U.S. Department of Health and Human Services

Office of Inspector General

MEDICARE ADVANTAGE

Industry Segment-Specific Compliance Program Guidance

February 2026

User's Guide

Welcome to OIG's Industry Segment-Specific Compliance Program Guidance for Medicare Advantage (Medicare Advantage ICPG).

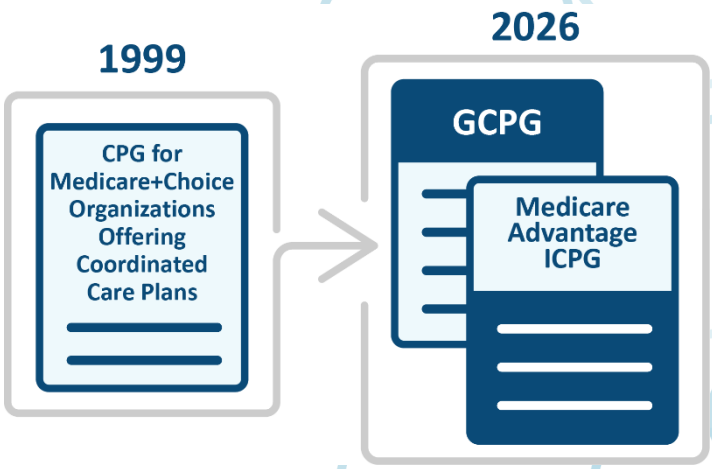
The Medicare Advantage ICPG describes:

- Risk areas for the wide range of entities and individuals participating in or engaged with the Medicare Advantage (MA) program (which we reference in this ICPG collectively as "MA Parties");
- Recommendations and practical considerations for mitigating those risks; and
- Other important information OIG believes MA Parties should consider when implementing, evaluating, and updating their compliance programs.

The Medicare Advantage ICPG—together with OIG's General Compliance Program Guidance (GCPG) that applies to all individuals and entities involved in the health care industry—serves as OIG's updated and centralized source of voluntary compliance program guidance for Medicare Advantage. MA Parties can use the ICPG to help identify their own risks and implement an effective compliance program to reduce those risks.

These resources are not one-size-fits-all, comprehensive, or inclusive of all compliance considerations or risks. They are not binding on any individual or entity. Of note, OIG uses the word "should" in the Medicare Advantage ICPG and GCPG to present voluntary, nonbinding guidance. This means that the documents do not create any new obligations or standards for any individual or entity.

The Medicare Advantage ICPG updates prior guidance OIG issued in its 1999 Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans (1999 CPG). We have carried forward certain pertinent risk areas and relevant considerations from the 1999 CPG in this document. The absence of a previously identified risk area or consideration in the Medicare Advantage ICPG does not signal that a risk no longer exists, has become irrelevant, or is otherwise inapplicable. Individuals and entities may still wish to address the risk area or consideration in their compliance programs. The 1999 CPG will continue to be available on our website as an archived resource.



The Medicare Advantage ICPG's detailed table of contents allows the user to directly access specific topics of interest. Many sections contain hyperlinks to the GCPG, OIG's resources, laws and regulations, other internet locations with useful information, or related topics within this ICPG. We highlight that the laws and regulations impacting the MA industry are subject to change. Although we will make efforts to update this document to reflect relevant changes, MA Parties may need to consult directly with those laws and regulations for up-to-date information about their relevant legal obligations.

GCPG

- Key Federal authorities for entities engaged in health care business
- Seven elements of a compliance program
- Adaptations for small and large entities
- Other compliance considerations
- OIG processes and resources

Medicare Advantage ICPG

- Tailored to compliance risk areas for the MA industry segment
- Compliance measures that entities and individuals in the MA industry can take to reduce risk

If you have information about any individuals or entities engaging in potential fraud, waste, or abuse within the MA program, please submit a complaint online to the OIG Hotline or contact the OIG Hotline at 1-800-447-8477 (1-800-HHS-TIPS).

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I. Introduction

Many Medicare enrollees rely on managed care for their healthcare benefits, which is called the MA program in Medicare. Effective oversight of the MA program (also known as Medicare Part C) is a priority for OIG. OIG has developed a strategy to align its audits, evaluations, investigations, and enforcement of managed care.[1] Through its oversight work, OIG aims to ensure that the MA program and parties operating within it provide high-quality care in an efficient way.

This Medicare Advantage ICPG—together with the GCPG—is intended to serve as a key resource for the MA industry and interested stakeholders. These resources address the goals shared by Government, private industry stakeholders, taxpayers, and Medicare enrollees of reducing fraud, waste, and abuse; promoting high-quality, cost-effective care; enhancing MA Parties' operations; and propelling improvements in compliance and quality of care. Having an effective compliance program is a sound business investment that can enhance operations without imposing undue burdens on MA Parties.

This Medicare Advantage ICPG incorporates information and recommendations that are based on OIG's: (1) findings and observations from our decades of work on matters involving the MA program, including audits, evaluations, investigations, enforcement actions, data analyses, development of industry resources, and monitoring under Corporate Integrity Agreements; (2) current enforcement priorities; (3) work with our Government partners; and (4) interactions with MA Parties and other industry stakeholders, many of whom have long requested an update to the 1999 CPG. In creating this guidance, OIG partnered with industry representatives to hold listening sessions, during which we heard compliance concerns and solutions directly from a wide range of affected parties. The excitement and support both before and during the sessions helped propel development of this document into a tool eagerly anticipated by the industry.

A. Use of the Medicare Advantage ICPG

We encourage MA Parties to use the Medicare Advantage ICPG as a tool in identifying their own risk areas and in implementing, evaluating, and updating their compliance programs to mitigate these risk areas. As each MA Party reflects on how to best use this tool, OIG notes the following:

- Many MA Parties and their employees are dedicated to providing high-quality and cost-effective services to MA enrollees. Industry representatives repeatedly highlighted this dedication during listening sessions with OIG.

[1] *HHS-OIG Strategic Plan: Oversight of Managed Care for Medicare and Medicaid*, August 2023.

- Adhering to legal obligations and avoiding pitfalls can present challenges in the complex and evolving MA program. This ICPG is intended to synthesize and coalesce OIG's knowledge base to offer recommendations that may help to alleviate or overcome some of those challenges.
- Centers for Medicare & Medicaid Services (CMS) regulations require Medicare Advantage Organizations (MAOs)—which are public or private companies that offer MA plans—to adopt and implement effective compliance programs, including measures to prevent, detect, and correct fraud, waste, and abuse.[2] CMS sets forth additional guidelines regarding its compliance plan requirements and recommendations in its *Medicare Managed Care Manual*. Many of the requirements in these CMS regulations overlap with the voluntary seven elements of an effective compliance program described in section 3 of the GCPG. We underscore that these program requirements may change; we recommend MA Parties consult the applicable laws and regulations directly as the primary source for those legal obligations.

