U.S. Department of Health and Human Services

Office of Inspector General



Medicaid Fraud Control Units Fiscal Year 2020 Annual Report

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Deputy Inspector General for Evaluation and Inspections March 2021, OEI-09-21-00120



U.S. Department of Health and Human Services

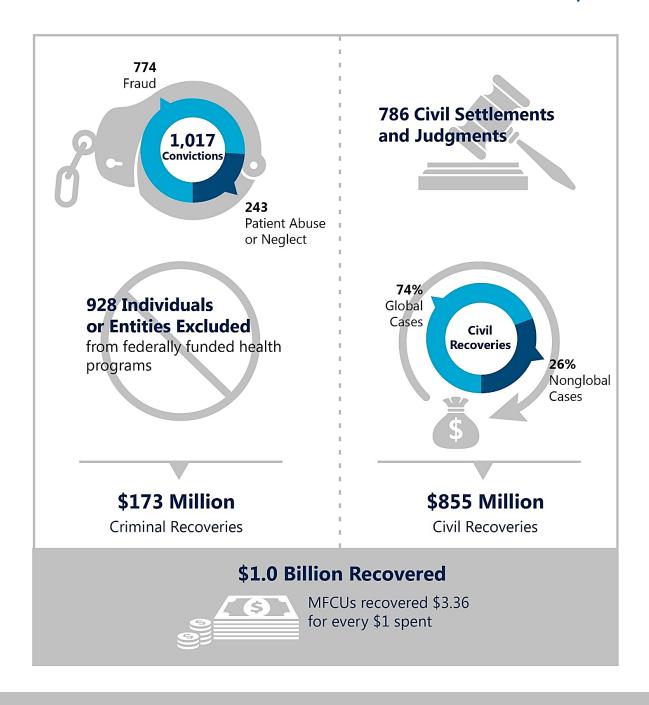
Office of Inspector General

At a Glance

March 2021, OEI-09-21-00120



Medicaid Fraud Control Units Fiscal Year 2020 Annual Report



Medicaid Fraud Control Units (MFCUs) investigate and prosecute Medicaid provider fraud and patient abuse or neglect. The Department of Health and Human Services Office of Inspector General (OIG) is the designated Federal agency that oversees and annually approves Federal funding for MFCUs through a recertification process. For this report, OIG analyzed the annual statistical data on case outcomes (such as convictions, civil settlements and judgments, and recoveries) that 53 MFCUs submitted to OIG for fiscal year 2020. Those MFCUs operated in all 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. In June 2020, OIG also administered a survey to all MFCUs about the effects of the COVID-19 pandemic on MFCU operations.

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BACKGROUND

The function of Medicaid Fraud Control Units (MFCUs or Units) is to investigate and prosecute Medicaid provider fraud and patient abuse or neglect.¹ The Social Security Act (SSA) requires each State to effectively operate a MFCU, unless the Secretary of Health and Human Services (HHS) determines that (1) the operation of a Unit would not be cost-effective because minimal Medicaid fraud exists in a particular State; and (2) the State has other adequate safeguards to protect beneficiaries from abuse or neglect.² In fiscal year (FY) 2020, all 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands operated MFCUs.^{3, 4}

MFCUs are funded jointly by Federal and State Governments. Each Unit receives a Federal grant award equivalent to 90 percent of total expenditures for new Units and 75 percent for all other Units.⁵ In FY 2020, combined Federal and State expenditures for the Units totaled approximately \$306 million, of which approximately \$230 million represented Federal funds.⁶

As illustrated in Exhibit 1, MFCU cases typically begin as referrals from external sources or are generated internally from data mining. MFCU staff review referrals of possible fraud and patient abuse or neglect to determine the potential for criminal prosecution and/or civil action. If the Unit accepts a referral for investigation, the case may result in various possible outcomes. Criminal prosecutions may result in convictions and civil actions may result in civil settlements or judgments. Both criminal prosecutions and civil actions may include the assessment of monetary recoveries. The Office of Inspector General (OIG) has the authority to exclude convicted individuals and entities from any federally funded health care program on the basis of convictions referred from MFCUs. In addition to achieving these case outcomes, Units may also make programmatic recommendations to their respective State Governments to help strengthen program integrity and efforts to fight patient abuse or neglect.

Exhibit 1: The typical life cycle of a MFCU case.



Oversight of the MFCU Program

Reducing Medicaid fraud is a top priority for OIG, and its role in overseeing MFCUs helps achieve that priority. OIG oversees the MFCU grant program by recertifying Units, conducting reviews or inspections (hereinafter referred to as inspections) of Units, providing technical assistance to Units, and monitoring key statistical data about Unit caseloads and outcomes. Further, OIG has identified enhancing Medicaid program integrity—including efforts to maximize the effectiveness of MFCUs—as an OIG Priority Outcome. (See Appendix A for details.)

OIG reviews each Unit's application for recertification annually—OIG's approval of this application is necessary for the Unit to receive Federal reimbursement.¹¹ To recertify a Unit, OIG performs a desk review to assess the Unit's compliance with the Federal requirements for MFCUs contained in statute, regulations, and OIG policy transmittals. OIG also examines the Unit's adherence to 12 performance standards, such as those regarding staffing, maintaining adequate referrals, and cooperating with Federal authorities.¹²

OIG further assesses a Unit's performance by conducting inspections of Units that may identify findings and make recommendations for improvement. During an inspection, OIG also makes observations regarding Unit operations and practices, and may identify beneficial practices that may be useful to other Units. Finally, OIG provides training and technical assistance to Units, as appropriate.

OIG also provides ongoing technical assistance and guidance to Units. These activities may include conducting outreach, responding to questions from the Units, providing training to Units, and issuing policy transmittals to all Units. OIG also collects and presents statistical data reported by each MFCU annually, such as the numbers of open cases, indictments, and convictions and amounts of recoveries. These data can be accessed on the OIG website in two formats: a <u>statistical chart</u> and an <u>interactive map</u>.

Methodology

For this report, we analyzed information from the FY 2020 Annual Statistical Reports that 53 MFCUs submitted to OIG, the recertification materials that the MFCUs submitted to OIG, and OIG exclusions data. This report also includes information collected from a survey that OIG administered to all 53 MFCUs in June 2020 about the effects of the COVID-19 pandemic (pandemic) on MFCU operations.¹³

We aggregated case outcomes across all Units for FY 2020 and for each of the preceding 4 years—FYs 2016 through 2019. These outcomes include convictions, civil settlements and judgments, and recoveries. For convictions and recoveries, we calculated an average across the 5-year period of FYs 2016 through 2020. We also calculated the return on investment (ROI) for MFCUs. We identified the provider types with the highest numbers of criminal and civil outcomes in FY 2020 and the numbers of exclusions that OIG imposed in FY 2020 on individuals and entities as a

result of conviction referrals from MFCUs. We also analyzed MFCU drug diversion cases using data for FYs 2016 through 2020. Additionally, we highlight the beneficial practices described in each Unit's more recent inspections, as described in Appendix B.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of Inspectors General on Integrity and Efficiency. OIG inspections of the MFCUs and this annual report differ from other OIG evaluations in that they support OIG's direct administration of the MFCU grant program, but they are subject to the same internal quality controls as other OIG evaluations, including internal and external peer review.

