oversight is essential to protect Medicare and its beneficiaries from fraud, waste, and abuse. OIG conducted this evaluation in response to a congressional mandate outlined in the Comprehensive Addiction and Recovery Act of 2016 (CARA). CARA requires OIG to conduct a study and submit a report on the effectiveness of the MEDIC's efforts to identify, combat, and prevent fraud in Medicare Part C and Part D.

How OIG Did This Review

We analyzed Workload Statistic Reports related to the MEDIC's Part C and Part D benefit integrity activities from fiscal years 2012 through 2017 to determine how these activities have changed throughout the years. In addition, we followed up with the MEDIC (Health Integrity, LLC, now Qlarant Integrity Solutions, LLC) to ask about its barriers and challenges in performing these activities. From the MEDIC, we also requested its results regarding the identification of high-risk pharmacies and providers. To gauge the MEDIC's financial effectiveness, we developed a return on investment measure comparing the amount paid to the MEDIC with actual recoveries reported by the MEDIC. We reviewed information from CMS regarding the measures and data it uses to determine the MEDIC's overall effectiveness.

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BACKGROUND

Objectives

1. To determine the extent to which the Medicare Drug Integrity Contractor (MEDIC) performed benefit integrity activities to identify, combat, and prevent fraud, waste, and abuse in Medicare Part C and Part D from fiscal years (FYs) 2012 to 2017.
2. To describe barriers the MEDIC encountered in performing its benefit integrity activities.
3. To determine how the Centers for Medicare & Medicaid Services (CMS) measures the MEDIC's effectiveness.

The MEDIC is CMS's benefit integrity contractor tasked with detecting and preventing fraud, waste, and abuse in Medicare Part C and Part D. These programs involve billions of dollars in expenditures and cover millions of beneficiaries. Therefore, effective and proactive oversight is essential to protect Medicare and its beneficiaries from fraud, waste, and abuse. The Comprehensive Addiction and Recovery Act of 2016 (CARA) requires the Office of Inspector General (OIG) to conduct a study and submit a report, due July 2018 to Congress, on the effectiveness of the MEDIC's efforts to identify, combat, and prevent Medicare fraud.[1] OIG conducted this evaluation in response to the congressional mandate outlined in CARA.

Medicare Part C and Part D

Under Medicare Part C, CMS contracts with private insurance companies, known as Medicare Advantage organizations, to provide coverage of Medicare Part A and Part B services under managed care arrangements.[2] Under Medicare Part D, CMS contracts with private insurance companies called prescription drug plan sponsors to offer beneficiaries coverage for outpatient prescription drugs, including opioids. Beneficiaries also can obtain prescription drug coverage through a Medicare Advantage prescription drug plan. We use the term "plan sponsor" to refer to Medicare Advantage organizations and prescription drug plan sponsors.

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[1] CARA established new authorities for plan sponsors and the MEDIC. However, we were unable to review these new requirements because they will not be implemented until January 1, 2019.

[2] Medicare Parts A and B include hospital care; skilled nursing facility care; hospice care; home health care; physician services; and durable medical equipment, prosthetics, orthotics, and supplies.

MEDIC Responsibilities

The MEDIC is responsible for detecting and preventing fraud, waste, and abuse in Medicare Part C and Part D.

The MEDIC's responsibilities are outlined in its statement of work and task orders.[3, 4] These responsibilities include, but are not limited to:

- conducting investigations,

- referring cases to OIG and other law enforcement agencies for consideration of civil and criminal prosecution and/or application of administrative sanctions,

- immediately advising OIG of certain types of allegations,

- fulfilling requests for information from law enforcement agencies,

- analyzing data to identify risks to Part C and Part D,

- identifying high-risk pharmacies, providers, and beneficiaries in Part C and Part D,

- identifying vulnerabilities in the Part C and Part D programs,

- recommending administrative actions such as revocations and exclusions, and

- receiving and processing complaints.

The MEDIC is required to identify potential fraud and abuse through both external sources and proactive methods. Examples of external sources of fraud leads include beneficiaries, law enforcement agencies, plan sponsors, and CMS. Proactive methods include the analysis of claims data to identify fraud. According to the *MEDIC Statement of Work*, the MEDIC is required to access data from a variety of sources, and its ability to apply innovative analytical methodologies is critical to the success of its benefit integrity activities. Appendix A provides a detailed description of the MEDIC's responsibilities.

MEDIC's New Responsibilities Under CARA. CARA expands the MEDIC's responsibilities to include assistance in the identification of beneficiaries at risk for drug abuse.[5] CARA authorizes the MEDIC to directly accept prescription and necessary medical records from pharmacies, plan sponsors, and physicians to help determine whether the beneficiary in question is at risk for prescription drug abuse. The MEDIC is required to acknowledge the receipt of referrals regarding at-risk beneficiaries from plan sponsors. In addition, the MEDIC is required to respond within 15 days after being contacted by the plan sponsors for assistance in determining whether a

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[3] *MEDIC Statement of Work*, September 2009, Revision #5.
[4] CMS, *National Benefit Integrity (NBI) Medicare Drug Integrity Contractor (MEDIC) Task Order (TO)*, April 2017.
[5] P.L. No. 114-198, § 704(c)(1).

beneficiary is at risk for prescription drug abuse. The MEDIC's new responsibilities begin in 2019. In April 2018, CMS issued the final rule to implement the CARA requirements.[6]

MEDIC Reporting Requirements

CMS requires the MEDIC to submit several monthly and quarterly reports. These reports include a monthly Workload Statistic Report with information such as the number of investigations, immediate advisements, case referrals, requests for information, and number of data analyses. The MEDIC also is required to submit to CMS a monthly Vulnerability Report, a quarterly Exclusions Report, a quarterly Revocation Report, and an annual Lessons Learned Report that outlines what worked particularly well during the performance period and recommends solutions for unanticipated problems.

Prior OIG Work

Past OIG work found that the MEDIC encountered problems with accessing and using data, which hindered its ability to investigate potential fraud and abuse.[7] Specifically, the MEDIC lacked access to centralized Part C data and was prohibited from sharing specific information with other program integrity contractors. The MEDIC also reported issues with accessing necessary prescription drug event (PDE) data, which hindered its ability to analyze claims data. In addition, the MEDIC's lack of authority to directly obtain information from pharmacies, pharmacy benefit managers, and physicians hindered its ability to investigate incidents of potential fraud and abuse.

In response to our 2013 report, CMS implemented a number of changes to its procedures and regulations. CMS provided the MEDIC with access to centralized Part C data. CMS also provided guidance to the MEDIC on when it is appropriate to share information with other program integrity contractors. Additionally, CMS established in Federal regulations that CMS or its designee (the MEDIC) has the right to collect information directly from pharmacy benefit managers, pharmacies, and other entities that contract or subcontract with plan sponsors.[8]

In 2016, OIG issued a data compendium report on benefit integrity activities conducted by benefit integrity contractors, including the MEDIC, from 2012 to 2013.[9] OIG found variation in the level of benefit integrity activities conducted across contractors and across years, even when we accounted for differences in the size of contractors' oversight responsibility and the amount paid for their contracts.

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[6] 83 Fed. Reg. 16440 (Apr. 16, 2018).
[7] OIG, *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, OEI-03-11-00310, January 2013.
[8] 79 Fed. Reg. 29844 (May 23, 2014).
[9] OIG, *Medicare Benefit Integrity Contractors' Activities in 2012 and 2013: A Data Compendium*, OEI-03-13-00620, May 2016.

Methodology

To gauge the MEDIC's financial effectiveness, we developed a return on investment measure. We calculated this measure by dividing the amount of actual monetary recoveries reported by the MEDIC by the amount paid to the MEDIC. The MEDIC began reporting actual recoveries to CMS in FY 2015. Therefore, this return on investment analysis is calculated for FYs 2015 through 2017. We also requested from CMS the measures it uses to gauge MEDIC effectiveness.

The monetary recoveries represent actual monetary recoveries the MEDIC reported on the basis of three different activities—data analysis projects, self-audits, and case referrals.[10] What is included in the reported recoveries differs depending on which activity generates the recovery. For recoveries reported from data analysis projects and self-audits, the amounts represent recoveries to the Medicare program. Also, the recovery data from self-audits was not reported by the MEDIC for 2015.[11] For recoveries from case referrals, the amounts represent recoveries to all payers. MEDIC staff stated that the reported actual recoveries from case referrals may include recoveries made to other entities such as Medicaid, in addition to Medicare. In other words, the MEDIC did not report recoveries in a way that we could capture Medicare-only recoveries.

We analyzed MEDIC activities to better understand how these activities protect Part C and Part D. To conduct this analysis, we collected Workload Statistic Reports and other reports from FY 2014 through FY 2017. When possible, we trended activities from FY 2012 to FY 2017 (hereafter, when we refer to the years 2012 through 2017, we are referring to the FY) using data collected for a previous report for 2012 and 2013.[12]

To assist in our evaluation, we collected information from the MEDIC. We conducted an onsite interview with the MEDIC to gain a better understanding of its benefit integrity activities. Finally, we analyzed information provided by the MEDIC detailing the barriers it sees to its ability to protect the Part C and Part D programs.