We emphasize that the Medicare Advantage ICPG and the GCPG (which provide voluntary, nonbinding guidance) are intended to complement CMS's compliance program regulations (which are mandatory for MAOs). CMS's regulations provide the minimum requirements for MAO compliance program structure and operation. The recommendations and practical considerations in the Medicare Advantage ICPG and GCPG—if incorporated by MA Parties—could help facilitate compliance with CMS's compliance program regulations and other statutory and regulatory obligations. Moreover, the Medicare Advantage ICPG has a broader scope than the CMS compliance program regulations, which impose mandatory legal obligations only on MAOs. That is, the Medicare Advantage ICPG applies to a wider range of MA Parties and offers additional voluntary measures, beyond the compulsory CMS compliance program regulations, that may further focus and enhance compliance.

B. Motivating Factors

The following factors have motivated the creation of this Medicare Advantage ICPG:

- The growing popularity of managed care—and, in particular, the MA program—over the past decade has changed fundamental aspects of the Medicare program. This significant shift has transformed how millions of Medicare enrollees access health care and how the Government pays for that care.
- OIG is uniquely positioned to have both a bird's-eye view and a granular understanding of the MA industry and the fraud, waste, and abuse risks within it. We synthesized our skills and findings to create this document to fulfill the industry's request for this insight and to further promote efficient and effective compliance by MA Parties.
- Managed care oversight is a top OIG priority. OIG's work relating to the MA program has uncovered fraud, waste, and abuse involving MA Parties. Ongoing work by OIG, CMS, the Department of Justice, and other law enforcement partners continues to identify potentially abusive practices involving MA Parties. Proactive efforts by MA Parties to establish effective

[2] 42 CFR § 422.503(b)(4)(vi).

compliance systems and processes can detect and prevent violations of the law and promote the delivery of high-quality, cost-effective care to MA enrollees.

- OIG last published compliance program guidance for the MA program in 1999. Since that time, the MA program has become increasingly complex with a proliferation in the number and types of different entities participating in it. We have heard repeatedly from MA Parties that the industry would welcome an update to the 1999 CPG. Through this Medicare Advantage ICPG, OIG seeks to improve the usefulness, timeliness, accessibility, and usability of our compliance program guidance for MA Parties.

C. Medicare Advantage Industry Overview

This section provides an overview of the MA industry as context for the risk areas described in section 2. MA is a managed care program through which Medicare-eligible individuals may choose to enroll in private health plans that administer Medicare benefits. Congress established the MA program in 1997, and since then it has grown as millions of Americans have chosen to enroll. MA plans, which are offered by MAOs, are required to provide at least the services covered by Medicare Parts A and B (also known as traditional or Original Medicare).

MAO Health Plan Examples:

- Health maintenance organizations
- Preferred provider organizations
- Private fee-for-service plans

Special Needs Plans Available To:

- Medicare-eligible individuals with Medicare and Medicaid dual eligibility
- Those who live in long-term care institutions
- Those who have severe or disabling chronic conditions

Plans May Include:

- Prescription drug coverage
- Supplemental benefits not covered by tradional Medicare, such as dental and vision services

Within the MA program, MAOs offer a range of health plans to Medicare-eligible individuals, including coordinated care plans (e.g., health maintenance organizations and preferred provider organizations), Medical Savings Accounts, and private fee-for-service plans. MAOs may also offer special needs plans, which are restricted to Medicare-eligible individuals who are dually eligible for Medicare and Medicaid, live in long-term care institutions, or have certain severe or disabling chronic conditions.[3] Many MA plans include prescription drug coverage, and plans also may provide supplemental benefits not covered by traditional Medicare (e.g., dental and vision services). Medicare beneficiaries have a choice whether to enroll in an MA plan and typically have a wide array of available options. Many beneficiaries learn of plan options through various communications—including marketing communications—from MAOs and their agents, brokers, and others.

MAOs contract with health care providers to provide care to individuals enrolled in the plans, and CMS regulates the adequacy of the MAOs' plan networks to ensure beneficiary access to covered services. Certain providers and suppliers report diagnosis and other information about MA plan enrollees to

[3] 42 CFR § 422.4(a)(1)(iv). "Special needs plans" here refers to CMS's defined term "Specialized MA Plans for Special Needs Individuals." 42 CFR § 422.2.

MAOs, which MAOs submit to CMS. CMS uses certain reported diagnosis codes to help determine the amount of the risk-adjusted payments it pays to MAOs for each person enrolled in the plan. The MA plans use a portion of those risk-adjusted payments to pay providers for furnishing services to the plan enrollees. The risk-adjusted payments reflect the predicted cost of providing care to each plan enrollee, with CMS generally paying more for individuals with higher expected health care costs based on the health status and demographic characteristics of each plan enrollee.[4]

Many features of the MA subsector present an evolving set of challenges:

- MAOs have relationships with a constellation of other entities and individuals, including health care professionals; management service organizations; individual practice associations; agents, brokers, and other entities that perform marketing and enrollment activities; and other vendors.
- Such relationships may include entities that share common ownership (discussed further below) and others may be solely contractual. Owners may include private equity firms that may lack extensive experience in the MA industry and may be particularly well suited to use this document as a resource at the outset of a new venture.
- CMS regularly updates its MA regulations and guidance. We recommend that MA Parties consult the regulations and guidance directly and regularly for the latest versions of those resources.
- New companies and contractors are continually entering the market.
- Merger activity has created novel combinations of different entity types.

In addition to these compliance challenges, the structure of the MA program's capitated payment model provides a potential incentive for insurers to increase profits by denying enrollees access to services and denying payments to providers, while maximizing payment from the government. MAOs are generally paid a fixed amount of money each month for each enrollee, regardless of the number or cost of services they pay on behalf of that enrollee. The monthly amount is adjusted for the relative risk associated with individual enrollees' demographic characteristics and health status. This payment adjustment (risk adjustment) turns on MAOs' submission of diagnosis codes and helps ensure that beneficiaries who need a costlier level of care have continued access to MA plans. However, the risk adjustment payment system also creates financial incentives for MAOs to make beneficiaries appear as sick as possible to increase these payments.

[4] *See* 42 CFR § 422.308(c); 42 CFR § 422.310.

SECTION II
Compliance Risk Areas and Recommendations for Mitigation

Return to TOC

II. Compliance Risk Areas and Recommendations for Mitigation

This section describes the following key risk areas relevant to the MA program and MA Parties and provides recommendations that may help mitigate these risks:

A. Access to Care (Network Adequacy and Prior Authorization)

B. Marketing and Enrollment

C. Risk Adjustment

D. Quality of Care

E. Oversight of Third Parties

F. Compliance Programs Within Vertically Integrated Organizations and Other Ownership Structures

G. Submission of Accurate Claims

DISCLAIMER

The risk areas identified in this document are not the only risk areas relevant to MA Parties. Our discussion of risk areas is not intended to be a substitute for MA Parties' own compliance efforts, which could identify and address other significant risk areas. We recommend that MA Parties conduct their own individualized risk assessment and mitigation efforts.

OIG's discussion of a particular practice or activity in this section is not intended to imply that the practice or activity is necessarily illegal in all circumstances or that it may not have a valid or lawful purpose. This guidance is not intended as a substitute for consultation with CMS or other relevant parties with respect to the application and interpretation of the guidance and regulations applicable to MA Parties.