CASE OUTCOMES

MFCUs reported that the pandemic created significant challenges for staff, operations, and court proceedings, which led to lower case outcomes in FY 2020

MFCUs that responded to OIG's June 2020 survey reported that the pandemic created significant challenges for staff and operations, which limited case outcomes—particularly criminal outcomes. For example, as MFCUs initially moved to a telework environment, some staff reported experiencing challenges conducting work because of limitations with computer equipment and network infrastructure. Field work was also limited. To help protect staff and members of the public from the pandemic, MFCUs reported curtailing some in-person field work, such as interviews of witnesses and suspects. These activities were further limited because of an initial lack of personal protective equipment that was needed in order to conduct similar activities in nursing homes and other facilities. According to MFCUs, these cumulative challenges slowed the progress of investigations.

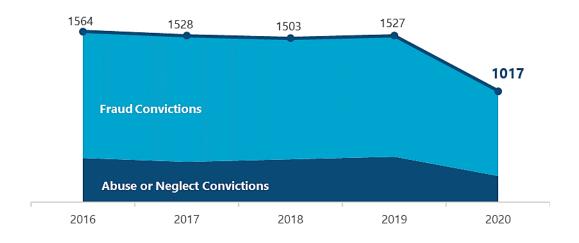
MFCU staff also experienced challenges involving court proceedings, which often delayed the prosecution phase of cases. MFCUs reported that, as a result of the pandemic, court systems in general had closed their in-person operations and postponed or reduced the number of grand jury proceedings, criminal jury trials, and in-person court appearances. MFCUs reported that some court systems eventually began to adopt new methods to facilitate court proceedings, such as routinely using video conferences for hearings and limiting court appearances to certain persons, such as individuals that were incarcerated. However, MFCUs reported challenges associated with initially transitioning to these new methods. For example, several MFCUs reported challenges with presenting documentary and other evidence through video and remote audio technology.

Although the pandemic had a significant effect on MFCU operations and case outcomes, MFCUs reported implementing steps to mitigate the pandemic's impact. For example, MFCUs developed guidelines to ensure safe in-person interactions—both in the office and in the field—and to ensure the use of available personal protective equipment. MFCUs also developed practices for interviewing witnesses remotely. To support employee-teleworking, MFCUs reported increasing communication among staff and management through regular video meetings, using shared team calendars, and having staff complete weekly activity logs. MFCUs also established various approaches to gathering and using information about the pandemic's effect on Medicaid program integrity. Some of these approaches included establishing a pandemic Medicaid fraud working group, developing a repository for information related to the pandemic to triage allegations and efficiently allocate resources, and creating a mechanism for tracking pandemic outbreaks in nursing homes and other residential facilities.

MFCUs reported 1,017 total convictions in FY 2020

Total convictions resulting from MFCU cases declined from 1,527 in FY 2019 to 1,017 in FY 2020. In FY 2020, MFCU cases resulted in 774 convictions for fraud and 243 convictions for patient abuse or neglect, similar to the distribution in previous years. Exhibit 2 shows the total number of convictions during FYs 2016 through 2020.

Exhibit 2: Fraud convictions accounted for about three-quarters of all FY 2020 convictions.



Source: OIG analysis of Annual Statistical Reports for FYs 2016–2020.

MFCU convictions lead to the exclusion of individuals and entities from participation in federally funded health care programs, broadening the impact of those convictions. When MFCUs make referrals to OIG regarding convictions for fraud and patient abuse or neglect in their respective States, OIG has the authority to exclude those convicted individuals and entities from federally funded health care programs. Through these referrals, MFCUs help ensure that individuals and entities convicted in one State are excluded from Medicaid programs in other States, as well as from other Federal programs related to health care.¹⁵

In FY 2020, OIG imposed a total of 2,148 exclusions on individuals and entities. MFCU cases were responsible for 928 of those exclusions imposed by OIG. In addition to these 928 MFCU-generated exclusions, MFCUs participated in a large number of joint cases with the OIG Office of Investigations that also may have resulted in exclusions.

Similar to previous years, significantly more convictions for fraud involved personal care services (PCS) attendants and agencies than any other provider type

Compared to other provider types, PCS attendants and agencies had the highest number of fraud convictions each year during FYs 2016 through 2020.

Exhibit 3 shows the number of PCS fraud convictions, as compared to total fraud convictions, in FYs 2016–2020.

Exhibit 3: Fraud convictions involving PCS attendants and agencies accounted for a significant portion of total fraud convictions in FYs 2016–2020.

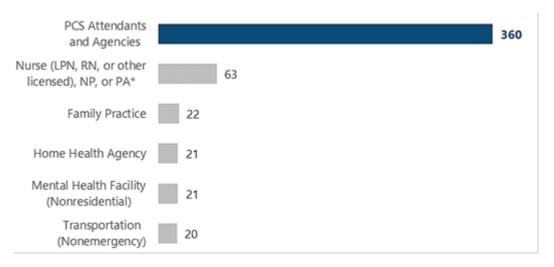


Source: OIG analysis of Annual Statistical Reports for FYs 2016–2020.

In FY 2020, fraud convictions involving PCS attendants and agencies accounted for 360 of the total 774 fraud convictions (47 percent). Additional information on the prevalence of Medicaid fraud involving PCS and efforts to combat such fraud can be found in OIG's <u>2020 Top Management and Performance Challenges Facing HHS</u> (page 14).

Exhibit 4 shows the provider types with the most fraud convictions in FY 2020. See Appendix C for detailed statistics on the number of convictions and recovery amounts for criminal cases, as well as MFCU caseloads and outcomes by provider type.

Exhibit 4: Convictions of PCS attendants and agencies for fraud were significantly higher than for any other provider type in FY 2020.

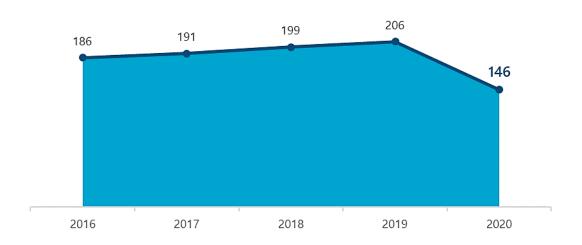


^{*}LPN=Licensed Practical Nurse, RN=Registered Nurse, NP=Nurse Practitioner, and PA=Physician Assistant. Source: OIG analysis of FY 2020 Annual Statistical Reports.