Appendix B provides a more detailed methodology.

Limitations

The return on investment calculation includes only actual monetary recoveries that the MEDIC reported to us. It does not include other results or benefits that the MEDIC may be providing. While we reviewed the data

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[10] After the MEDIC uncovers issues through its data analysis projects, it may employ desk audits to identify recoveries. The MEDIC works with specific plan sponsors to assist them in conducting self-audits of selected PDE records identified by CMS and the MEDIC.
[11] According to CMS, the self-audit process was in its initiation phase in 2015.
[12] OIG, *Medicare Benefit Integrity Contractors' Activities in 2012 and 2013: A Data Compendium*, OEI-03-13-00620, May 2016.

provided by CMS and the MEDIC for inconsistencies, we did not independently validate the workload statistic and recovery data.

While we provide information on the number of activities for 2012 and 2013 in our findings, we are unable to provide information on what may have caused any changes in these numbers during this time period. Data regarding MEDIC's benefit integrity activities for 2012 and 2013 was collected for OIG's 2016 data compendium report.[13] This report provided descriptive information on MEDIC workload activities and did not explore underlying policy and procedural changes that may have caused shifts in these activities.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.
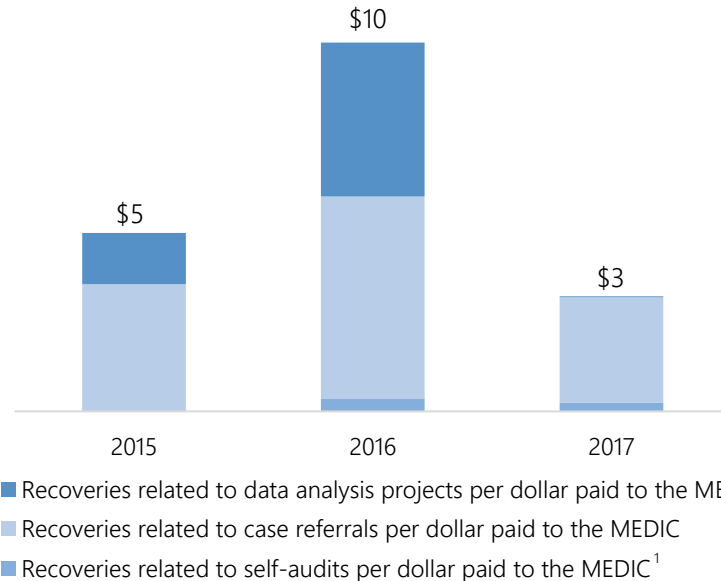
[13] Ibid.

FINDINGS

The MEDIC returned $3 for every $1 it was paid in 2017, but its return on investment declined from 2016 to 2017

The MEDIC consistently made a positive return on investment from 2015 through 2017.[14] In 2017, the MEDIC reported recoveries totaling $58 million. During that same year, CMS paid $19 million to the MEDIC. This resulted in the MEDIC returning $3 for every $1 it was paid in 2017. The MEDIC's recoveries result from its data analysis projects, self-audits, and case referrals and the level of these activities can vary from year to year.

The MEDIC's return on investment decreased in 2017 after increasing from 2015 to 2016, as shown in Exhibit 1.[15] In 2015, the first year the MEDIC submitted actual-recovery reports to CMS, the MEDIC returned $5 for every $1 it was paid. In 2016, the MEDIC returned $10 for every $1 it was paid. The increase in 2016 was likely due to two data analysis projects that each produced recoveries of over $15 million, and one case referral that produced recoveries of nearly $21 million. The MEDIC did not identify any Part C recoveries from data analysis projects and self-audits because it has yet to perform audits that would yield actual recoveries on Part C data.

Exhibit 1: The MEDIC's return on investment increased from 2015 to 2016, but decreased sharply in 2017

■ Recoveries related to data analysis projects per dollar paid to the MEDIC
■ Recoveries related to case referrals per dollar paid to the MEDIC
■ Recoveries related to self-audits per dollar paid to the MEDIC[1]

Source: OIG analysis of CMS's and the MEDIC's responses to OIG's request for information.
[1] Recovery data related to the MEDIC's self-audit work was not reported for 2015.

[14] The MEDIC began reporting actual recoveries to CMS in 2015. Therefore, OIG could not calculate the MEDIC's return on investment for prior years.
[15] Recovery data related to the MEDIC's self-audit work was not reported for 2015.

CMS has no measures that specifically assess the MEDIC's effectiveness in identifying fraud

The MEDIC's primary responsibility is to detect and prevent fraud, waste, and abuse by conducting benefit integrity activities. When we asked CMS how it measures the MEDIC's effectiveness, CMS stated that it uses four performance metrics to evaluate the MEDIC's effectiveness, as shown in Exhibit 2.

However, these metrics do not measure how effective the MEDIC's benefit integrity activities are at detecting and preventing fraud, waste, and abuse. Instead, these metrics focus on the timeliness of the MEDIC's work and its adherence to requirements described in the *MEDIC Statement of Work* and task order. They do not provide insight into the effectiveness of the MEDIC's efforts to detect and prevent fraud, waste, and abuse.

Exhibit 2: CMS uses four metrics to evaluate the MEDIC's effectiveness

Metric	Standard	Acceptable Quality Level
Quality of Data Projects/Audits Reports Submission	Data projects and audits reports were error free, i.e., no quality errors, grammatical errors, and/or spelling errors, and accepted by CMS	90%
Timeliness of Complaints	All complaints are acknowledged within 5 business days after receipt of the complaint—excluding complaints received from CMS or law enforcement or complaints misdirected	95%
Timeliness of Investigations	Investigations were moved to all appropriate administrative action(s) (i.e., revocation and exclusion), law enforcement referral, or closure within 180 calendar days	85%
Quality of Medicare Investigations	Investigations were moved to all appropriate administrative action(s) (i.e., revocation and exclusion), law enforcement referral, or closure	85%

Source: OIG analysis of CMS response to OIG request for information.

The MEDIC has increased its proactive data analyses, but the number of investigative results and administrative actions have declined

Although the number of new data analysis projects conducted by the MEDIC increased significantly from 2012 to 2017, the overall number of MEDIC investigations, case referrals, and administrative actions decreased. Appendix C provides analyses of additional benefit integrity activities, not addressed in this finding, that the MEDIC conducted from 2012 to 2017, including immediate advisements, requests for information, and complaint activities.

The number of proactive data analysis projects has increased

The number of proactive data analysis projects increased from 14 in 2012 to 201 in 2017. The 2014 *NBI MEDIC Task Order to the Umbrella Statement of Work* instructed the MEDIC to increase the number of senior and mid-level data analysts with expertise in identifying fraud, waste, and abuse. These analysts search for fraud trends within Part D data and examine information from complaints and news sources. In addition, the MEDIC implemented the Predictive Learning Analytics Tracking Outcome (PLATO) system in April 2015. PLATO includes a real-time predictive-modeling fraud detection process. As shown in Exhibit 3, the number of proactive data analysis projects the MEDIC started has increased dramatically over the years.

Exhibit 3: The MEDIC started more proactive data analysis projects each year from 2012 to 2017
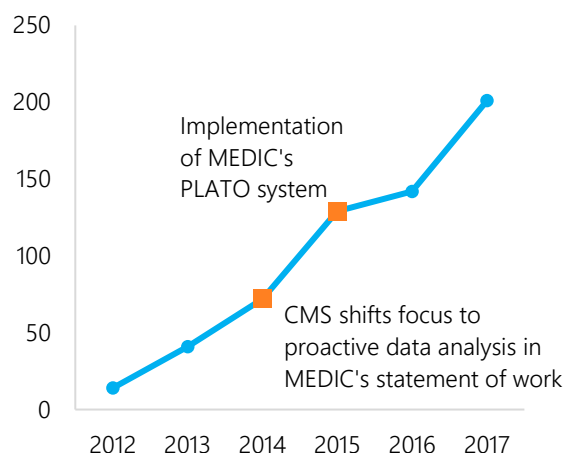
Source: OIG analysis of MEDIC workload statistics for 2012 through 2017.

The number of new investigations the MEDIC started each year steadily declined from 2012 to 2017

The number of investigations the MEDIC started decreased by nearly half from 2,069 in 2012 to 1,075 in 2014 and continued to decrease by over a third to 675 in 2017, as shown in Exhibit 4.

According to both CMS and the MEDIC, the MEDIC started fewer new investigations after 2014 because of a change to the MEDIC's statement of work, which shifted the MEDIC's focus from investigations to increasing the proactive data analysis workload.[16] The MEDIC staff reported that because of this increased focus on proactive data analysis, the MEDIC shifted

[16] Changes to the MEDIC's statement of work are reflected in task orders issued to the MEDIC.

resources toward data analysis projects and reduced its number of investigators.