A. Access to Care

Ensuring access to care is a core requirement of the MA program. Under CMS regulations, MAOs must ensure that enrollees can access all covered services and any applicable supplemental services.[5] MAOs' obligations include these two key areas: (1) adequacy of provider networks and accuracy of directories; and (2) access to services (subject to utilization management tools, including prior authorization). Besides imposing risks of delayed or missed care to enrolled individuals, MAOs' failure to meet these core program requirements can introduce legal and compliance risks for those MAOs.

[5] 42 CFR § 422.112.

1. Network Adequacy and Provider Directory Accuracy

Under Medicare requirements, MAOs must maintain and monitor provider networks that are sufficient to provide their enrollees with adequate access to covered services to meet their needs.[6] CMS regulations impose certain standards with respect to the adequacy of provider networks, including requiring MA plans to contract with enough providers, including specific provider types, so that to allow most enrollees to access care within specific travel time and distance maximums.[7] Applicants for a new or expanding service area must demonstrate compliance with CMS network adequacy standards as part of the application. In addition, CMS monitors compliance by reviewing networks on a triennial basis.[8]

MAOs typically meet their network adequacy requirements through a contracted network of providers within the network service area.[9] MAOs should take proactive measures to ensure that their provider networks are adequate to meet the needs of enrollees. Failing to do so may negatively impact enrollees and can lead to compliance risks for MAOs. As part of the bidding process, MAOs routinely make representations about their provider networks, and MAOs must subsequently make timely updates to provider directories once they become aware of information requiring updates.[10] In addition, MAOs must submit provider directory information to CMS for online publication in the Medicare Plan Finder and attest to its accuracy.[11] If these representations are false or misleading, MAOs could potentially face administrative sanctions or liability for making false statements to the Government. Moreover, Medicare-eligible individuals could be misled into enrolling into an MA plan that does not have sufficient access to providers if the plan's provider information in its directory is false, outdated, or incomplete during the enrollment period. Inaccurate or out-of-date directories also can lead to additional negative impacts to enrollees, including greater use of out-of-network providers and higher out-of-pocket costs.[12]

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[6] Section 1852(d)(1) of the Social Security Act (the Act), 42 U.S.C. § 1395w-22(d)(1). 42 CFR §§ 422.112(a)(1), 422.116.

[7] 42 CFR § 422.116.

[8] CMS, *Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance*, December 2023.

[9] 42 CFR § 422.112(a).

[10] 42 CFR § 422.2267(e)(11).

[11] 42 CFR § 422.111(m).

[12] Under CMS regulations, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs, MAOs must arrange for and cover any medically necessary covered benefit outside of the plan provider network and the patient cannot be charged more than the in-network cost-sharing amount. 42 CFR § 422.112(a)(1)(iii).

An MAO's compliance program should address provider network adequacy and accuracy of the MAO's provider directory. Strategies may include:

- contacting providers regularly to update directory information (CMS suggests such contact should occur at least quarterly[13]);
- using an independent third-party verification company to confirm the provider directory information meets a specific accuracy threshold;
- ensuring that enrollees are only assigned to primary care providers that have been recently verified by the MAO as actively accepting new patients;
- indicating in directories if providers have unverified information;
- reviewing claim submission volumes of in-network providers to prevent so-called ghost networks (inaccurate or misleading network directories that give the appearance of broader provider availability than is actually present) to determine whether each provider delivers care to enrollees;
- using claims data to confirm whether the conditions or procedures billed by providers align with the specialty type listed in the directory and to verify the provider actively practices at the location or locations specified in the directory;[14]
- promptly removing providers from the directory when they are no longer participating in the network;
- conducting secret shopper surveys using independent entities to confirm provider availability and other pertinent directory information;
- reviewing and tracking enrollee complaints about providers and conducting follow-up inquiries based on such complaints, including removing providers from directories, if appropriate;
- performing time and distance analyses of contracted providers, for example, by using the "Evaluate my Network" functionality in CMS's Health Plan Management System and by participating annually in CMS's network adequacy "Consultation," which is an opportunity for the MAO to upload its provider network data for CMS to conduct an informal review and provide technical assistance relating to network adequacy; and
- responding promptly to enrollee inquiries about specific providers' network participation status.

Also, MAOs may perform audits using Government sources that reflect basic information about providers, such as CMS's Provider Supply File, the National Plan and Provider Enumeration System NPI Registry, or PECOS (Provider, Enrollment, Chain, and Ownership System). MAOs also may use data sources that indicate when providers may not be legally permitted to furnish services to Medicare enrollees or when MAOs may not pay providers for furnishing such services, such as OIG's List of Excluded Individuals/Entities (LEIE) and CMS's Preclusion List and Provider Opt-Out Affidavits Look-up Tool.

[13] *Medicare Managed Care Manual*, ch. 4, § 110.2.2.

[14] For outpatient behavioral health providers, develop specific policies to ensure CMS's criteria are met. *See* 42 CFR § 422.116(b)(2)(xiv).

Strategies to ensure adequate provider networks and an accurate provider directory may vary depending on the size of a plan, the type of plan,[15] and the medical practices with which it contracts. For instance, an MAO may collect and audit rosters from larger medical practices—to ensure that they are up-to-date and accurate—before adding them to the MAO's network provider database. For smaller medical practices, MAOs may have a periodic (e.g., quarterly) verification process whereby the MAOs contact those practices to verify their location and availability. In either case, MAOs may require each provider to attest to the accuracy of availability and location information to ensure the accuracy of provider directories.

2. Utilization Management Tools, Including Prior Authorization

MAOs must, at a minimum, provide their members all benefits covered under Medicare Parts A and B.[16] MAOs must ensure, through individual medical necessity determinations, that only medically necessary care is provided.[17] MAOs' compliance programs, therefore, should evaluate whether utilization management tools, such as prior authorization, could inappropriately limit or impede access to medically necessary covered services and consider drafting policies and procedures to guard against these risks.[18]

OIG oversight has highlighted serious concerns about improper denials or delays in care resulting from prior authorization programs.[19] CMS regulations require that MAOs base medical necessity determinations on the individual patient's circumstances, including the patient's medical history, physician recommendations, and clinical notes.[20] MAOs must act timely[21] and ensure specific practice and utilization management standards are

[15] For instance, CMS provides Institutional Special Needs Plans with additional options for exception requests. *See* 42 CFR § 422.116(f).

[16] 42 CFR § 422.101.

[17] 42 CFR §§ 422.112(a)(6), 422.101.

[18] MAOs must adopt procedures for making determinations regarding whether an enrollee is entitled to receive a particular health service and the amount (if any) that the individual is required to pay with respect to such service. Section 1852(g)(1)(A) of the Act, 42 U.S.C. § 1395w-22(g)(1)(A); 42 CFR § 422.566. CMS has underscored that this mandate "applies to both prior authorization determinations and to post-service decisions about coverage and payment." CMS, Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 88 Fed. Reg. 22,120, 22,185 (Apr. 12, 2023).