MFCUs reported 146 convictions from drug diversion cases in FY 2020

MFCU convictions related to drug diversion declined from 206 in FY 2019 to 146 in FY 2020, and associated criminal recoveries totaled \$3.16 million in FY 2020. In a Medicaid context, drug diversion cases generally involve the fraudulent billing of Medicaid for drugs diverted from legal and medically necessary uses, or the fraudulent activities by Medicaid providers related to drug diversion regardless of whether the Medicaid program was billed. MFCUs may conduct drug diversion investigations jointly with other State or Federal agencies, such as OIG or the U.S. Drug Enforcement Administration. Exhibit 5 shows the number of convictions associated with drug diversion cases during FYs 2016 through 2020.

Exhibit 5: Convictions from drug diversion cases rose steadily each year before the pandemic.

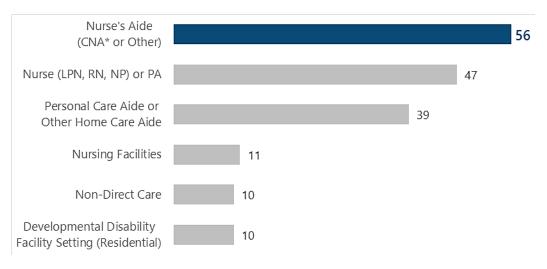


Source: OIG analysis of Annual Statistical Reports for FYs 2016-2020.

In FY 2020, more convictions for patient abuse or neglect involved nurse's aides or nurses than any other provider type

In FY 2020, convictions of nurse's aides or nurses accounted for 103 of the total 243 convictions for patient abuse or neglect (42 percent). Exhibit 6 shows the provider types with the most convictions for patient abuse or neglect.

Exhibit 6: In FY 2020, convictions of nurse's aide and nurses for patient abuse or neglect were higher than any other provider type.



*CNA=Certified Nurse Assistant.

Source: OIG analysis of FY 2020 Annual Statistical Reports.

MFCUs reported criminal recoveries of \$173 million in FY 2020

MFCU criminal recoveries declined from \$305 million in FY 2019 to \$173 million in FY 2020. Total criminal recoveries varied over the 5-year period ending in FY 2020. There was a significant spike in criminal recoveries during FY 2017, which elevated the average for FYs 2016 through 2020 (see Exhibit 7). The spike in criminal recovery amounts in FY 2017 was a result of a single, large fraud case with a recovery amount totaling \$268 million.¹⁷

Exhibit 7: Criminal recoveries varied during FYs 2016 through 2020.

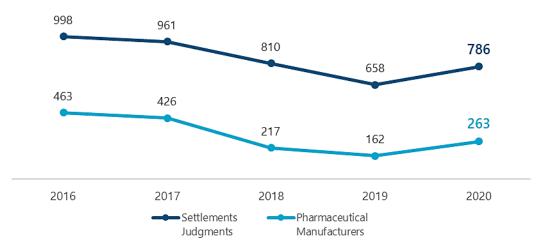
Source: OIG analysis of Annual Statistical Reports for FYs 2016–2020.

As an example of a case that resulted in criminal recoveries, the Ohio MFCU worked with Federal partners to prosecute six defendants for health care fraud conspiracy. The defendants billed Medicaid \$48 million for services related to drug and alcohol recovery, many of which were not provided, were not medically necessary, or lacked proper documentation. The court ordered the defendants to pay approximately \$43 million in restitution, with sentences ranging from 1 year of probation to 7.5 years in prison.¹⁸

MFCUs reported 786 civil settlements and judgments in FY 2020

In contrast to the decline of criminal convictions in FY 2020, the total number of civil settlements and judgments increased from 658 in FY 2019 to 786 in FY 2020.¹⁹ As shown in Exhibit 8, the total number of civil settlements and judgments increased in FY 2020 after a steady decline since FY 2016. Similar to FY 2019, more civil settlements and judgments involved pharmaceutical manufacturers than any other provider type in FY 2020. The number of pharmaceutical civil settlements and judgment increased in FY 2020, accounting for 263 of the 786 civil settlements and judgments (33 percent).

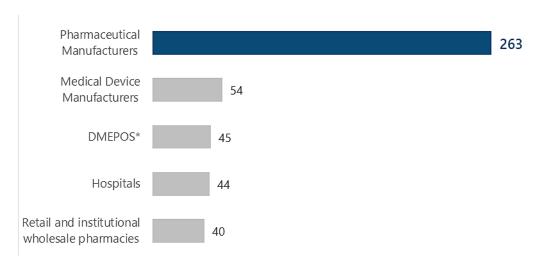
Exhibit 8: The total number of civil settlements and judgments increased in FY 2020, after declining from FY 2016 to FY 2019.



Source: OIG analysis of Annual Statistical Reports for FYs 2016-2020.

Medical device manufacturers had the second-highest level of civil settlements and judgments (see Exhibit 9).

Exhibit 9: Pharmaceutical manufacturers had the highest number of civil settlements and judgments in FY 2020, followed by medical device manufacturers.



*DMEPOS=Durable Medical Equipment, Prosthetics, Orthotics and Supplies. Source: OIG analysis of FY 2020 Annual Statistical Reports.

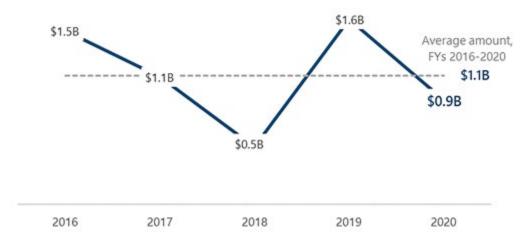
MFCUs reported civil recoveries of \$855 million in FY 2020

In FY 2020, civil recoveries decreased by 48 percent, from \$1.6 billion in FY 2019 to \$855 million. As shown in Exhibit 10, civil recoveries were substantially higher in FY 2016 and FY 2019, relative to other years.²⁰ In FY 2016, over half of the civil recoveries were attributable to two global cases that totaled \$982 million. In FY 2019,

two global cases accounted for a significant portion of the civil recoveries and totaled more than \$1.3 billion.

Exhibit 10: Civil recoveries in FY 2020 were slightly lower than the average for FYs 2016-2020.

Large monetary settlements or judgments may contribute to annual variability.



Note: Dollar values are rounded to the nearest tenth. Source: OIG analysis of Annual Statistical Reports for FYs 2016-2020.

The distribution of *global* and *nonglobal* cases in FY 2020 remained similar to the distribution of FY 2019. Approximately \$637 million (or 74 percent) of the \$855 million in civil recoveries derived from global cases.²¹ The remaining \$218 million (26 percent) derived from nonglobal cases.

In one global case involving a pharmaceutical manufacturer, 28 States partnered with Federal agencies to pursue allegations that the pharmaceutical manufacturer provided kickbacks to health care practitioners in exchange for

Types of Civil Cases

A global case involves both the Federal Government and a group of States and is coordinated by the National Association of Medicaid Fraud Control Units.