Exhibit 4: The MEDIC started fewer new investigations each year from 2012 to 2017
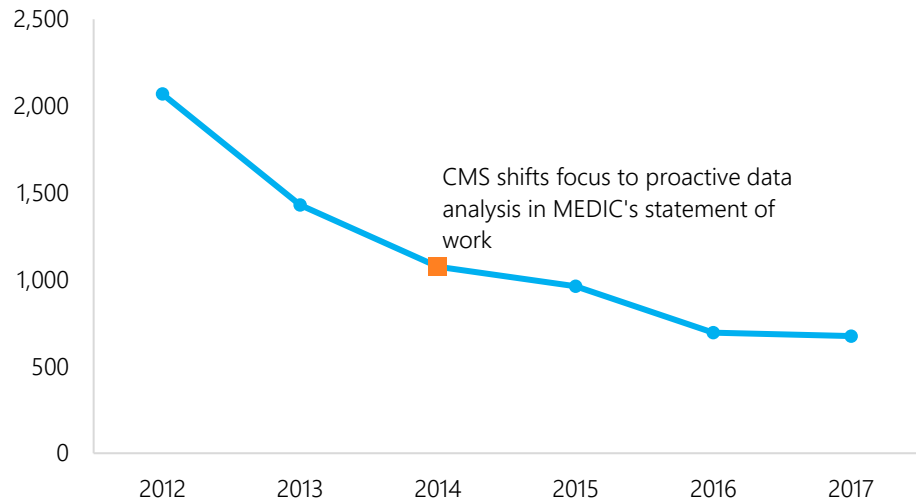
Source: OIG analysis of MEDIC workload statistics for 2012 through 2017.

## The number of cases referred by the MEDIC fell significantly in 2017

The MEDIC referred considerably fewer cases to both OIG and other organizations in 2017 than in previous years. After increasing from 2012 to 2014, the number of cases referred to OIG decreased steadily from 196 in 2014 to 88 in 2017, a decrease of more than half. In contrast, the MEDIC's case referrals to other organizations increased from 2014 through 2016 before dropping drastically in 2017.

The sharp decline in case referrals was the result of CMS's instruction to prioritize certain MEDIC activities. The number of cases referred to all organizations decreased sharply from 482 cases in 2016 to 216 cases in 2017, as shown in Exhibit 5. The MEDIC staff reported that the drastic decrease in case referrals to all organizations from 2016 to 2017 was because the MEDIC, at the direction of CMS, focused resources on determining whether previously referred cases could be closed. In addition, the MEDIC staff reported that CMS instructed it to use its resources to identify monetary recoveries from case referrals. Therefore, it could not focus on developing new case referrals.

In addition, according to both the MEDIC and CMS, the decrease in case referrals to OIG was further impacted by CMS's instruction to focus on administrative actions beginning in 2015. CMS stated that prior to 2014, the MEDIC's focus was on investigations and referrals to OIG. Since then, CMS has instructed the MEDIC to focus on data analysis projects and administrative actions. Additionally, CMS stated that in 2016, it specifically

instructed the MEDIC to fully develop an investigation prior to making a referral to OIG.

**Exhibit 5: Case referrals to all organizations and OIG decreased in 2017**
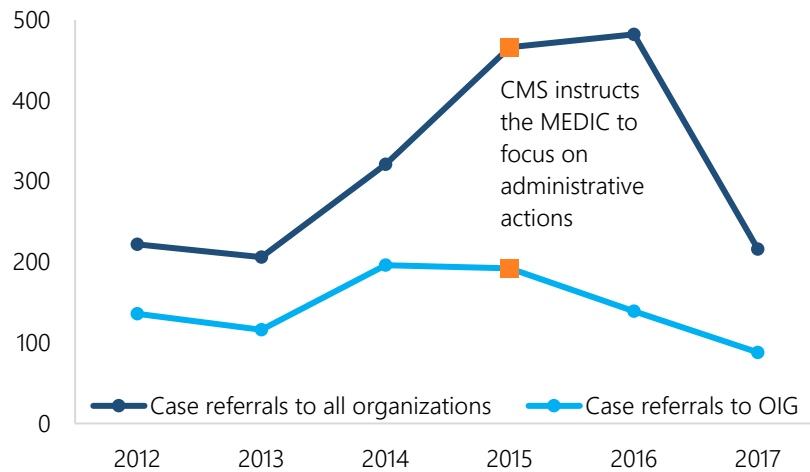
Source: OIG analysis of MEDIC workload statistics for 2012 through 2017.

After an upward trend in administrative actions in recent years, there was a sharp decline in 2017

CMS instructed the MEDIC to prioritize administrative actions in 2015. From 2015 to 2016, there was a marked increase in both the number of exclusions and revocations that the MEDIC recommended to CMS, as shown in Exhibit 6. However, there was then a sharp decrease in these administrative actions in 2017.

Exhibit 6: Although the number of revocations and exclusions that the MEDIC recommended to CMS increased in prior years, they decreased sharply from 2016 to 2017
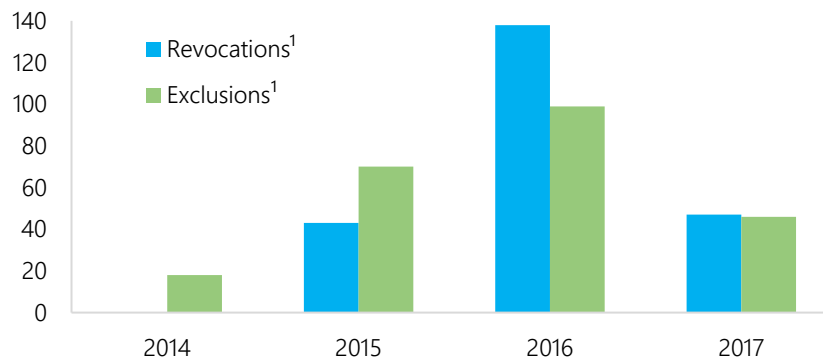
Source: OIG analysis of MEDIC workload statistics for 2012 through 2017.
[1] Prior to the fourth quarter of 2015, the MEDIC was not required to submit a Revocation Report to CMS. Prior to the first quarter of 2015, the MEDIC was not required to submit an Exclusions Report to CMS. However, the MEDIC did report exclusions for the last two quarters of 2014.

According to MEDIC staff, the decline in administrative actions in 2017 was the result of CMS guidance to discontinue scanning public information, including news articles focused on providers and State records containing license suspensions. The MEDIC used these sources to identify providers to recommend to CMS for possible exclusion or revocation. CMS reported that it instructed the MEDIC to discontinue scanning public information because another CMS contractor performs that work. The MEDIC staff also reported that the decline in revocations was related to the implementation of stricter revocation criteria by CMS.

The MEDIC identified thousands of leads involving drugs, but plan sponsors' actions in response to these leads is unknown

Given the extent of opioid abuse across the nation, the U.S. Department of Health and Human Services has prioritized addressing the opioid epidemic. The MEDIC reported that it has consistently conducted benefit integrity activities related to controlled substances that have the potential for abuse, including opioids and other Schedule II drugs.[17]

The MEDIC's proactive data analysis has led to the identification of thousands of high-risk entities

The MEDIC uses various data analysis projects to identify high-risk pharmacies and providers that may facilitate the abuse or diversion of prescription drugs, including opioids. This information can then be used by the MEDIC to open investigations on these entities. The high-risk leads identified by the MEDIC are also provided to plan sponsors and shared in PLATO. The MEDIC identified 7,302 high-risk pharmacies and 10,737 high-risk providers from 2014 through 2017.

Pharmacies. The MEDIC identified more than 1,600 high-risk pharmacies in each year from 2015 through 2017, as shown in Exhibit 7. The MEDIC conducts multiple analyses to identify these high-risk pharmacies. One of these is the Pharmacy Risk Assessment, which scores pharmacies on 16 metrics to determine if they are high,

Exhibit 7: The MEDIC identified more than a thousand high-risk pharmacies in each year from 2015 through 2017
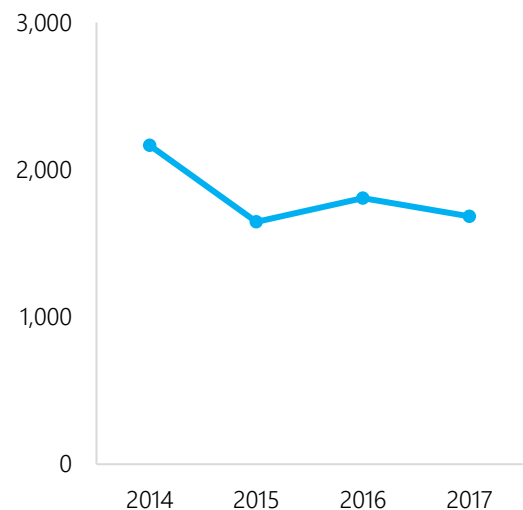
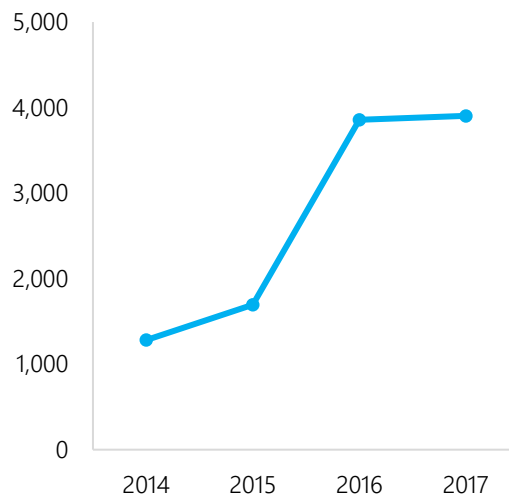Source: OIG analysis of the MEDIC responses to OIG request for information.