[19] OIG, *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care* (OEI-09-18-00260), Apr. 17, 2022. Testimony of Megan Tinker, Chief of Staff, Office of Inspector General, Department of Health and Human Services, before the Senate Committee on Homeland Security and Governmental Affairs, Permanent Subcommittee on Investigations, *Examining Health Care Denials and Delays in Medicare Advantage* (May 17, 2023). OIG has raised similar concerns with respect to Medicaid managed care. OIG, *High Rates of Prior Authorization Denials by Some Plans and Limited State Oversight Raise Concerns About Access to Care in Medicaid Managed Care* (OEI-09-19-00350), July 17, 2023.

[20] 42 CFR § 422.101(c).

[21] *See* 42 CFR §§ 422.122, 422.568(b), 422 572(a).

met.[22] CMS also requires MAOs to establish a utilization management committee and identifies mandates for the committee composition and responsibilities.[23] Consistent with these regulations, CMS has warned that MAOs must ensure that they are making medical necessity determinations based on the circumstances of the specific individual as opposed to solely using an algorithm or software that does not account for an individual's circumstances.[24]

Although the use of algorithms based on artificial intelligence technology is an emerging area with potential benefits, such algorithms may also present potential compliance risks when used in making prior authorization and other coverage decisions. CMS regulations require MAOs to make medical necessity determinations based on the individual patient's circumstances. Accordingly, an algorithm may not be compliant with those regulations if it determines coverage based on a larger data set instead of the individual patient's medical history, the physician's recommendations, or clinical notes.[25]

OIG recommends that MA Parties' compliance programs not only follow CMS's regulations but go beyond them to establish robust safeguards to oversee utilization management practices.[26] Examples of compliance steps include:

- reviewing trends in claims denials and prior authorization denials to ensure that policies: (1) are applied consistently and in accordance with stated standards and (2) do not inappropriately restrict coverage;
- analyzing trends in appeals of denied claims, including the volume of appeals and the percentage of denials that are overturned on appeal;
- identifying a sample of denied claims or denied prior authorization requests for individualized medical necessity reviews and analyzing the results; and
- reviewing the use of any artificial intelligence or other algorithm-based tools to ensure that decisions on claims and prior authorization focus on patients' individualized circumstances, such as their medical history, physicians' recommendations, and medical records.

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[22] 42 CFR § 422.202(b).

[23] 42 CFR § 422.137.

[24] 88 Fed. Reg. at 22,195.

[25] CMS, "Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)," memo to all Medicare Advantage Organizations and Medicare-Medicaid plans (Feb. 6, 2024).

[26] In June 2025, some health insurers made a pledge to take specific steps to address problems with the prior authorization process in Medicare Advantage, the Health Insurance Marketplace, and Medicaid managed care. Participating health insurers pledged to:

- Standardize electronic prior authorization submissions using Fast Healthcare Interoperability Resources (FHIR®)-based application programming interfaces.
- Reduce the volume of medical services subject to prior authorization by January 1, 2026.
- Honor existing authorizations during insurance transitions to ensure continuity of care.
- Enhance transparency and communication around authorization decisions and appeals.
- Expand real-time responses to minimize delays in care with real-time approvals for most requests by 2027.
- Ensure medical professionals review all clinical denials.

B. Marketing and Enrollment

Marketing and enrollment activities are key parts of an MAO's business.[27] Because MAOs commonly delegate significant aspects of their marketing and enrollment activities—to agents, brokers, field marketing organizations, and other third-party marketing organizations (TPMOs)—compliance programs should carefully oversee the tasks delegated and the compensation paid to these third parties. CMS has issued regulations that govern MAO marketing and enrollment activities in an effort to curb abusive practices,[28] and various administrative sanctions could apply to abusive conduct. For example, administrative sanctions could be imposed in situations in which an individual is transferred from one plan to another without prior consent or is transferred solely for the purpose of earning a commission.[29] In addition, the Federal anti-kickback statute could apply to certain marketing activities, as described below.

In 2024, OIG published a Special Fraud Alert that warns about certain marketing schemes involving the Medicare Advantage program. These schemes involve questionable payments and referrals between Medicare Advantage plans, health care professionals, and third-party marketers such as agents and brokers. These schemes can mislead Medicare enrollees into choosing specific health plans or health care providers that may not meet the enrollees' needs.

1. Improper Financial Incentives

MA Parties should avoid marketing and enrollment practices that could harm Medicare-eligible individuals. Improper financial incentives related to marketing and enrollment could skew enrollment in ways that may not be in the best interests of enrollees and potential enrollees. For example, if an MAO offers excessive payments for steering a targeted set of potential

[27] CMS regulates MAOs' marketing and enrollment communications with current and prospective enrollees. 42 CFR Part 422, Subpart V.
[28] 42 CFR § 422.2274.
[29] 42 CFR § 1003.400.

enrollees to that particular MAO's plans, those potential enrollees could miss opportunities to enroll in plans that could be better suited to their individual needs.

Payments for MA marketing and enrollment activities should not create incentives for agents and brokers to enroll individuals in MA plans that may not best meet the individuals' health care needs.

Furthermore, improper financial incentives could subject MA Parties to various legal sanctions. Improper financial incentives relating to marketing could subject MA Parties to administrative sanctions,[30] civil liability under the False Claims Act,[31] or liability under the Federal anti-kickback statute. The Federal anti-kickback statute makes it a criminal offense to, among other things, knowingly and willfully offer or pay for referrals of individuals to a person for the furnishing of any item or service reimbursable under a Federal health care program.[32] One purpose of the Federal anti-kickback statute is to protect individuals from referrals that may be influenced by improper financial incentives.

Many marketing scenarios in the context of the MA program could implicate the Federal anti-kickback statute. Although liability under the Federal anti-kickback statute depends in part on a party's intent, it is incumbent on MAOs to identify arrangements with referral sources and referral recipients that present a potential for fraud and abuse under the Federal anti-kickback statute. The GCPG provides some illustrative questions to consider when attempting to identify problematic arrangements. Those questions—and appropriate follow-up questions—can help MAOs identify, address, and avoid potentially problematic arrangements. Here, MA Parties' compliance programs may focus on arrangements among:

- agents, brokers, and other TPMOs;
- First Tier, Downstream, or Related Entities (FDRs);
- health care providers or their staff members;
- corporations that contract with or employ health care providers;
- management services organizations with which health care providers contract; and
- Federal health care program enrollees.

[30] 42 CFR § 422.752(a)(10); 42 CFR § 1003.400.
[31] 31 U.S.C. §§ 3729–3733.
[32] Section 1128B(b) of the Act, 42 U.S.C. § 1320a-7b(b). The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program. In this ICPG, we use the term "referral" to include the full range of activities that falls within the scope of the Federal anti-kickback statute. In addition, this ICPG uses the term "kickback" to refer to any remuneration prohibited by the Federal anti-kickback statute.

Some examples of marketing and enrollment activities that may present compliance risks include:

- MAO payments to health care providers or their staff members that incentivize or reward them for steering patients to the MAO's plans;
- MAO payments to agents, brokers, and other TPMOs that exceed the permitted compensation amounts set forth in CMS's regulations;
- MAO payments to agents, brokers, and other TPMOs conditioned on meeting enrollment volume targets;
- MAO payments to agents, brokers, and other TPMOs to *not* recommend or *not* offer particular plans offered by specific competitors;
- MAO payments tied to the health status of enrollees, which could cause agents and brokers to steer relatively healthy individuals to particular plans while directing less healthy individuals to other plans; and
- Remuneration given to a potential or current enrollee to choose a particular plan.