A nonglobal case is conducted by a Unit—individually or with other law enforcement partners—and is not coordinated by the National Association of Medicaid Fraud Control Units.

prescribing medications that treat hypertension or Type 2 Diabetes. As a result of the investigation, the pharmaceutical manufacturer agreed to pay a total of \$678 million—\$103 million of which was related to State Medicaid programs.²²

CONCLUSION

The pandemic created significant challenges for MFCU staff, operations, and court proceedings. However, MFCUs reported taking steps to mitigate the effects of the pandemic and, despite challenges, continued to carry out their Medicaid program integrity functions in FY 2020. Overall, MFCUs' efforts in FY 2020 contributed to total recoveries of \$1 billion, with an ROI of \$3.36 for every \$1 spent.

MFCUs reported implementing practices to address the challenges caused by the pandemic, a few of which we highlight in the "Case Outcomes" section in this report. As in past MFCU annual reports, Appendix B describes the many beneficial practices implemented by the MFCUs identified by OIG during our inspections, which other MFCUs may want to consider for adoption. Beneficial practices from inspection reports published in FY 2020 include the following:

- Designating staff as subject matter experts: The Arkansas Unit director designated Unit investigators as subject matter experts of specific, common provider types for efficient assignment and improved investigation of cases.
- Creating in-house training videos: The Missouri Unit's Chief Auditor created in-house training videos for Unit investigators and attorneys. The videos contained step-by-step tutorials for creating and using investigative and trial tools.
- Participating in an Elder Abuse Task Force to provide training to law
 enforcement and first responders: To encourage referrals, the Montana Unit
 regularly trained cadets at the Montana Law Enforcement Academy and
 trained other law enforcement and first responder personnel through its
 participation in the Montana Elder Abuse Task Force. The training focused on
 the Unit's mission and how the Unit can assist with crimes that law
 enforcement personnel and first responders might encounter.

In addition to identifying beneficial practices to spur continued improvement, OIG annually recognizes the efforts of one MFCU with the Inspector General's Award for Excellence in Fighting Fraud, Waste, and Abuse. In 2021, the Maine MFCU received this award for its high number of case outcomes across a mix of case types, excellent partnership with OIG and other Federal partners, and active participation in the National Association of Medicaid Fraud Control Units' activities.

APPENDIX A

Office of Inspector General's Priority Outcome: Maximizing the Effectiveness of Medicaid Fraud Control Units

It is a top OIG priority to strengthen the effectiveness of MFCUs as key partners in combating fraud and abuse. As part of its oversight, OIG strives to support the MFCUs in ways that maximize their effectiveness. Over the past few years, OIG has engaged in numerous actions to help drive MFCU effectiveness. These include activities in five categories: (1) enhancing OIG oversight; (2) increasing the use of data; (3) expanding the MFCU program to better align with a growing and evolving Medicaid program; (4) enhancing MFCU training where it can be of greatest assistance to MFCUs; and (5) increasing collaboration between MFCUs and OIG.

To assess the impact of these efforts, OIG has established two key performance indicators: (1) indictment rate and (2) conviction rate. The table below shows these rates for FYs 2016 through 2020 and the targets that OIG aims to achieve in FYs 2021 through 2022.

Key Performance Indicators	FY 2016 (actual)				FY 2020 (actual)		FY 2022 Target
Indictment Rate	16.3%	17.2%	16.7%	18.8%	17.2%	19.0%	18.4%
Conviction Rate	89.6%	88.7%	89.8%	90.3%	87.7%	89.1%	89.0%

Calculations:

Indictment rate = (total number of criminal cases with indictments or charges

plus number of nonglobal civil cases open, filed, or referred for filing)

divided by

(total number of open cases)

Conviction rate = (total number of criminal cases resulting in a defendant convicted)

divided by

(total number of cases resulting in a defendant acquitted, dismissed, or convicted)

To calculate these measures, OIG aggregates data that Units submit through Annual Statistical Reports.

APPENDIX B

Beneficial Practices Described in Office of Inspector General Inspection Reports

This appendix summarizes MFCU practices that OIG has highlighted as being beneficial to Unit operations. Other Units should consider whether adopting similar practices in their States may yield similar benefits.

All of OIG's MFCU reports are available at https://oig.hhs.gov/reports-and-publications/oei/m.asp#mfcu.

STANDARD 4	A Unit takes steps to maintain an adequate volume and quality of referrals from the State Medicaid agency and other sources.
Arizona OEI-07-15-00280 December 2015	Engaging with Medicaid partners and providing guidance to ensure quality referrals: MFCU staff attended quarterly meetings with the State Medicaid agency and Managed Care Organizations (MCOs). These meetings provided guidance to MCOs about what constitutes a quality referral and the types of referrals that will result in the Unit opening a case for investigation.
California OEI-09-15-00070 February 2016	Providing training to MCO representatives to increase fraud referrals: The Unit provided quarterly training for MCO representatives that resulted in increased fraud referrals from MCOs to the Unit. Hiring an outreach liaison to increase referrals: The Unit hired a field representative to provide outreach and increase the number of fraud referrals sent to the Unit. The field representative acted as a liaison between the Unit and other State agencies, and trained staff from these agencies about Medicaid fraud and the Unit's role in combating fraud and patient abuse or neglect by providers.
Kansas OEI-12-18-00210 July 2019	Supplementing reviews of referrals for patient abuse or neglect and enhancing referral coordination: The Unit's nurse investigator reviewed complaints about patient abuse or neglect that had been previously closed by the State's survey and certification agency to determine whether the complaints warranted further investigation. In addition, the nurse investigator arranged for the Unit to receive complaints of patient abuse or neglect at the same time the State's survey and certification agency sent the complaints to local law enforcement agencies. After reviewing the complaints, the nurse investigator contacted the law enforcement agencies to help determine whether further investigation by those agencies or the Unit was warranted.

A Unit takes steps to maintain an adequate volume and quality of referrals from the State Medicaid agency and other sources. (continued)
Engaging with Medicaid partners to encourage fraud referrals and enhance collaboration: The Unit regularly met with the State Medicaid agency, other State agencies, and MCOs to encourage fraud referrals and improve communication and collaboration. The results included improved quality, completeness, and timeliness of fraud referrals.
Co-developing a streamlined process for referring patient abuse or neglect cases with a State licensing agency: Unit management and the Michigan Department of Licensing and Regulatory Affairs developed a streamlined process for referring cases of patient abuse or neglect. This process helped to ensure that referrals from the Department of Licensing and Regulatory Affairs were consistent with the Unit's statutory functions, thereby promoting Unit efficiency.
Participating in an Elder Abuse Task Force to provide training to law enforcement and first responders: To encourage referrals, the Unit regularly trained cadets at the Montana Law Enforcement Academy and trained other law enforcement and first responder personnel through its participation in the Montana Elder Abuse Task Force. The training focused on the Unit's mission and how the Unit can assist with crimes that law enforcement personnel and first responders might encounter.
Establishing data analytics working groups to improve the Unit's ability to data mine: The Unit established data analytics working groups to provide guidance, training, and an assessment of the Unit's data mining efforts. The groups include the Data Analytics Tool Group, the Data Sources Groups, the Fraud and Abuse Group, and the Governance Group.
Co-developing a referral process with the State Medicaid agency to ensure receipt of referrals: Unit management and the State Medicaid agency worked closely to develop and implement an improved referral process that ensures that the Unit receives all appropriate fraud referrals generated by MCOs.
Establishing a program integrity group comprised of personnel from other Medicaid program integrity entities: The Unit established the Ohio Program Integrity Group, which combines the knowledge and resources of all the State agencies that are responsible for Medicaid program integrity. In addition, the Unit spearheaded the Managed Care Program Integrity Group, which meets quarterly.