[17] The Drug Enforcement Agency (DEA) classifies drugs into five categories called "schedules" on the basis of the drugs' acceptable medical use and abuse or dependency potential. Schedule II drugs are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence.

medium, or low risk. The metrics on which pharmacies are scored include the total amount paid, the average number of prescriptions per prescriber identification number, and the percentage of prescriptions that were for Schedule II drugs.

In addition, the MEDIC employs the quarterly Pharmacy Spike Analysis to identify pharmacies with more than 100 percent increases in payment amounts from one quarter to the next. These pharmacies are targeted for investigation involving opioid abuse.

Exhibit 8: The number of high-risk providers the MEDIC identified more than tripled from 2014 through 2017

Source: OIG analysis of the MEDIC responses to OIG request for information.

Providers. The MEDIC also conducts projects to identify high-risk providers. For example, in 2016, CMS instructed the MEDIC to conduct a data analysis project to identify prescribers of Schedule II drugs with irregular billing patterns compared to their peers. In response, the MEDIC developed its Outlier Prescribers of Schedule II Controlled Substances project to score providers that prescribe Schedule II drugs as high, medium, or low risk. As shown in Exhibit 8, the number of high-risk providers identified by the MEDIC more than tripled from 1,281 providers in 2014 to 3,903 in 2017.

In addition to the Outlier Prescribers project, in 2017 CMS instructed the MEDIC to complete an opioid-focused Schedule II drugs data analysis project. In response, the MEDIC developed the Opioid Analgesic Schedule II Controlled Substances project to specifically score providers that prescribe Schedule II opioids.

The MEDIC has conducted additional opioid-related projects. The TRIO model in PLATO identifies prescribers with a high risk of facilitating beneficiary drug abuse by prescribing a combination of carisoprodol and alprazolam, with either hydrocodone or oxycodone—one of the most widely abused combinations of drugs. Another example of the MEDIC's opioid-related work is a project that identifies prescribers who may be culpable in the overdose death of a beneficiary by comparing the date of death with the date of opioid prescriptions.

As with pharmacies, the MEDIC conducts a quarterly Prescriber Spike Analysis, which identifies prescribers who meet a dollar threshold in one of four categories of drugs, including Schedule II drugs. The Prescriber Spike Analysis reviews various databases for additional criteria and identifies outlier prescribers for further review and possible investigation.

The MEDIC's investigative results involving opioids declined from 2014 to 2017

Despite an increase in opioid-related data analysis projects, the MEDIC started fewer investigations and referred fewer cases related to opioids from 2014 to 2017. As shown in Exhibit 9, from 2014 to 2017, the MEDIC initiated more data analysis projects related to opioids, but the number of opioid-related investigations the MEDIC conducted decreased. The number of opioid-related case referrals increased from 2014 through 2016 before dropping sharply in 2017.

Exhibit 9: While the MEDIC started more proactive data analysis projects related to opioids from 2014 to 2017, it started fewer investigations and referred fewer cases related to opioids
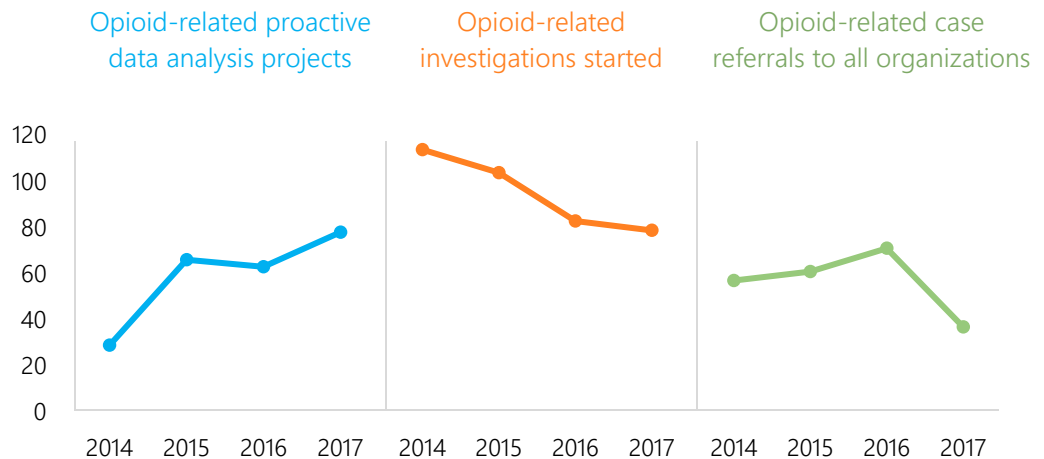
Source: OIG analysis of MEDIC responses to OIG request for information.

The outcome of the MEDIC's leads to plan sponsors is unknown because sponsors are not required to report the actions taken in response to these leads

According to the 2017 *NBI MEDIC Task Order*, PLATO shall house the results of actions taken by all plan sponsors on pharmacies and providers. However, the task order for the MEDIC cannot create requirements for plan sponsors to share information on their responses to leads from the MEDIC, and CMS has not separately required the plan sponsors to do so.

Should plan sponsors voluntarily choose to use PLATO, they can share information on the results of their reviews of high-risk pharmacies and providers. Plan sponsors can enter in PLATO actions taken against providers and pharmacies, identify providers and pharmacies within their

networks as "Suspect" or "Non-Suspect," and track in PLATO the progress of any investigations they are undertaking.

Because only 60 percent of plan sponsor organizations have requested access to PLATO, complete information on how plan sponsors respond to the MEDIC's leads is not available. Additionally, we do not know whether plan sponsors with access to PLATO are entering all relevant information. In previous reports, OIG has recommended to CMS that plan sponsors be required to report (1) all potential fraud and abuse to CMS and/or the MEDIC and (2) data on the inquiries and corrective actions they take in response to incidents of fraud and abuse.[18] Again, because plan sponsors' participation in PLATO is voluntary, there is no comprehensive information on plan sponsors' actions in response to fraud, waste, and abuse. Hence, there is no way to make a judgment on the overall impact of the MEDIC's work—particularly as it relates to the leads the MEDIC produced as a result of CMS's instruction to focus on proactive data analysis.

The MEDIC identified a number of factors that limit its ability to protect the Medicare program

The MEDIC described barriers similar to those cited in past OIG work.[19] Once again, the MEDIC identified issues regarding access to all centralized Part C encounter data and obtaining information from providers, pharmacies, and pharmacy benefit managers. While CMS has made efforts to address these issues in response to previous OIG recommendations, the MEDIC reports that these barriers and others continue to hinder its benefit integrity efforts.

Restricted access to Part C encounter data limits the MEDIC's benefit integrity activities in Medicare Part C

Although the MEDIC has access to some variables in the Part C encounter data, such as procedure codes, it is restricted from accessing others that may be important to its benefit integrity activities, such as number of services rendered. Encounter data are records of items and services provided to beneficiaries enrolled in Part C and are accessed through CMS's Integrated Data Repository (IDR). Because it is unable to access certain variables in the IDR, the MEDIC must request information from individual plan sponsors to obtain the number of services and the dollar amount billed for an encounter record. Having access to the number of services would enable the MEDIC to conduct more robust data analysis of Part C services to

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[18] OIG, *Ensuring the Integrity of Medicare Part D*, OEI-03-15-00180, June 2015; *Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse*, OEI-03-13-00030, March 2014; *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012; *Medicare Advantage Organizations' Identification of Potential Fraud and Abuse*, OEI-03-10-00310, February 2012; *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse*, OEI-03-08-00420, October 2009; and *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse*, OEI-03-07-00380, October 2008.
[19] OIG, *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, OEI-03-11-00310, January 2013 and *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse*, OEI-03-08-00420, October 2009.

identify questionable billing patterns. Having access to the dollar amount billed would enable the MEDIC to quantify the financial risk to the Medicare program when sending case referrals to law enforcement agencies. MEDIC staff reported that they requested these variables from CMS, but the MEDIC has not been provided access to them.