A common thread among these compliance risks is that they may impede the ability of patients to find plans that are most appropriate for them.

To address compliance risks relating to marketing and enrollment payments to third parties, MAOs should, among other things:

- ensure that any compensation arrangements do not create incentives to inappropriately influence enrollments;
- develop and monitor systems and policies for initiating arrangements for marketing and enrollment functions, including policies that identify the individuals with authority to initiate an arrangement and that specify the legitimate business need or business rationale required to initiate an arrangement;
- develop systems for documenting all fair market value (FMV) determinations for any arrangement for marketing or enrollment services, including the FMV amount or range and corresponding time periods, the dates of completion of the fair market valuations, the individuals or entities that determined the FMV amount or range, and the names and positions of the individuals who received or were otherwise involved with the FMV determinations;
- develop systems to formalize tracking of arrangements in which there are payments to agents, brokers, other TPMOs, and any other third parties for marketing or enrollment;
- review and monitor payment data and associated work (service and activity logs) performed under any such arrangements to ensure that parties are performing the services required;
- develop and monitor systems to ensure the accuracy of records of payment amounts and recipients;
- conduct periodic audits of marketing-related payments to third parties;
- provide compliance-focused training to agents and brokers as well as to MAO employees who oversee marketing expenditures to third parties; and

- ensure that brokers and other TPMOs verify that their staff and contractors receive compliance-focused training.

2. Deceptive Marketing Practices

MA Parties' compliance programs should ensure that their marketing efforts—including activities performed by third parties—are accurate and not misleading or discriminatory. Fraud and abuse laws, including the False Claims Act,[33] the Federal anti-kickback statute,[34] the exclusions statute,[35] and the Civil Monetary Penalties Law,[36] can apply to MA Parties who engage in marketing activities that improperly mislead or deceive individuals to enroll in MA plans.[37] CMS regulations provide that MAOs may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees.[38] MAOs' inappropriate marketing and enrollment practices also may have the effect of denying, limiting, or conditioning the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan on the basis of any factor that is related to health status.[39] MAOs are responsible for all materials used by their subcontractors to market their plans. MAOs' compliance programs should oversee third parties conducting marketing on behalf of the MAO.

In recent years, OIG has issued several studies focused on risk adjustment:

Billions in Estimated Medicare Advantage Payments From Chart Reviews Raise Concerns, OEI-03-17-00470 (December 2019).

Billions in Estimated Medicare Advantage Payments From Diagnoses Reported Only on Health Risk Assessments Raise Concerns, OEI-03-17-00471 (September 2020).

Some Medicare Advantage Companies Leveraged Chart Reviews and Health Risk Assessments To Disproportionately Drive Payments, OEI-03-17-00474 (September 2021).

Medicare Advantage: Questionable Use of Health Risk Assessments Continues To Drive Up Payments to Plans by Billions, OEI-03-23-00380 (October 2024).

To address risks associated with deceptive marketing practices, MAOs should, among other things:

- establish a consistent process to review and approve marketing and communications materials, including using the latest model marketing materials published by CMS;

[33] 31 U.S.C. §§ 3729–3733.
[34] Section 1128B(b) of the Act, 42 U.S.C. § 1320a-7b(b).
[35] Section 1128 of the Act, 42 U.S.C. § 1320a-7.
[36] Section 1128A of the Act, 42 U.S.C. § 1320a-7a.
[37] Compliance officers also should be aware that other laws could apply to deceptive marketing practices, such as Federal Trade Commission rules and State consumer protection laws. *See also* 18 U.S.C. § 1347 and 42 CFR § 1003.400.
[38] 42 CFR § 422.2262.
[39] 42 CFR § 422.504; *see also* section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. § 18116; 42 CFR § 422.110(a)(7).

- ensure that all marketing messaging clearly states when certain benefits may not be available to all enrollees;
- monitor marketing and enrollment activities by third parties acting on behalf of the MAO, including via periodic attestations and audits;
- track and, as necessary, investigate complaints filed against any agents or brokers acting on behalf of the MAO;
- monitor agent and broker activities to identify potentially problematic outliers, such as rapid disenrollments or enrollments or a high volume of complaints, and appropriately respond to any identified outliers or trends; and
- monitor the volume of enrollments outside of the annual enrollment period and verify enrollees' eligibility for enrollment during any special enrollment period.

C. Risk Adjustment

CMS relies on risk adjustment methodologies to make appropriate and accurate payments to MAOs to arrange for care for Medicare enrollees with expected differences in health care costs. CMS typically pays MAOs a capitated, per member per month (PMPM) rate for each person who enrolls in an MA plan. These capitated payments are based, in part, on enrollees' health status from the prior year. For each person enrolled, CMS calculates a risk score derived, in part, from diagnoses the MA plans submit to CMS.[40] Sicker patients generally receive higher risk scores, and higher risk scores result in higher PMPM payments to the MA plans. This risk adjustment process is designed to align PMPM payments with the MA plans' expected costs and to help ensure that MA plans do not have an incentive to target healthy enrollees or avoid sicker enrollees. However, the risk adjustment process is vulnerable to fraud and abuse. Strong compliance measures may help.

Through focused oversight, OIG and others have identified a range of abusive practices involving MA risk adjustment.[41] OIG audit and evaluation reports have focused on the diagnosis codes that MAOs submit to CMS in support of enrollees' risk adjustment scores,[42] examining instances of potentially problematic conduct. For example, OIG has examined MAOs reporting diagnoses based solely on chart reviews or health risk assessments (HRAs) and providing no other records in the encounter data that

[40] The diagnoses that MAOs submit to CMS must, among other things, be supported by documentation in the beneficiaries' medical records. *Medicare Managed Care Manual*, ch. 7, § 40.

[41] For example, the Government Accountability Office (GAO) has raised concerns that diagnoses collected from MAOs' chart reviews may be less likely to be supported by medical records than diagnoses submitted to MAOs by providers. GAO, *Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments*, April 2016. In addition, CMS and the Medicare Payment Advisory Commission (MedPAC) have questioned whether MAOs use health risk assessments primarily as a strategy to submit more diagnoses to increase payments rather than to improve the care provided to their beneficiaries. Since 2016, MedPAC has recommended that HHS eliminate health risk assessments as a source of diagnoses for risk adjustment payments. MedPAC, *Report to the Congress: Medicare Payment Policy*, March 2016.

[42] OIG, "All Reports and Publications."

enrollees received services for the diagnoses.[43] OIG concluded that the MA Parties may be leveraging chart reviews and in-home HRAs to maximize risk adjustment payments. OIG's work raises concerns about the appropriateness of risk-adjusted payments generated solely by diagnoses from HRAs and chart reviews, the quality of care for enrollees, and the completeness of encounter data. OIG has also audited specific diagnosis codes, which are at a high risk for being miscoded, that MAOs submitted to CMS. OIG reviewed medical records that MAOs provided as support; however, a high percentage of the associated HCCs could not be validated. Thus, OIG has seen indications that MAOs are submitting diagnosis codes for payment that are not verifiable.