STANDARD 4	A Unit takes steps to maintain an adequate volume and quality of referrals from the State Medicaid agency and other sources. (continued)
Oregon OEI-09-16-00200 December 2016	Establishing an outreach group to increase referrals for patient abuse or neglect cases from broader areas of the State: The Unit created a group that provided outreach to help increase referrals for patient abuse or neglect and facilitate Unit work in broader areas of the State. This group provided outreach about the Unit's mission and legal authorities by establishing Unit liaisons for each county in Oregon and attending multidisciplinary team meetings at the county level.
South Dakota OEI-07-16-00170 September 2016	Having providers teach their peers about implications of Medicaid fraud: The Unit used providers who had previously been investigated for Medicaid fraud to educate their peers. These providers gave presentations alongside Unit staff at training conferences—this helped to highlight Medicaid billing issues and the implications of Medicaid fraud.
Washington OEI-09-16-00010 September 2016	Revising its MOU and contracts with State Medicaid partners to ensure the receipt of fraud referrals from MCOs: The Unit worked with the State Medicaid agency to revise both the memorandum of understanding between the Unit and the agency and the agency's contracts with MCOs to ensure that the Unit received copies of all fraud referrals from MCOs.
STANDARD 5	A Unit takes steps to maintain a continuous case flow and to complete cases in an appropriate timeframe based on the complexity of the cases.
Arkansas OEI-12-19-00450 September 2020	Designating staff as subject matter experts: The Unit director designated Unit investigators as subject matter experts of specific, common provider types for efficient assignment and improved investigation of cases.
New York OEI-12-17-00340 September 2018	Developing a strategic plan to optimize and prioritize resources: The Unit developed a written strategic plan to help Unit staff make informed decisions regarding the optimal use of resources. The plan provides guidance to prioritize certain types of investigations, such as criminal investigations that are related to systematic patient abuse and neglect, fraud allegations against managed care companies, and fraud investigations of large providers. The plan also establishes a priority for false claims investigations with higher potential for monetary recoveries or risk of patient harm.
Ohio OEI-07-14-00290 April 2015	Establishing a technical support team: The Unit employed a special projects team to provide technical support to all its investigative teams.

STANDARD 7	A Unit maintains case files in an effective manner and develops a case management system that allows efficient access to case information and other performance data.
Massachusetts OEI-07-15-00390 June 2016	Using an intranet system to streamline case management: The Unit used its intranet system to streamline its administrative processes, such as periodic supervisory reviews of case files. The Unit found that this helped improve case management and the effectiveness of investigations and prosecutions.
STANDARD 8	A Unit cooperates with OIG and other Federal agencies in the investigation and prosecution of Medicaid and other health care fraud.
Alaska OEI-09-16-00430 September 2017	Improving communication with stakeholders to increase joint cases with Federal partners: Unit stakeholders reported that the MFCU Director made efforts to improve communication with agencies such as OIG and the State Medicaid agency. As a result, the number of joint OIG-MFCU cases tripled from FY 2012 to FY 2015. Also, the Unit collaborated with Federal and State partners to investigate allegations of PCS fraud that led to convictions and significant monetary recoveries.
California OEI-09-15-00070 February 2016	Co-locating Unit and OIG staff to facilitate referrals and communication: Unit investigators have workstations at an OIG field office—this facilitated the mutual referral of cases and improved communication and cooperation with OIG on joint cases.
Florida OEI-07-15-00340 June 2016	Co-locating Unit and OIG staff to improve cooperation on joint cases: Unit staff have workstations at an OIG field office—this improved communication and cooperation with OIG on joint cases, including fraud cases generated through the U.S. Department of Justice (DOJ) Medicare Strike Force.
Idaho OEI-12-18-00320 August 2019	Monitoring media sources to report convictions of providers to OIG: The Unit's legal secretary monitored media sources for convictions of patient abuse and neglect cases. Although the convictions were a result of investigations by local authorities and not the Unit, the legal secretary reviewed the conviction information and submitted the police reports and court documents to OIG. As a result of those efforts, OIG has excluded seven individuals from federally funded health programs.
Massachusetts OEI-07-15-00390 June 2016	Developing partnerships with law enforcement and clinical experts to investigate drug cases: The Unit developed partnerships with other State and Federal agencies and used clinical experts to facilitate the investigation and prosecution of drug diversion and pharmaceutical cases.

STANDARD 8	A Unit cooperates with OIG and other Federal agencies in the investigation and prosecution of Medicaid and other health care fraud. (continued)
Virginia OEI-07-15-00290 August 2016	Developing partnerships with agencies composed of diverse professional disciplines: The Unit's partnerships with the Food and Drug Administration, the Internal Revenue Service, and the Social Security Administration led to successful Medicaid fraud prosecutions, particularly with regard to pharmaceutical manufacturers, and increased Unit recoveries.
STANDARD 9	A Unit makes statutory or programmatic recommendations, when warranted, to the State government.
Alaska OEI-09-16-00430 September 2017	Making program integrity recommendations to fight PCS fraud: The Unit made program integrity recommendations to safeguard against PCS provider fraud, and worked with the State Medicaid agency to implement these recommendations.
Minnesota OEI-06-13-00200 March 2014	Developing legislation to protect Medicaid beneficiaries from abuse: The Unit helped develop legislation to protect Medicaid beneficiaries by strengthening background checks for individuals who serve as guardians and conservators of Medicaid beneficiaries.
New Mexico OEI-09-14-00240 February 2015	Partnering with the Medicaid agency to revise MCO contracts and improve referral coordination: The Unit consistently provided program integrity recommendations to the State Medicaid agency during quarterly joint protocol meetings. One of these recommendations resulted in the inclusion of language in MCO contracts that clarified the State Medicaid agency role in referring to the MFCU all "verified" allegations of fraud, waste, or abuse in a managed care setting.
Washington OEI-09-16-00010 September 2016	Using information from a case closure form to make program integrity recommendations to State agencies: The Unit used a case closure form to make numerous program integrity recommendations to State agencies and tracked the responses to these recommendations in a database.
STANDARD 12	A Unit conducts training that aids in the mission of the Unit.
Kentucky OEI-06-17-00030 September 2017	Implementing a mentoring program to develop Unit attorneys: The Unit created an executive advisor position to help Unit attorneys develop litigation skills. The executive advisor also mentored new attorneys and served as a cochair on Unit prosecutions.