The MEDIC also raised concerns about both the completeness and accuracy of encounter data in the IDR extracts for Part C. For instance, the MEDIC reported that its IDR extracts for Part C data only provide up to three diagnosis codes even though more diagnosis codes associated with a patient are in the IDR. The MEDIC is authorized by CMS to use Part C diagnosis codes data to validate the appropriateness of Part D prescriptions. Expanding the number of diagnosis codes in the IDR extracts for Part C data would improve the MEDIC's ability to determine whether drugs were dispensed for reasons not approved by the Food and Drug Administration (FDA). In addition, the MEDIC identified discrepancies between information provided by plan sponsors and the data included in the IDR. These discrepancies included missing tax identification numbers, invalid National Provider Identifiers, and claims that were missing entirely.

The MEDIC's restricted access to Part C data has resulted in fewer activities addressing fraud in Part C. A small percentage of the MEDIC's benefit integrity activities were related to only Part C from 2015 through 2017. Six percent of the 466 referrals made in 2015 and 8 percent of the 482 referrals made in 2016 were related to Part C only, as shown in Exhibit 10.

Exhibit 10: In 2015 and 2016 the MEDIC's case referrals related to Part C were nominal compared to case referrals related to Part D
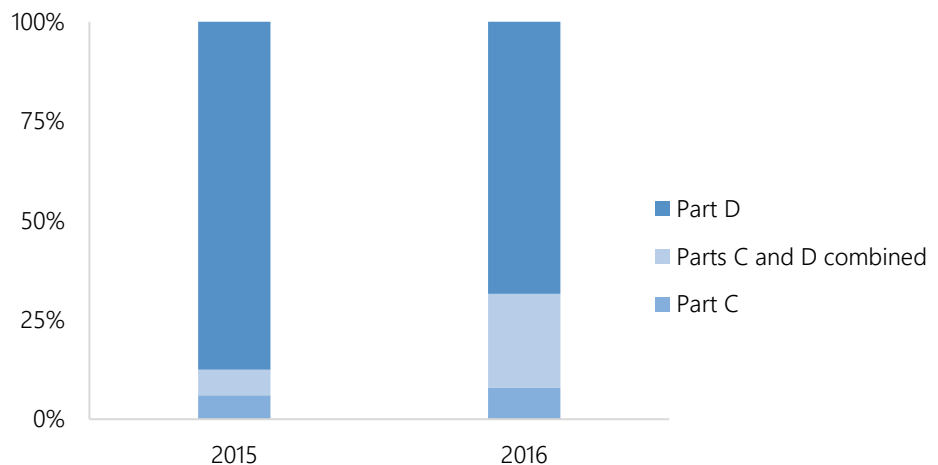
Source: OIG analysis of MEDIC workload statistics for 2015 and 2016.

CMS did not require case referral numbers to be separated by Part C and Part D in 2017. However, CMS did require investigation numbers to be broken out by Part C and Part D in 2017. Nineteen percent of the 675 new investigations started in 2017 were related to Part C only. MEDIC staff also

reported currently having approval for only a few data analysis projects using Part C encounter data. MEDIC staff reported that one project is not as robust as it could be because of the MEDIC's limited Part C data access. MEDIC staff also reported that the MEDIC has yet to enter Part C data into PLATO.

Lack of a Part C and Part D enrollment requirement limits the actions the MEDIC can pursue

Without a Part C and Part D enrollment requirement, the MEDIC is limited in its ability to pursue administrative actions against non-enrolled providers and pharmacies. This is because CMS can only revoke providers and pharmacies if they are enrolled in Medicare. Because Part C and Part D providers and pharmacies are not required to be enrolled in Medicare, the MEDIC reported that opening investigations on them is ineffective as it cannot recommend them for administrative action. Of the 279 outlier pharmacies identified in the last quarter of 2013 through the Pharmacy Spike Analysis, 70 percent were not enrolled in Medicare.[20]

Lack of authority to compel pharmacies, providers, and pharmacy benefit managers to provide requested medical records impedes the MEDIC's work

According to the MEDIC, it does not have the authority to require pharmacies, providers, and pharmacy benefit managers to provide medical records requested by the MEDIC. According to MEDIC staff, although the vast majority of entities respond to its requests, it has no recourse against those that fail to do so.

As previously stated, CMS established in Federal regulations that CMS or its designee (the MEDIC) has the right to collect information directly from pharmacy benefit managers, pharmacies, and other entities that contract or subcontract with Part C and Part D sponsors.[21] These regulations were released after OIG recommended that the MEDIC be given the authority to directly obtain information that it needs from pharmacies, pharmacy benefit managers, and physicians.[22] When we asked CMS to clarify the MEDIC's authority, CMS stated that pharmacies, pharmacy benefit managers, and other entities that are under contract with Part C and Part D plan sponsors are required to submit documentation, such as medical records, in response to the MEDIC's request for documentation. This includes providers under contract with Part C plan sponsors. However, providers who prescribe prescription drugs covered under Part D are not under contract with Part D

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[20] In order to bill Medicare, pharmacies that are suppliers of Part B durable medical equipment, prosthetics, orthotics, and supplies would need to enroll in Medicare.
[21] 79 Fed. Reg. 29844 (May 23, 2014).
[22] OIG, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse*, OEI-03-08-00420, October 2009 and *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, OEI-03-11-00310, January 2013.

plan sponsors. Therefore, these providers are not required to submit medical records requested by the MEDIC.

CONCLUSION AND RECOMMENDATIONS

In response to a mandate from Congress, OIG evaluated the MEDIC's efforts to identify, combat, and prevent fraud in Medicare Part C and Part D. While the MEDIC's reported recoveries resulted in a positive return on investment ($3 in recoveries for every $1 invested in 2017), CMS has no measures that specifically assess the MEDIC's effectiveness. Without specific measures, it is unclear how CMS assesses the MEDIC's effectiveness in fighting fraud.

CMS directed the MEDIC to devote more resources to proactive data analysis and administrative actions in 2014 and 2015, which led to a sharp increase in proactive data analysis, but a decrease in the MEDIC resources available to follow up on the results of these analyses. As a result, there have been fewer MEDIC investigations and referrals to law enforcement agencies, including OIG. The direction did lead to an initial upswing in administrative actions (revocations and exclusions); however, those declined precipitously in 2017 due to other procedural changes.

Through its increased proactive analyses, the MEDIC was able to identify thousands of high-risk leads involving drugs, including opioids. The impact of these activities, however, cannot be measured as plan sponsors are not required to report to CMS the actions taken in response to these leads. To address this issue, OIG has consistently recommended that CMS require plan sponsors to report information on fraud and abuse.

In addition, MEDIC staff described numerous barriers that limit the MEDIC's overall impact. These barriers include the MEDIC's lack of access to complete Part C encounter data; its inability to recommend certain administrative actions, such as revocation of billing privileges, against Part C and Part D providers and pharmacies not enrolled in Medicare; and its inability to obtain all requested medical records from pharmacies, providers, and pharmacy benefit managers. Prior OIG reports have identified some of these barriers and although CMS has made efforts to remove these barriers by addressing OIG recommendations, some still exist.

<ins>To improve the MEDIC's overall effectiveness, CMS should</ins>:

Require plan sponsors to report Part C and Part D fraud and abuse incidents and the corrective actions taken to address them to a centralized system

Requiring plan sponsors to use PLATO or some other centralized system to report suspect providers and pharmacies, investigative information, and corrective actions would provide the MEDIC and plan sponsors with valuable information to use in their fraud-fighting efforts. It would also enhance CMS oversight by providing transparency into the plan sponsors' efforts to protect the program from fraud, waste, and abuse. OIG has

recommended CMS take this action in multiple reports over numerous years.

Currently, plan sponsors voluntarily report in PLATO their identification of suspect pharmacies and providers and any actions they have taken against them. Only 60 percent of plan sponsor organizations have requested access to PLATO. Therefore, PLATO is not capturing comprehensive information on potential fraud, waste, and abuse within Medicare Part C and Part D.

Provide the MEDIC centralized access to all Part C encounter data

Access to unrestricted centralized Part C data would enable the MEDIC to more effectively and proactively identify potential fraud, waste, and abuse in the Part C program. The MEDIC's access to limited Part C encounter data in the IDR prevents it from determining the billed amount associated with the encounter services and the number of services rendered during the encounter. According to the MEDIC, this limits its ability to utilize Part C data in conducting its benefit integrity activities. OIG identified the lack of access to centralized Part C data as a concern in previous work on the MEDIC.[23] As a result, CMS provided the MEDIC with access to centralized Part C data in the IDR. However, the MEDIC still does not have access to all the variables it needs to efficiently carry out its activities. In addition, the MEDIC raised concerns about the quality of some data in the IDR. An OIG report issued in January 2018 also found issues with the accuracy and completeness of some Part C data and recommended that CMS take actions to address these issues.[24]

Require that Part C and Part D providers and pharmacies enroll in Medicare

A lack of an enrollment requirement for providers and pharmacies that serve Part C and Part D beneficiaries creates a vulnerability to Medicare because there is no mechanism for CMS or the MEDIC to provide effective oversight of these entities. Requiring providers and pharmacies to enroll in Medicare would help ensure that only qualified entities are providing services to Part C and Part D beneficiaries. Such an enrollment requirement also would help ensure that CMS could identify all providers and pharmacies who deliver care to Medicare beneficiaries. Lastly, an enrollment requirement would provide CMS with an opportunity to take

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[23] OIG, *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, OEI-03-11-00310, January 2013.
[24] OIG, *Medicare Advantage Encounter Data Show Promise for Program Oversight, But Improvements Are Needed*, OEI-03-15-00060, January 2018.

additional administrative action, such as revoking the enrollment of problematic providers and pharmacies.