Federal investigations have revealed potentially fraudulent and abusive conduct by MAOs, providers, and others involved in the risk adjustment process, such as:

- using chart reviews to identify additional diagnoses that increased risk scores inappropriately;
- failing to remove diagnosis codes previously submitted to CMS when chart reviews provide information that those codes were unsupported or otherwise invalid;
- conducting in-home HRAs to generate additional diagnoses that were not considered in the care, treatment, or management of the enrollees or that were otherwise unsupported;
- querying physicians via electronic medical record platforms (including prompts generated by artificial intelligence algorithms) or otherwise prompting physicians to add risk-adjusting diagnoses that patients did not have or that did not affect the care, treatment, or management of the patient; and
- providers submitting diagnoses that were not supported by the enrollees' medical records to inflate the payments MAOs made to the providers under risk-sharing or other arrangements.

CMS regulations require MAOs to adopt and implement effective compliance programs, which must include measures that prevent, detect, and correct noncompliance with CMS's program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse.[44] With respect to risk adjustment, CMS requires MAOs to:

- have procedures to monitor and evaluate the accuracy of the risk adjustment data they submit to CMS;
- ensure that diagnosis codes submitted are documented in the medical record as the result of a face-to-face visit and coded according to *International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting* and the *AHA Coding Clinic for ICD-10-CM and ICD-10-PCS* quarterly newsletters;
- ensure that diagnoses are from acceptable data sources (e.g., hospital inpatient facilities and physicians);

[43] *See* OIG, Some Medicare Advantage Companies Leveraged Chart Reviews and Health Risk Assessments To Disproportionately Drive Payments, OEI-03-17-00474 (September 2021).
[44] 42 CFR § 422.503(b)(4)(vi).

- promptly respond to any detected problems, including any related to risk adjustment data (e.g., by expanding the scope of the audit or review, educating a provider, or submitting data to CMS for payment adjustments); and
- certify that the risk adjustment data[45] they submit to CMS are accurate, complete, and truthful to their best information, knowledge, and belief after having taken steps to help ensure the accuracy, completeness, and truthfulness of such data.

OIG has published a toolkit that MAOs and their contractors may use to analyze high-risk diagnosis codes.

MAOs should implement additional oversight of the risk adjustment process, including audits of diagnoses data, both before and after submission of risk adjustment data to CMS. Relatedly, MAOs should scrutinize reporting of particularly high-risk diagnosis codes (i.e., those at greater risk of being miscoded).

Additional oversight steps may include:

- pairing processes designed to ensure complete diagnosis data via reporting of additional diagnoses (e.g., through chart reviews or HRAs) with processes to ensure data accuracy and appropriate care; such pairing could increase quality of care and organizational efficiencies and simultaneously decrease the risk of submission of unsupported diagnoses codes;
- evaluating and overseeing any in-home HRA programs or chart review programs that result in submission of risk-adjusting diagnoses;
- educating employees and, as appropriate, first tier, downstream, or related entities (FDRs),[46] on the appropriate use of queries and other prompts and overseeing their use;
- educating providers, including employed and contracted providers, on proper coding;
- education and training of coders and others employed or engaged by the MAO on proper coding;
- reviewing any software or systems used including those created by vendors for plan use and also those used by providers;
- implementing data filtering logic[47] to identify anomalies, outliers, or other potentially inaccurate diagnosis data;
- analyzing provider reporting of diagnoses using algorithms (including, potentially, artificial intelligence platforms) to identify outliers and anomalies, such as providers coding at higher rates

[45] These data are not limited to diagnosis codes but include, for instance, the provider type. CMS sets forth details of its data requirements for risk adjustment submissions in its *Medicare Managed Care Manual*, ch. 7.

[46] 42 CFR § 422.2 (defining FDRs). See also "What is an FDR?" below.

[47] Filtering logic in this context typically means using a set of procedure codes to help determine whether a particular encounter data record should be used as an acceptable source for risk adjustment. MAOs may establish a set of clinical rules to identify which codes appear to be appropriate and which codes may need additional review to determine their appropriateness before they are submitted to CMS.

than similar providers, and conducting follow-up audits, education, and appropriate corrective action, including submitting data to CMS for payment adjustments;

- benchmarking risk scores and Hierarchical Condition Category prevalence rates (i.e., the frequency and prevalence of particular reported codes) to compare changes in prevalence rates over time (e.g., across years) and identify potential outliers, then conducting reviews of medical documentation focused on the outliers based on the benchmarking and rate results;
- analyzing providers' coding intensity, focusing particularly on changes or outliers with respect to specific codes or other trends;
- developing systems to monitor FDR compliance regarding risk adjustment data development and submission, considering enhanced systems when providers and vendors receive financial incentives tied to risk adjustment data (e.g., risk-sharing arrangements or bonuses for diagnosis capture), which systems may include requiring provisions in contracts to ensure that the entities conduct self-audits and regularly report results to the MAO;
- investigating allegations, through compliance hotline reporting or otherwise, of provider or contractor fraud regarding risk adjustment coding; and
- ensuring that fraud, waste, and abuse reporting methods such as internal and external hotlines are designed to document any risk adjustment issues and report identified issues to the appropriate parties.

MA Parties should take appropriate corrective actions (including provider contract termination) based on results of investigations or reviews of providers or contractors. MAOs and other MA Parties must also report to CMS: (1) unsupported and otherwise invalid diagnosis codes through the systems designated by the agency; and (2) overpayments in accordance with Medicare overpayment law (42 U.S.C. § 1320a-7k) and CMS's Part C and D overpayment rule at 42 CFR §§ 422.326 and 423.360.[48]

Given the importance of risk adjustment within the MA program, MAOs' compliance programs should consider oversight to be a broad and collaborative effort among various departments within the MAO. Depending on the structure of the MAO, the compliance officer may consider collaborating with other departments, such as the special investigations unit, legal, clinical services, and provider risk assessment/auditing. Collaboration may include establishment of committees such as a Medicare Compliance Committee chaired by the compliance officer with a membership including executive members from the various departments. When providing oversight of third parties, risk adjustment should be a top priority.

[48] Jennifer R. Shapiro, Director, Medicare Plan Payment Group, "Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data," memo to All Medicare Advantage Organizations, PACE Organizations, Medicare-Medicaid Plans, Section 1876 Cost Contractors, and Demonstrations (Apr. 15, 2022).

D. Quality of Care

Providing high quality care to enrollees is a key component of the MA program as reflected by CMS's development of the quality bonus payment program, efforts to ensure enrollee access to care, and oversight of providers. MA Parties' compliance programs should prioritize quality-of-care oversight. Under the MA program reimbursement is tied to quality of care.[49] More specifically, CMS makes quality bonus payments ("QBPs") to MAOs that achieve at least 4 stars in a 5-star quality rating system. To that end, MAOs need to provide CMS with data that permits the measurement of health outcomes and other indices of quality, and MA organizations must ensure their submitted data is unbiased, accurate, and complete.[50]

Potential enrollees use information about quality assessments (including "Star Ratings") along with benefits and cost information to compare MA plans and make the best decisions for themselves. MA Parties' compliance programs should ensure that the MA Parties provide accurate information about Star Ratings, benefits, and costs. The compliance programs also should ensure that MA Parties meet other metrics related to quality, such as the health outcomes survey or accreditation scorecards. Ensuring the integrity of the data used for Star Ratings' quality and performance measures is a key component for MA Parties' quality-of-care compliance oversight.