STANDARD 12	A Unit conducts training that aids in the mission of the Unit. (continued)
Maryland OEI-07-16-00140 September 2016	Developing an internal boot camp to train new staff: The Unit developed an internal "boot camp" training program that helped new staff develop a full understanding of the Unit's work. Experienced MFCU staff gave 1- to 2-hour lectures on topics such as civil and criminal investigation procedures, interviewing techniques, and understanding medical codes.
Missouri OEI-12-18-00490 January 2020	Creating in-house training videos: The Unit's Chief Auditor created in-house training videos for Unit investigators and attorneys. The videos contained step-by-step tutorials for creating and using investigative and trial tools.
New York OEI-12-17-00340 September 2018	Using a moot-court approach for training attorneys: The Unit used moot-court training to train Unit attorneys. This training helped the Unit attorneys practice opening arguments to prepare for trial.
North Carolina OEI-07-16-00070 September 2016	Partnering with another State agency to establish an academy for financial investigators: The Unit partnered with another State agency to create the North Carolina Financial Investigators Academy. The academy provided instruction to financial investigators on topics such as elements of criminal law, search and seizure procedures, interviewing, and testifying. The Unit required all its newly hired financial investigators to attend the academy, regardless of previous experience.
Wyoming OEI-09-16-00530 September 2017	Using staff from another MFCU to train a new investigator: The Unit used a MFCU investigator from a neighboring State to help train its newly hired investigator. As part of the training, the newly hired investigator observed work on active Medicaid fraud cases and met with the MFCU's management and attorneys from the neighboring State to discuss progress. This was a cost-effective training option for the Unit and furthered a positive working relationship with the neighboring MFCU.

OTHER	Beneficial practices not relating directly to a specific performance standard.
Vermont OEI-02-13-00360 December 2013	Co-developing provider focus teams with the State Medicaid agency to improve program integrity: The Unit director created provider focus teams in collaboration with the State Medicaid agency. These teams facilitated existing cases, developed training for providers, and made program recommendations.
	Co-developing a working group with State and Federal partners to improve health care for the elderly: The Unit director helped create the Vermont Elder Justice Working Group, which consisted of representatives from State and Federal advocacy groups, regulatory agencies, and law enforcement agencies. The group's mission was to improve health care for the elderly living in long-term care facilities by improving communication among stakeholders and law enforcement agencies.
Virginia OEI-07-15-00290 August 2016	Using specialty software to better analyze, maintain, and share documentary evidence: The Unit used specialty software designed to read the text in a document, analyze it for keywords, and systematically code it according to criteria established by an analyst. This improved the Unit's abilities to process and track evidence collected during investigations and to share that evidence with Federal and State partners working on joint cases.

APPENDIX C

Medicaid Fraud Control Unit Case Outcomes and Open Investigations by Provider Type and Case Type for Fiscal Year 2020

Exhibit C1: Number of convictions, settlements and judgments, and recoveries by provider type and case type

	CRIMINAL		CIVIL	
PROVIDER TYPE	Convictions	Amount of Recoveries	Settlements and Judgments	Amount of Recoveries
Patient Abuse or Neglect				
Assisted Living Facility	8	\$45,093	1	\$4,788
Developmental Disability Facility	10	\$13,956	1	\$0
Hospice	0	\$0	0	\$0
Nondirect Care Staff	10	\$79,421	0	\$0
Nurse Aide (CNA or Other)	56	\$282,430	0	\$0
Nursing Facilities	11	\$55,069	9	\$1,366,143
Nurse (LPN, RN, or NP) or Physician Assistant	47	\$59,574	0	\$0
Personal Care Aide or Other Home Care Aide	39	\$323,264	0	\$0
Other	62	\$1,485,814	1	\$144,440
Fraud—Facility-Based Medicaid Provid	ers and Progra	ms—Inpatient a	and/or Residen	tial
Assisted Living Facility	1	\$1,147,322	2	\$577,506
Developmental Disability Facility (Residential)	1	\$37,075	0	\$0
Hospice	2	\$347,035	2	\$1,282,364
Hospital	10	\$23,679,690	44	\$50,697,061
Inpatient Psychiatric Services for Individuals under Age 21	0	\$0	12	\$20,163,475
Nursing Facility	1	\$0	9	\$23,895,840
Other Inpatient Mental Health Facility	0	\$0	23	\$10,336,054
Other Long-Term Care Facility	0	\$0	4	\$423,604

Number of convictions, settlements and judgments, and recoveries by provider type and case type (continued)

	CRIMINAL		CIVIL	
PROVIDER TYPE	Convictions	Amount of Recoveries	Settlements and Judgments	Amount of Recoveries
Fraud—Facility-Based Medicaid Provid	ers and Progra	ms—Outpatien	t and/or Day Se	rvices
Adult Day Center	1	\$32,633	4	\$661,119
Ambulatory Surgical Center	0	\$0	1	\$5,613
Developmental Disability Facility (Nonresidential)	2	\$68,425	2	\$40,349
Dialysis Center	0	\$0	0	\$0
Mental Health Facility (Nonresidential)	21	\$10,255,952	11	\$17,373,695
Substance Abuse Treatment Center	9	\$24,799,396	7	\$4,738,537
Other Facility (Nonresidential)	8	\$1,911,689	7	\$3,993,545
Fraud—Licensed Practitioners				
Audiologist	0	\$0	0	\$0
Chiropractor	1	\$100,180	1	\$30,418
Clinical Social Worker	10	\$1,943,242	4	\$628,193
Dental Hygienist	0	\$0	3	\$131,154
Dentist	13	\$2,560,572	18	\$4,932,636
Nurse (LPN, RN, or Other Licensed)	52	\$1,161,395	6	\$246,432
Nurse Practitioner	9	\$7,170,015	1	\$11,156
Optometrist	1	\$95,000	1	\$6,073
Pharmacist	11	\$7,074,522	1	\$171,713
Physician Assistant	2	\$2,390	0	\$0
Podiatrist	1	\$57,240	1	\$366,125
Psychologist	7	\$1,378,172	2	\$43,511
Therapist (Non-Mental Health, PT, ST, OT, or RT)	7	\$1,151,551	3	\$96,118
Other Practitioner	12	\$911,342	9	\$742,815
Fraud—Medical Services				
Ambulance	2	\$851,987	1	\$385,000
Billing Services	4	\$1,193,307	7	\$3,156,236

Number of convictions, settlements and judgments, and recoveries by provider type and case type (continued)