From 2014 through 2016, CMS released final regulations requiring that (1) providers enroll in or validly opt-out of Medicare in order for a drug prescribed by the provider to be covered under Part D and (2) providers and suppliers be enrolled in Medicare before they provide services covered under Part C.[25] However, the compliance date for these regulations was extended to January 1, 2019. In April 2018, CMS issued a final rule that requires plan sponsors to deny payments provided by individuals and entities on a preclusion list, rather than requiring the enrollment of providers. The preclusion list will include individuals or entities that (1) are revoked from Medicare, under a reenrollment bar, and the conduct that led to the revocation is detrimental to the best interests of Medicare or (2) have engaged in behavior for which they could have been revoked had they been enrolled in Medicare and the conduct that would have led to the revocation is detrimental to the best interests of Medicare.[26] However, OIG believes that enrollment is a more robust program integrity tool than the preclusion list alone.[27]

Clarify the MEDIC's authority to require records from pharmacies, pharmacy benefit managers, and other entities under contract with Part C and Part D plan sponsors

Access to this information would allow the MEDIC to conduct more thorough investigations and make more robust referrals. CMS should clarify for the MEDIC that it has the authority to require the submission of records from pharmacies, pharmacy benefit managers, and other entities that are under contract with Part C and Part D plan sponsors.

Ensure that the MEDIC has the ability to require medical records from prescribers of Part D drugs not under contract with plan sponsors, obtaining legislative authority, if necessary

Providing the MEDIC with the ability to obtain non-contracted providers' medical records would help the MEDIC conduct more thorough investigations and make more robust Part D referrals, including those related to opioids. CMS should ensure that the MEDIC has the ability to require the submission of medical records from prescribers of prescription drugs covered under Part D, i.e., from physicians, eligible professionals, and other authorized prescribers, obtaining legislative authority, if necessary.

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[25] 79 Fed. Reg. 29844 (May 23, 2014), 80 Fed. Reg. 25958 (May 6, 2015) and 81 Fed. Reg. 80170 (Nov. 15, 2016).
[26] 83 Fed. Reg. 16440 (Apr. 16, 2018).
[27] OIG made a similar recommendation regarding the enrollment of all providers participating in Medicaid managed care (OIG, *Providers Terminated From One State Medicaid Program Continued Participating in Other States*, OEI-06-12-00030, August 2015). In May 2016, CMS published final regulations requiring State Medicaid programs to enroll all providers participating in Medicaid managed care (81 Fed. Reg. 27497, May 6, 2016).

Currently, the MEDIC has the authority to obtain medical records from entities that are under contract with plan sponsors. However, because prescribers under Part D do not contract with Part D plan sponsors, the MEDIC is unable to directly obtain medical records from these providers.

<u>To improve the measurement of the MEDIC's effectiveness, CMS should</u>:

Establish measures to assess the MEDIC's effectiveness

Metrics that measure the MEDIC's effectiveness would allow CMS to determine whether the MEDIC is fulfilling its role in protecting Part C and Part D. CMS's current metrics evaluate the MEDIC's adherence to policies and procedures, rather than its effectiveness in identifying and combating fraud, waste, and abuse.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with four of the six recommendations.

CMS concurred with our recommendation to require plan sponsors to report Part C and Part D fraud and abuse incidents and corrective actions to a centralized system. CMS stated that it will work with plan sponsors to implement reporting requirements.

CMS concurred with our recommendation to provide the MEDIC with centralized access to all Part C encounter data. CMS stated that it provided the MEDIC with access to centralized Part C encounter data and is continuing to work with the MEDIC to provide access to all Part C encounter data fields.

CMS concurred with our recommendation to clarify the MEDIC's authority to require records from pharmacies, pharmacy benefit managers, and other entities under contract with Part C and Part D plan sponsors.

CMS concurred with our recommendation to establish measures to assess the MEDIC's effectiveness. CMS stated that when the current MEDIC contract ends it will revise metrics and develop a Quality Assurance Surveillance Plan to better measure the MEDIC's effectiveness of its benefit integrity activities for the next MEDIC contract.

CMS did not concur with our recommendation that Part C and Part D providers and pharmacies enroll in Medicare. CMS noted that it recently established a preclusion list in Part C and Part D and prohibits payments to prescribers or providers on this list. The list includes certain individuals and entities revoked from Medicare or those who have engaged in behavior for which CMS could have revoked the individual or entity if they had been enrolled in Medicare. CMS believes that the preclusion list is less burdensome to prescribers and providers than enrollment. OIG understands that provider burden needs to be carefully weighed when considering how best to protect Medicare. In this instance, OIG believes that requiring enrollment in Medicare would help ensure that only reputable and qualified individuals and entities are providing services to Part C and Part D beneficiaries. Therefore, OIG continues to recommend that Part C and Part D providers and pharmacies enroll in Medicare.

CMS did not directly concur nor nonconcur with our recommendation to ensure that the MEDIC has the ability to require medical records from prescribers of Part D drugs not under contract with plan sponsors. Instead, CMS stated that it would take the recommendation into consideration as it continues to evaluate and work to strengthen program integrity in Part C and Part D. We ask that CMS clarify its concurrence status in its final management decision. The full text of CMS's comments is provided in Appendix D.

APPENDIX A: MEDIC Responsibilities

This appendix provides information on the MEDIC responsibilities outlined in its statement of work from CMS.

Conducting Investigations. The MEDIC is required to conduct investigations when it receives allegations of fraud from external sources or proactively identifies potential fraud. A MEDIC investigation is performed to determine the facts and the magnitude of potential fraud and may include a review of claims, beneficiary medical records, prescriptions, or cost reports; and conducting interviews. A MEDIC investigation is intended to gather enough information to make a referral to law enforcement or recommend to CMS an administrative action.

Referring Cases to Law Enforcement and Making Immediate Advisements. According to the *MEDIC Statement of Work*, a case exists when the MEDIC has substantiated a fraud allegation through an investigation and made a referral to law enforcement. The MEDIC identifies cases of suspected fraud and makes referrals of all such cases to OIG, regardless of dollar amounts or subject matter. If a case has been referred to OIG, it has 60 calendar days to accept the referral, refer the case to the Department of Justice (DOJ), or reject the case. If there is no response from OIG within 60 calendar days following the referral, the MEDIC can refer the case to the Federal Bureau of Investigation (FBI) and/or any other investigative agency with interest in the case. The MEDIC closes a case once all appropriate administrative actions have been considered or implemented by CMS and law enforcement have declined the case, if the case was referred.

Certain allegations are referred directly to OIG without a MEDIC investigation. These are called immediate advisements and include complaints by current or former employees of a suspected provider or plan sponsors and/or their subcontractors.

Fulfilling Requests for Information. The MEDIC receives requests for information from OIG and DOJ as well as other entities including plan sponsors, Medicaid Fraud Control Units, and State Attorneys General. CMS requires the MEDIC to respond to requests from OIG and DOJ within 30 days or 45 days, depending on priority level.

Analyzing Data. According to the *MEDIC Statement of Work*, the MEDIC should use research and experience in the field to develop new approaches and data analysis techniques to identify risks to Medicare Part C and Part D. Analyses of data should identify areas vulnerable to fraud, waste, and abuse and identify potential incidents of fraud, waste, and abuse.

The MEDIC is required to use the PLATO modeling system to identify fraud, waste, and abuse patterns. PLATO incorporates a real-time predictive-modeling fraud detection process. According to the *NBI MEDIC*

Task Order, PLATO shall house the results of the MEDIC's proactive analyses to more effectively identify providers involved in fraud schemes as well as actions taken by all plan sponsors on pharmacies and prescribers. PLATO also enables the MEDIC to share results and outcomes of analyses with plan sponsors and law enforcement agencies.[28]

Identifying High-Risk Entities. The MEDIC, in collaboration with CMS, develops numerous, proactive data analysis projects to identify high-risk entities. These projects focus on identifying trends, anomalies, and questionable physician and pharmacy practices. Examples of these projects include the Quarterly Pharmacy Risk Assessment—which categorizes pharmacies as high, medium, or low risks—and the Prescriber Risk Assessment, which provides a peer comparison of controlled substance prescribing practices. The results of these projects are provided to plan sponsors so that actions can be taken. [29]

Identifying Vulnerabilities. The MEDIC is required to submit a monthly Vulnerability Report, identifying any vulnerabilities it finds and addressing, to the extent possible, the scope of the vulnerability and the extent to which the vulnerability jeopardizes Medicare Part C and Part D. The MEDIC also may propose solutions to CMS as to the most effective and efficient ways to address the vulnerability.