To ensure that they are collecting and submitting accurate quality data, MAOs' compliance programs should develop procedures to regularly review the integrity of the data (e.g., complaints and systems used for quality assessment).

MA regulations address MA plans' quality of care in a variety of ways. CMS program rules cover provider network adequacy and utilization review tools, among other things. CMS's regulations put the responsibility on MA plans to ensure that their enrollees receive high-quality care. To do this, MA plans should make certain that: (1) their provider networks are adequate (see the provider network section above for more detail); (2) they collect, evaluate, and send to CMS accurate quality data; and (3) individuals receive care that is appropriate for their reported medical conditions. Relatedly, MAOs must ensure that Medicare enrollees can access medically necessary care irrespective of their location, identity, and other demographic factors.[51] MAO compliance programs should prioritize these responsibilities. CMS also directly assesses an MA plan's quality of care based on specific measures that CMS updates regularly.[52] Each measure falls under one of various domains that include health

[49] Section 1853(o) of the Act, 42 U.S.C. § 1395w-23(o).
[50] Section 1852(e) of the Act, 42 U.S.C. § 1395w-22(e); 42 CFR § 422.162(c).
[51] 42 CFR § 422.112(a)(8).
[52] Section 1852 of the Act, 42 U.S.C. § 1395w-22; 42 CFR § 422.152 et seq.

maintenance, chronic disease management, member experience, member complaints, and customer service.

MAOs also can help to improve quality of care by monitoring their contracted providers, including ensuring that MA payments are made only to eligible providers. CMS prohibits MAOs from paying for a health care item or service furnished by an individual or entity on the CMS Preclusion List.[53] CMS also requires MAOs to credential physicians and other health care professionals, and MA organizations may, as a condition of contracting, further enhance provider vetting by requiring providers to be enrolled in Medicare.[54] Additionally, institutional providers and suppliers must be enrolled in Medicare to be paid under the MA program.

As an additional step to potentially help bolster quality, MAOs may consider whether to require some or all network providers to be enrolled in Medicare.

Along with those requirements, **MAOs should implement processes to ensure that their networks avoid providers who are excluded by OIG or who have licenses suspended by a State licensing body or who were the subject of a disciplinary action that would limit the provider's ability to practice or bill Federal health care programs.**

E. Oversight of Third Parties

MAOs routinely delegate an expanding scope of services to third parties. Indeed, relationships between MAOs and third parties—including providers, marketers, and a wide range of vendors—are essential to the functioning of the MA program. MAOs also can gain efficiency and economies of scale by relying on third parties. But in outsourcing various functions, MAOs can find it challenging to maintain a consistent and effective level of control and oversight. Delegating duties to third parties presents a unique set of compliance challenges to MAOs and to the entities to which they delegate those duties.

[53] 42 CFR § 422.222.
[54] 42 CFR § 422.204.

CMS regulations and guidance recognize that MAOs delegate a range of tasks to different types of third parties. Much of the focus of CMS's regulatory oversight in this space focuses on the relationship between MAOs and entities that CMS defines as "First Tier, Downstream, or Related Entities" (known as FDRs).[55] For example, CMS guidance specifies what types of compliance functions—such as compliance program administrative functions (e.g., compliance officer, compliance committee)—may not be delegated to FDRs and what types of compliance functions—such as monitoring, auditing, and training—MAOs may outsource to FDRs.[56] CMS regulations also require MAOs to conduct auditing and monitoring of FDRs.[57] CMS regulations emphasize that MAOs maintain the ultimate responsibility for fulfilling the obligations of their contracts with CMS and meeting Medicare program requirements, even if certain functions are delegated to third parties.[58] Medicare program requirements also explicitly apply to FDRs to whom an MAO has delegated administrative or health care service functions. As a result, if an FDR fails to comply with program requirements, CMS can hold the MAO responsible.[59]

What is an FDR? An FDR is a **F**irst Tier, **D**ownstream, or **R**elated Entity. A first tier entity is any party that enters into a written arrangement, acceptable to CMS, with an MAO to provide administrative services or health care services to a Medicare-eligible individual under the MA program. A downstream entity is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MAO and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. A related entity means any entity that is related to an MAO by common ownership or control and that: (1) performs some of the MAO's management functions under contract or delegation, (2) furnishes services to Medicare enrollees under an oral or written agreement, or (3) leases real property or sells materials to the MAO at a cost of more than $2,500 during a contract period.

MAOs and third parties may need to determine whether a party meets the definition of an FDR to determine the appropriate level of oversight and to help third parties to fully understand their obligations. The term FDR comprises three broad categories of entities, which are defined in CMS regulations.[60]

CMS guidance offers a list of factors to consider when determining whether an entity is an FDR.[61]

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[55] *Medicare Managed Care Manual*, ch. 21, § 20.
[56] *Medicare Managed Care Manual*, ch. 21, § 40.
[57] 42 CFR § 422.503(b)(4)(vi)(F).
[58] 42 CFR § 422.504(i)(1).
[59] CMS also reviews FDR relationships as part of its program audits. 42 CFR § 422.504(i)(2).
[60] 42 CFR § 422.2.
[61] *Medicare Managed Care Manual*, ch. 21, § 40.

Tip **MAOs should adopt and consistently apply a clear policy that includes specific criteria for determining whether to categorize an entity as an FDR based on CMS's definition.**

Regardless of whether a third party meets the definition of an FDR, MAOs and other MA Parties should consider the roles of third parties when assessing potential compliance risks arising from those relationships and calibrate an appropriate compliance strategy. Fraud and abuse risks associated with MAO interactions with third parties are not limited to interactions with FDRs, because liability under fraud and abuse laws does not turn on any entity's status as an FDR (as defined by CMS). More specifically, when delegating MA-related functions to third parties, MAOs may be liable for the actions of those third parties beyond MAOs' accountability to CMS for delegated functions. Third parties themselves also could be vulnerable to liability under certain fraud and abuse laws for their own conduct or for the actions of downstream entities.

Some factors MA Parties should consider when developing a compliance strategy in connection with third parties include: (1) the types of tasks an MAO has delegated to the third party, (2) compliance risks associated with those tasks, (3) the third party's sophistication and preexisting compliance infrastructure, and (4) current Government enforcement and oversight trends.

1. Selecting Third Parties

MAOs should be thoughtful about the third parties they select as business partners. Many MAOs maintain a pre-delegation process to conduct due diligence before entering into any delegation arrangements. The formality of this process may vary by the size of the MAO and the third party; however, it is valuable to have a defined and consistent approach to initiating formal relationships with third parties in order to minimize compliance risks. In addition, MAOs should check OIG's LEIE and CMS's Preclusion List before contracting with any third parties and should periodically check the LEIE to determine the exclusion status of current contractors.