	CRIMINAL		CIVIL	
PROVIDER TYPE	Convictions	Amount of Recoveries	Settlements and Judgments	Amount of Recoveries
Fraud—Medical Services (continued)				
Home Health Agency	21	\$4,948,195	9	\$15,195,008
Lab (Clinical)	0	\$0	19	\$4,133,672
Lab (Radiology and Physiology)	0	\$0	2	\$16,176
Lab (Other)	1	\$257,500	4	\$1,882,218
Medical Device Manufacturer	0	\$0	54	\$3,123,112
Pain Management Clinic	2	\$1,331,324	7	\$4,274,810
Personal Care Services Agency	21	\$4,700,311	7	\$3,190,996
Pharmaceutical Manufacturer	0	\$0	263	\$549,147,525
Pharmacy (Hospital)	0	\$0	0	\$0
Pharmacy (Institutional Wholesale)	0	\$0	6	\$6,710,024
Pharmacy (Retail)	17	\$6,573,002	34	\$20,366,201
Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and	5	\$4,214,477	45	\$2,567,637
Supplies (DMEPOS)				
Transportation (Nonemergency)	20	\$7,192,516	7	\$11,672,105
Other	8	\$399,633	42	\$15,329,992
Fraud—Other Individual Providers				
Emergency Medical Technician or Paramedic	1	\$3,604	0	\$0
Nurse's Aide (CNA or Other)	11	\$33,224	0	\$0
Optician	0	\$0	1	\$263,489
Personal Care Services Attendant	339	\$6,065,610	10	\$48,663
Pharmacy Technician	4	\$201,747	0	\$0
Unlicensed Counselor (Mental Health)	11	\$1,232,139	2	\$59,000
Unlicensed Therapist (Non-Mental Health)	2	\$4,367	0	\$0
Other	53	\$12,900,713	2	\$9,099

Number of convictions, settlements and judgments, and recoveries by provider type and case type (continued)

	CRIMINAL		CIVIL			
PROVIDER TYPE	Convictions	Amount of Recoveries	Settlements and Judgments	Amount of Recoveries		
Fraud—Physicians (MD/DO) by Medical Specialty						
Allergist/Immunologist	0	\$0	0	\$0		
Cardiologist	1	\$9,662	2	\$1,154,369		
Emergency Medicine	4	\$5,405	0	\$0		
Family Practice	22	\$27,154,788	11	\$3,550,748		
Geriatrician	0	\$0	0	\$0		
Internal Medicine	11	\$1,895,411	5	\$1,129,229		
Neurologist	1	\$3,100	1	\$253,273		
Obstetrician/Gynecologist	2	\$25,864	3	\$252,725		
Ophthalmologist	1	\$24	3	\$1,540,423		
Pediatrician	2	\$72,555	1	\$50,000		
Physical Medicine and Rehabilitation	1	\$48,030	1	\$2,007,377		
Psychiatrist	4	\$531,104	6	\$1,523,751		
Radiologist	0	\$0	0	\$0		
Surgeon	0	\$0	2	\$348,130		
Urologist	0	\$0	1	\$150,000		
Other MD/DO	16	\$3,081,223	7	\$1,700,435		
Fraud—Program Related						
Managed Care Organization (MCO)	0	\$0	21	\$48,728,862		
Medicaid Program Administration	0	\$0	0	\$0		
Other	5	\$34,336	10	\$7,770,320		
TOTAL	1,017	\$173,194,614	786	\$854,801,084		

Exhibit C2: Number of open investigations at the end of FY 2020 by provider type and case type

	OPE	OPEN INVESTIGATIONS	
PROVIDER TYPE	Criminal	Civil	Total
Patient Abuse or Neglect			
Assisted Living Facility	241	6	247
Developmental Disability Facility	161	5	166
Hospice	3	0	3
Nondirect Care Staff	126	0	126
Nurse Aide (CNA or Other)	426	5	431
Nursing Facilities	863	52	915
Nurse (RN, LPN, or NP) or Physician Assistant	313	1	314
Personal Care Aide or Other Home Care Aide	270	0	270
Other	843	6	849
Fraud—Facility-Based Medicaid Providers and Progra	ams—Inpatient a	nd/or Residen	itial
Assisted Living Facility	57	11	68
Developmental Disability Facility (Residential)	41	6	47
Hospice	76	34	110
Hospital	75	202	277
Inpatient Psychiatric Services for Individuals under Age 21	11	12	23
Nursing Facility	136	209	345
Other Inpatient Mental Health Facility	19	39	58
Other Long-Term Care Facility	29	29	58
Fraud—Facility-Based Medicaid Providers and Progra	ams—Outpatient	and/or Day S	ervices
Adult Day Center	76	4	80
Ambulatory Surgical Center	3	8	11
Developmental Disability Facility (Nonresidential)	31	14	45
Dialysis Center	0	68	68
Mental Health Facility (Nonresidential)	354	59	413
Substance Abuse Treatment Center	140	51	191
Other Facility (Nonresidential)	103	66	169
		continued o	n the next page

Exhibit C2: Number of open investigations at the end of FY 2020 by provider type and case type (continued)

	OPEN INVESTIGATIONS		
PROVIDER TYPE	Criminal	Civil	Total
Fraud—Licensed Practitioners			
Audiologist	6	2	8
Chiropractor	26	6	32
Clinical Social Worker	80	6	86
Dental Hygienist	2	3	5
Dentist	309	52	361
Nurse (LPN, RN, or Other Licensed)	491	7	498
Nurse Practitioner	83	5	88
Optometrist	33	9	42
Pharmacist	62	23	85
Physician Assistant	31	0	31
Podiatrist	27	10	37
Psychologist	61	17	78
Therapist (Non-Mental Health, PT, ST, OT, or RT)	92	32	124
Other Practitioner	132	15	147
Fraud—Medical Services			
Ambulance	60	42	102
Billing Services	31	79	110
Home Health Agency	674	130	804
Lab (Clinical)	104	490	594
Lab (Radiology and Physiology)	22	41	63
Lab (Other)	36	193	229
Medical Device Manufacturer	4	666	670
Pain Management Clinic	57	21	78
Personal Care Services Agency	197	10	207
Pharmaceutical Manufacturer	161	2,690	2,851
Pharmacy (Hospital)	1	4	5
Pharmacy (Institutional Wholesale)	11	227	238
Pharmacy (Retail)	320	911	1,231
Transportation (Nonemergency)	254	25	279
Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)	177	569	746
Other	79	341	420
		continued o	n the next page

Exhibit C2: Number of open investigations at the end of FY 2020 by provider type and case type (continued)