Recommending Administrative Actions. The MEDIC may recommend two types of administrative actions to CMS—revocations and exclusions. A provider's Medicare enrollment may be revoked for a number of reasons, including noncompliance with enrollment requirements and abusive prescribing patterns.[30] The MEDIC is required to identify providers for revocation through data analysis, case referrals, and other means. Once a provider has been identified, the MEDIC prepares a referral for revocation and submits it to CMS.

Additionally, the MEDIC must refer providers for exclusion from Federal health care programs to OIG (through CMS) when a provider's license has been revoked for reasons related to the provider's professional competence, professional performance, or financial integrity. The MEDIC must provide documentation to support a recommendation for exclusion.[31] The MEDIC also must prepare a separate revocation package to provide to CMS when a provider identified for exclusion also meets the criteria for revocation.

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[28] CMS, *National Benefit Integrity (NBI) Medicare Drug Integrity Contractor (MEDIC) Task Order (TO)*, April 2017.

[29] CMS, *CMS Opioid Misuse Strategy 2016*, January 5, 2017. Accessed at https://www.cms.gov on April 30, 2018.

[30] Under 42 CFR 424.535(a), there are 14 reasons for revocation of a provider's Medicare enrollment.

[31] Supporting documentation includes, but is not limited to, a summary of the case, provider license report, consent order, enforcement order, judgment, and indictment.

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Receiving and Processing Complaints. The MEDIC may receive potential complaints from a variety of sources, including beneficiaries. If the MEDIC receives an actionable complaint, it must further investigate the complaint, resolve the complaint investigation, or make referrals as needed to CMS, appropriate law enforcement agencies, or other outside entities. If the MEDIC receives any complaints (or inquires) that it is not responsible for handling, the MEDIC refers the complainant to the plan sponsor, the 1-800-MEDICARE phone number, or the CMS Regional Office, as appropriate.

APPENDIX B: Detailed Methodology

This appendix provides more detailed information on our data collection and analyses.

Measures of MEDIC effectiveness

We requested, received, and reviewed information from CMS regarding the measures and data it uses to determine the MEDIC's effectiveness.

To gauge the MEDIC's financial effectiveness, we developed a return on investment measure. We calculated this measure by dividing the amount of actual monetary recoveries reported by the MEDIC by the amount paid to the MEDIC. The MEDIC began reporting actual recoveries to CMS in 2015. Therefore, this return on investment analysis is calculated for the years 2015 through 2017. We also requested from CMS the measures it uses to gauge MEDIC effectiveness.

The monetary recoveries represent actual monetary recoveries the MEDIC reported on the basis of three different activities—data analysis projects, self-audits, and case referrals.[32] What is included in the reported recoveries differs depending on which activity generates the recovery. For recoveries reported from data analysis projects and self-audits, the amounts represent recoveries to the Medicare program. Also, the recovery data from self-audits was not reported by the MEDIC for 2015.[33] For recoveries from case referrals, the amounts represent recoveries to all payers. MEDIC staff stated that the reported actual recoveries from case referrals may include recoveries made to other entities such as Medicaid, in addition to Medicare. In other words, the MEDIC did not report recoveries in a way that we could capture Medicare-only recoveries.

Benefit integrity activities

From CMS, we requested Workload Statistic Reports related to the MEDIC's Part C and Part D benefit integrity activities from 2014 through 2017. These data included the number of (1) investigations started, (2) cases referred, (3) immediate advisements made, (4) requests for information received and completed, (5) data analyses projects started and, (6) complaints received and processed. For this timeframe, we also requested the monthly Vulnerability Reports, quarterly Exclusions Reports, quarterly Revocation Reports, and annual Lessons Learned Reports.

To provide a comparison to work performed by the MEDIC in previous years, we also used workload statistics collected during prior OIG work to

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[32] After the MEDIC uncovers issues through its data analysis projects, it may employ desk audits to identify recoveries. The MEDIC works with specific plan sponsors to assist them in conducting self-audits of selected PDE records identified by CMS and the MEDIC.

[33] According to CMS, the self-audit process was in its initiation phase in 2015.

determine the MEDIC's benefit integrity activities conducted during 2012 and 2013.[34]

We reviewed the MEDIC workload statistics received from CMS and summarized select benefit integrity activities performed each year from 2014 through 2017. We compared the following workload statistics from year to year and also compared them to statistics previously collected by OIG for 2012 and 2013: proactive data analysis projects started, new investigations started, cases referred, immediate advisements, requests for information, and complaints received. When possible, we completed these analyses separately for Part C and Part D data.

We reviewed the quarterly Exclusions Reports and Revocation Reports to determine the number of exclusions and revocations the MEDIC recommended to CMS from 2014 to 2017. Because CMS did not require these reports prior to 2014, we could not include an analysis of 2012 and 2013 data. Prior to the fourth quarter of 2015, the MEDIC was not required to submit Revocation Reports. Prior to the first quarter of 2015, it was not required to submit Exclusions Reports; however, the MEDIC submitted Exclusions Reports for the last two quarters of 2014.

Activities related to opioids and high-risk entities
We requested the following information from the MEDIC:

- the number of high-risk pharmacies and high-risk providers that the MEDIC identified each year from 2014 through 2017, and

- information on the steps it has taken to detect and prevent fraud, waste, and abuse related to opioid misuse.

From OIG's request for MEDIC information, we determined what steps the MEDIC has taken to detect and prevent fraud, waste, and abuse related to opioid misuse. Specifically, we summarized the number of new investigations started, case referrals, and data analysis projects related to opioids.

From OIG's request for MEDIC information, we determined what measures the MEDIC has developed to help identify high-risk pharmacies and high-risk providers. We summarized the number of high-risk pharmacies and high-risk providers that the MEDIC identified for 2014 through 2017. Information on the MEDIC's opioid and high-risk activities for 2012 and 2013 was not included in this review because the data were not collected during the previous OIG work.

Barriers and challenges
We determined current barriers and challenges from the MEDIC's written responses and our interview with MEDIC staff. Once we determined the

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[34] OIG, *Medicare Benefit Integrity Contractors' Activities in 2012 and 2013: A Data Compendium*, OEI-03-13-00620, May 2016.

barriers and challenges, we also reviewed the Lessons Learned and Vulnerability reports to ascertain whether they contained additional information about these barriers and challenges.

# APPENDIX C: Analysis of Additional Benefit Integrity Activities Conducted by the MEDIC

This appendix provides analyses of additional benefit integrity activities the MEDIC conducted from 2012 to 2017, including immediate advisements, requests for information, and complaints.

The MEDIC made fewer immediate advisements after CMS changed the immediate advisement criteria

As shown in Exhibit 11, the MEDIC made fewer immediate advisements from 2012 to 2017. The number of immediate advisements decreased each year from 2012 through 2015. The MEDIC made 207 immediate advisements in 2012 and 111 in 2015. In 2017, the MEDIC made 23 immediate advisements, 81 percent fewer than the 119 made in 2016.

The MEDIC attributed this decrease to a change that CMS made to the MEDIC's immediate advisements criteria in 2016. This change removed the criterion that immediate advisements may result from "situations involving the subjects of current program investigations." Therefore, the MEDIC no longer refers immediate advisements to OIG based on OIG's current open and active investigations.

**Exhibit 11: The MEDIC made fewer immediate advisements from 2012 to 2017**
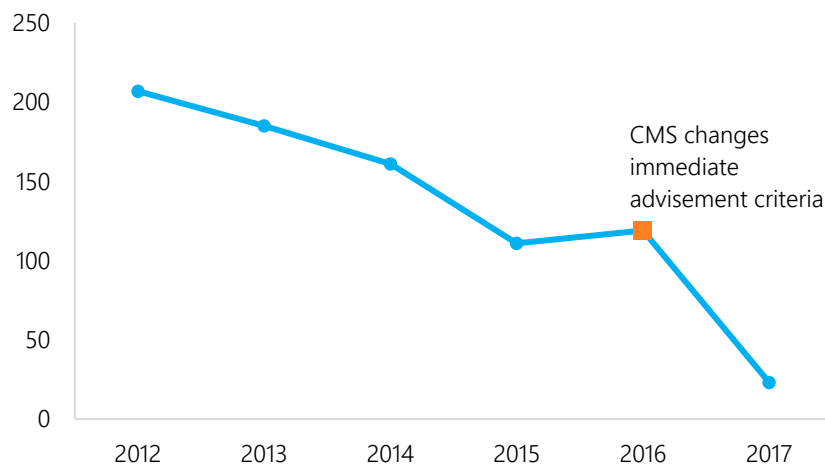
Source: OIG analysis of MEDIC workload statistics for 2012 through 2017.

The number of requests for information (RFIs) the MEDIC received and completed increased from 2012 to 2017

Both the number of RFIs received and completed increased from 2012 to 2017 as shown in Exhibit 12. In 2012, the MEDIC received 466 RFIs from OIG, DOJ, and other organizations. This total dipped to 456 in 2013, but rose

each year after, to 814 in 2017. The number of RFIs that the MEDIC completed overall increased from 2012 to 2017. The MEDIC completed 492 RFIs in 2012 and 449 in 2013. Over the next 3 years, the MEDIC increased the number of RFIs it completed to 812 in 2016. In 2017, this total decreased to 784.

Exhibit 12: The MEDIC received and completed more RFIs from 2012 to 2017
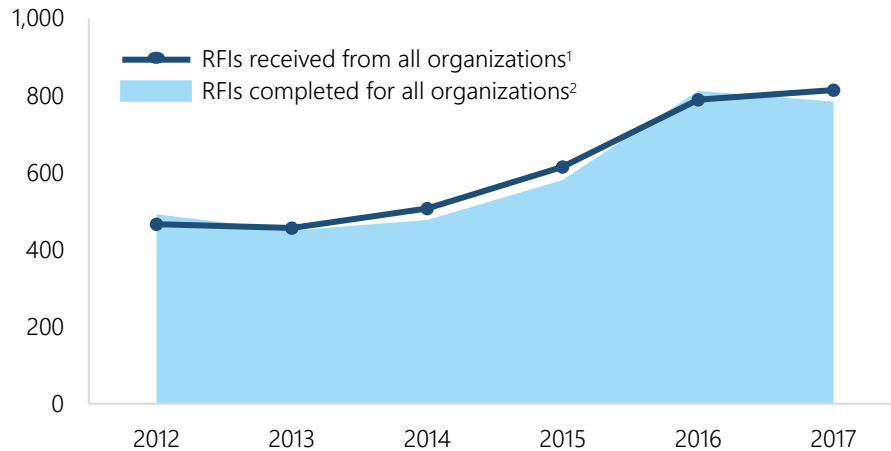
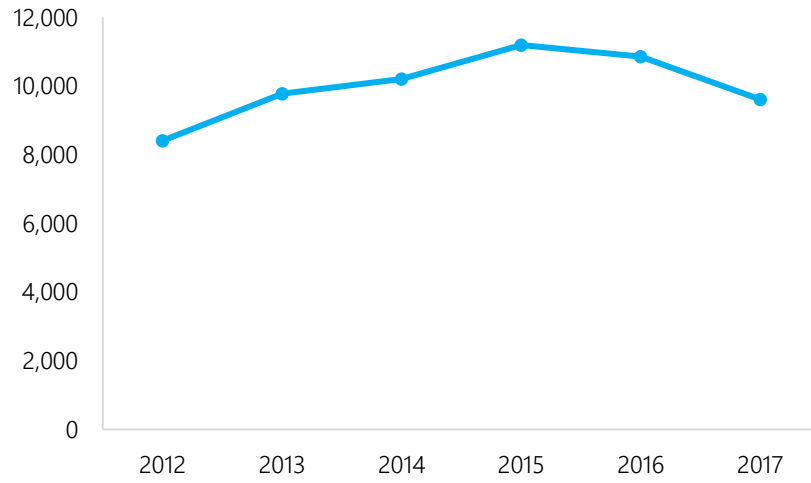Source: OIG analysis of MEDIC workload statistics for 2012 through 2017.

[1] RFIs received from OIG in 2012 are for calendar year 2012.

[2] RFIs completed during 2012 through 2014 do not include RFIs completed for organizations outside of OIG and DOJ. These data were not included in the MEDIC's 2012 through 2014 workload statistics.

The number of complaints the MEDIC received in 2012 to 2017 ranged between 8,400 and 11,200 complaints per year

The MEDIC continuously receives and processes complaints that may lead to the opening of a MEDIC investigation. Exhibit 13 provides the number of complaints received by the MEDIC in each of the 6 years reviewed. From 2012 through 2017, there have been both increases and decreases in the number of complaints received from year to year. Over these years, CMS repeatedly revised the reporting requirements for tracking the complaints processed by the MEDIC. Because of this, we were unable to provide trend data for the overall number of complaints processed by the MEDIC. However, from 2015 to 2017, the number of complaints referred to plan sponsors soared from 0 to 5,049.

Exhibit 13: From 2012 through 2017, the number of complaints the MEDIC received ranged from 8,400 to 11,200

Source: OIG analysis of MEDIC workload statistics for 2012 through 2017.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: JUN – 5 2018

TO: Daniel R. Levinson
              Inspector General

FROM: Seema Verma
              Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: The MEDIC Produced a Positive
              Return on Investment But Investigative Results Declined in 2017 (OEI-03-17-
              00310)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and
comment on the draft report from the Office of Inspector General (OIG). CMS is committed to
conducting robust program integrity efforts in Medicare Part C and Part D.

CMS utilizes the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) to
identify and investigate potential fraud, waste and abuse in Medicare Part C and Part D, and to
refer cases to law enforcement agencies when necessary. As OIG notes, the MEDIC has
produced a positive return on investment, returning $3 for every $1 it was paid in 2017.

The NBI MEDIC also conducts data analysis and other work to support ongoing law
enforcement activities. Examples include impact calculations, medical review of claims and
medical records, and prescription drug invoice reconciliation reviews. As a result of its work, the
NBI MEDIC makes recommendations for administrative action to both CMS and the OIG,
including revocations of Medicare billing privileges and exclusions from federally funded health
care programs, respectively.

Additionally, plan sponsors report potential fraud to the NBI MEDIC through the PLATO
system. This is a voluntary, web-based system that allows CMS, the NBI MEDIC, and plan
sponsors to more easily share information and help combat potential fraud, waste, and abuse in
the Medicare Part C and Part D programs. CMS's federal law enforcement partners can also
access PLATO data.

CMS has directed the NBI MEDIC to increase its focus on proactive data analysis in Part D,
including producing, at a minimum, quarterly reports to plan sponsors on specific data projects,
such as high-risk pharmacy assessments. As OIG found, the number of high-risk providers the
MEDIC identified more than tripled between 2014 and 2017.

CMS takes seriously its responsibility to oversee program integrity in Medicare Part C and Part D, as exemplified by the many efforts currently underway, and appreciates the OIG's additional review into this area. OIG's recommendations and CMS' responses are below.

OIG Recommendation
CMS should require plan sponsors to report Part C and Part D fraud and abuse incidents and the corrective actions taken to address them to a centralized system.

CMS Response
CMS concurs with this recommendation. CMS will work with plan sponsors to implement reporting requirements, taking their feedback into consideration.

OIG Recommendation
CMS should provide the MEDIC centralized access to all Part C encounter data.

CMS Response
CMS concurs with this recommendation. CMS has provided the MEDIC with access to centralized Part C encounter data. CMS is continuing to work with the MEDIC to provide access to all Part C encounter data fields.

OIG Recommendation
CMS should require that Part C and Part D providers and pharmacies enroll in Medicare.

CMS Response
CMS does not concur with this recommendation. CMS recently established a preclusion list in Medicare Parts C and D of certain individuals and entities that are revoked from Medicare or have engaged in behavior for which CMS could have revoked the individual or entity if they had been enrolled in Medicare. Payment to prescribers or providers on CMS's preclusion list is prohibited. CMS believes that the most effective means of reducing the burden of the Medicare Part C and Part D enrollment requirement on prescribers and providers is to concentrate our efforts on preventing Medicare Part D coverage of prescriptions written by prescribers who pose an elevated risk to Medicare beneficiaries, and preventing Medicare Part C payment for items and services furnished by providers and suppliers who pose an elevated risk to Medicare beneficiaries.

OIG Recommendation
CMS should clarify the MEDIC's authority to require records from pharmacies, pharmacy benefit managers, and other entities under contract with Part C and Part D plan sponsors.

CMS Response
CMS concurs with this recommendation. CMS will clarify the MEDIC's authority to require the submission of records from pharmacies and pharmacy benefit managers under contract with Part D plan sponsors and providers under contract with Medicare Advantage Organizations.

OIG Recommendation

CMS should ensure that the MEDIC has the ability to require medical records from prescribers of Part D drugs not under contract with plan sponsors, obtaining legislative authority, if necessary.

CMS Response

CMS will take OIG's recommendation into consideration as we continue to evaluate and work to strengthen program integrity in Medicare Part C and Part D.

OIG Recommendation

CMS should establish measures to assess the MEDIC's effectiveness.

CMS Response

CMS concurs with this recommendation. When the current MEDIC contract ends, CMS will revise metrics and develop a Quality Assurance Surveillance Plan to better measure the MEDIC's effectiveness of its benefit integrity activities for the next MEDIC contract.

ACKNOWLEDGMENTS

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

ABOUT THE OFFICE OF INSPECTOR GENERAL

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

Office of Audit Services

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

Office of Evaluation and Inspections

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

Office of Investigations

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

Office of Counsel to the Inspector General

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