	OPEN INVESTIGATIONS		
PROVIDER TYPE	Criminal	Civil	Total
Fraud—Other Individual Providers			
Emergency Medical Technician or Paramedic	3	1	4
Nurse Aide (CNA or Other)	72	1	73
Optician	1	6	7
Personal Care Services Attendant	1,719	16	1,735
Pharmacy Technician	21	0	21
Unlicensed Counselor (Mental Health)	69	5	74
Unlicensed Therapist (Non-Mental Health)	6	1	7
Other	441	48	489
Fraud—Physicians (MD/DO) by Medical Specialty			
Allergist/Immunologist	8	3	11
Cardiologist	15	13	28
Emergency Medicine	17	26	43
Family Practice	277	31	308
Geriatrician	1	0	1
Internal Medicine	147	23	170
Neurologist	29	4	33
Obstetrician/Gynecologist	26	5	31
Ophthalmologist	17	12	29
Pediatrician	46	8	54
Physical Medicine and Rehabilitation	32	13	45
Psychiatrist	87	18	105
Radiologist	9	17	26
Surgeon	32	13	45
Urologist	3	3	6
Other MD/DO	338	82	420
Fraud—Program Related			
Managed Care Organization (MCO)	22	84	106
Medicaid Program Administration	23	11	34
Other	164	118	282
Total	11,645	8,075	19,720

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ENDNOTES

- ¹ Social Security Act (SSA) § 1903(q)(3)–(4). Regulations at 42 CFR § 1007.11(b)(1) add that a Unit's responsibilities may include reviewing complaints of misappropriation of patients' private funds in residential health care facilities. Unit investigations of patient abuse and neglect are limited to incidents occurring in (1) health care facilities that receive Medicaid payments and (2) board and care facilities, which are residential settings that receive payments on behalf of two or more unrelated adults who reside in the facility and receive nursing care services or a substantial amount of personal care services (PCS). SSA § 1903(q)(4). As of December 27, 2020, MFCUs may also receive Federal financial participation to investigate and prosecute abuse or neglect of Medicaid beneficiaries in a noninstitutional or other setting. Consolidated Appropriations Act, 2021, P.L. No. 116-260, Division CC, § 207.
- ² SSA § 1902(a)(61).
- ³ The SSA authorizes the Secretary of HHS to award grants (SSA § 1903(a)(6)) and to certify and annually recertify Units (SSA § 1903(q)). The Secretary delegated this authority to OIG. See also 42 CFR § 1007.15. Units must meet several requirements established by the SSA and Federal regulations. For example, each Unit must (1) be a single, identifiable entity of State Government, separate and distinct from the State Medicaid agency (SSA § 1903(q)(2); 42 CFR §§ 1007.5(a) and 1007.9(a)); (2) employ an interdisciplinary staff that consists of at least an investigator, an auditor, and an attorney (SSA § 1903(q)(6); 42 CFR § 1007.13); (3) develop a formal agreement, such as a memorandum of understanding, describing the Unit's relationship with the State Medicaid agency (42 CFR § 1007.9(d)); and (4) have either statewide authority to prosecute cases or formal procedures to refer suspected criminal violations to an agency with such authority (SSA § 1903(q)(1); 42 CFR § 1007.7).
- ⁴ The territories of American Samoa, Guam, and the Northern Mariana Islands have not established Units. Puerto Rico and the U.S. Virgin Islands received certification to operate in FY 2019 and North Dakota received certification to operate in FY 2020.
- ⁵ SSA § 1903(a)(6). For a Unit's first 3 years of operation, the Federal Government contributes 90 percent of funding and the State contributes 10 percent. Thereafter, the Federal Government contributes 75 percent and the State contributes 25 percent.
- ⁶ OIG's analysis of MFCU Annual Statistical Reports from FY 2020.
- ⁷ 42 CFR § 1007.20. MFCUs must receive approval from OIG to conduct data mining. As of February 2021, 21 MFCUs were approved for data mining. OIG, *Data Mining Applications*, https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/data-mining.asp. Accessed on February 2, 2021.
- ⁸ SSA § 1128; 42 U.S.C. § 1320a-7. See also OIG, *Background Information*, https://oig.hhs.gov/exclusions/background.asp. Accessed on March 12, 2021.
- ⁹ These inspections were conducted onsite before the COVID-19 pandemic. Because of the pandemic, OIG has since conducted inspections in a remote, virtual format.
- ¹⁰ OIG provides information on MFCU operations and outcomes but does not direct or encourage MFCUs to investigate or prosecute a specific number of cases. MFCU investigators and prosecutors should apply professional judgment and discretion in determining what criminal and civil cases to pursue.
- ¹¹ 42 CFR § 1007.15.
- ¹² MFCU performance standards are published at 77 Fed. Reg. 32645 (June 1, 2012).
- ¹³ The survey collected information about (1) operational challenges that the MFCUs may have encountered during the pandemic, (2) how MFCUs addressed those challenges, and (3) practices that helped MFCUs address those challenges. In addition, the survey collected information from MFCUs about their broader needs for training.

- ¹⁴ To calculate the ROI for MFCUs, we first calculated the total recoveries by adding the \$173 million in criminal case recoveries to the \$855 million in civil case recoveries. We then divided the \$1 billion in total recoveries by the total MFCU grant expenditures of \$306 million, resulting in the overall ROI of \$3.36 for every \$1 spent.
- ¹⁵ OIG, *LEIE Downloadable Databases*, https://oig.hhs.gov/exclusions/exclusions list.asp. Accessed on January 22, 2021. The list of OIG-excluded individuals or entities can be found on the OIG website.
- ¹⁶ OIG, State Fraud Policy Transmittal 2020-3, MFCU Authority to Receive Federal Funding to Investigate and Prosecute Diversion and Misuse of Pharmaceuticals, October 28, 2020. This transmittal describes the situations when Units are eligible to receive Federal financial participation to investigate and prosecute drug diversion cases.
- ¹⁷ One large, 268-million-dollar case prosecuted in FY 2017 accounted for about 39 percent of all criminal recoveries in FY 2017. The Texas MFCU prosecuted this case, which involved a doctor and other codefendants who defrauded Medicaid and Medicare by improperly recruiting individuals and falsifying medical documents.
- ¹⁸ United States Department of Justice, *Last of Six Sentenced in Scheme to Defraud Medicaid of Millions*, June 16, 2020. https://www.justice.gov/usao-ndoh/pr/last-six-sentenced-scheme-defraud-medicaid-millions. Accessed on February 9, 2021.
- ¹⁹ Our data collection did not identify a specific cause for the rise in civil case outcomes, but one explanation could have been efforts to refocus prosecutive and court resources on civil cases during a time when criminal court proceedings were curtailed or stayed.
- ²⁰ The spikes in civil recoveries in FYs 2016 and 2019 significantly elevated the average for civil recoveries in FYs 2016–2020.
- ²¹ To calculate the percentages for civil global and nonglobal recoveries, we used the total civil recoveries of \$854,801,085 and rounded the dollar value to the nearest tenth. Total civil recoveries accounted for \$855 million and global cases accounted for \$637 million in FY 2020.
- ²² Wisconsin Department of Justice, \$678 Million National Kickback Settlement with Novartis Pharmaceuticals, September 24, 2020. https://www.doj.state.wi.us/sites/default/files/news-media/9.21.20 Novartis.pdf. Accessed on February 8, 2021.