In particular, MAOs should conduct basic due diligence on third parties before delegating any Medicare program functions. This process should include an initial risk evaluation to determine the level of compliance or fraud and abuse risk presented by working with a particular third party. Factors in determining the level of risk should include:

- the scope of functions delegated, including the proximity to core MA functions and whether the delegated duties would involve higher risk or sensitive tasks, such as direct interaction with Medicare enrollees, marketing, or other functions that overlap with fraud, waste, and abuse risk areas;

- whether a third party is likely to be considered an FDR (and therefore whether the delegation arrangement would be subject to additional CMS regulation);
- the third party's prior experience working with MAOs or other health care entities;
- whether a third party's prior experience gives the third party an appreciation of the risks and obligations of assuming delegations from an MAO;
- the level of sophistication of the third party's compliance program;
- the third party's relative level of information technology or data expertise and its ability to perform timely reporting as necessary; and
- whether the third party is enrolled in Medicare.

2. Crafting Compliance-Focused Agreements

MAOs can enhance their compliance oversight by explicitly securing certain compliance-related rights and obligations with FDRs.[62] For example, MAOs' contracts with FDRs may require certain attestations, which typically are formal statements signed by an authorized representative of the third party describing the third party's organization, business practices, and other key compliance-related information. Common attestations address the structure and operation of the third party's compliance program, requirements to conduct regular screenings of employees and downstream entities via OIG's LEIE, obligations to report potential violations, auditing and monitoring rights, and other provisions. Attestations should be tailored as necessary, such as special attestations for offshore subcontractors or for emerging legal requirements.

MAOs can implement other measures to improve oversight of FDRs, such as requiring FDRs to:

- report data to MAOs in a certain format and at defined intervals to facilitate oversight activities;
- conduct self-audits with associated obligations to report results of those audits to the MAO;
- adopt standardized credentialing functions with associated reporting to the MAOs; and
- conduct onboarding education for new FDR staff.

[62] State law may determine the enforceability of certain contractual terms; accordingly, compliance programs should take into account the impact of State law on the enforceability—and therefore, the effectiveness—of securing compliance-related rights and obligations with third parties by contract.

3. Ongoing Oversight of Third Parties and Corrective Action

Before and after delegation arrangements are underway, MAOs should ensure that third parties understand the applicable legal and compliance requirements and risks and how to mitigate those risks. MAOs should consider providing their FDRs with practical compliance resources. Some third parties, especially startups and smaller contractors that have not previously worked in the health care space, may lack an understanding of the compliance risks inherent in doing business with MAOs. Attestations may be a way to help mitigate risk, but they should be accompanied by additional compliance-related steps.

Possible steps MAOs could take to provide compliance education and resources to third parties include:

- developing manuals, guides, and toolkits for FDRs;
- reviewing or providing compliance training requirements and resources; and[63]
- developing and maintaining a centralized source and process for distributing to FDRs information on health care statutes and regulations and other program directives related to fraud, waste, and abuse.

Tip

Some MAOs have published compliance manuals on their public-facing websites. These manuals can be helpful resources for FDRs to understand compliance obligations and to find other useful materials and tools.

MAOs should calibrate the level and depth of ongoing oversight of third parties based on a risk evaluation of the third party and the relationship, similar to the pre-delegation risk evaluation described above. Higher-risk relationships with third parties merit a higher level of oversight. Risk evaluations vary based on a wide range of factors, including whether the party provides direct services to enrollees, past performance, complaint logs, changes to regulatory requirements, and business leader input. Thus, OIG cannot recommend a one-size-fits-all approach. The following are examples of possible oversight steps MAOs may consider implementing on an ongoing basis:

- requiring a periodic renewal of attestations;
- requiring reporting from FDRs in various formats, such as scorecards, dashboards, issue logs, and joint meeting agendas to allow two-way communication between the MAO and the third party;
- regularly auditing and monitoring third parties' core activities;

[63] CMS has developed and provided a standardized fraud, waste, and abuse training module to assist with compliance training.

- regularly auditing and monitoring third parties' compliance programs' structure and function;
- regularly auditing to ensure that the FDRs are identifying compliance concerns and implementing corrective actions as appropriate; and
- developing policies to implement corrective actions with respect to noncompliance by FDRs (to include termination of the relationship).

Some MAOs also maintain dedicated vendor oversight committees that direct compliance activities focused on third parties, including conducting initial risk evaluations, developing audit and monitoring plans, overseeing corrective actions, and other tasks.

When requesting attestations (and attestation renewals) from third parties, include information designed to foster an understanding of the attestations, such as contextual details and explanations about how to interpret the attestations and their relationship to contractual obligations. Such details and explanations are more helpful to third parties if they are in a practical and common-sense format rather than in dense legalese or citations to regulations.

4. Special Considerations for Providers

MAOs should consider tailored compliance processes with respect to FDRs that are health care providers. For example, if an MAO has delegated functions to a provider (such as to a first tier entity like an independent practice association), the MAO may establish a compliance or oversight team dedicated to monitoring and overseeing the provider and requiring reports. That oversight could include, for example, network adequacy, quality data and analytics, coding audits, and utilization management case logs. Separately, MAOs may have expanded or particular compliance obligations if the MAOs own or are under common ownership with the provider groups.

Internal investigations including by MAOs' Special Investigation Units (SIUs), referrals to law enforcement partners, and collaboration with Government officials are key to ensuring that providers are held accountable for MA-related fraud. Participation in joint data and information sharing efforts, such as the Healthcare Fraud Prevention Partnership, can assist in combating fraud across the program and within individual MAOs. Such oversight and collaboration efforts are essential components of effective MAO compliance programs.

F. Compliance Programs Within Vertically Integrated Organizations and Other Ownership Structures

As the MA program has grown, MA Parties have entered into increasingly large and complex partnerships and arrangements, including vertically integrated organizations. Provider and insurer lines of business increasingly have common ownership.[64] Some MAOs own health care providers and health systems, and, conversely, some health systems own MAOs. Vertical integration and consolidation in the MA subsector also include common ownership by MAOs and other related entities, such as data analytics firms or utilization review entities.

Integrated entities present unique compliance challenges. The compliance infrastructure of an MA-related business should have the appropriate expertise to oversee those functions, which may present different compliance risks than the larger organization's operations. For example, if a health system acquired an MAO, the health system's existing compliance program likely would not have the infrastructure or expertise to oversee MAO-related compliance. In such a case, the parent organization should implement strategies to ensure that compliance leaders at the subsidiary MAO have sufficient expertise, are fully empowered, and have access to senior leaders in the parent organization. In any organization with MA functions, organization-wide compliance risk assessments, audit plans, and other compliance planning should consider risks arising from MA-related functions, even if those represent a small part of the larger organization.

Some programmatic safeguards, such as the medical loss ratio requirements, may trigger unique risks when the MAOs and providers share common ownership or are otherwise related entities. In such situations, MAOs should take additional compliance steps to ensure that robust systems and policies are in place to accurately categorize and track data needed to calculate and verify the medical loss ratio and remittance amount, if any.

MAOs and other MA Parties also may be part of various business models, including ownership by private equity funds or other investors. Investors lacking experience in health care may be unfamiliar with fraud, waste, and abuse risks and the need for a vigorous compliance program, and the GCPG could be a good starting point to guide an effective compliance program. Ensuring robust training and, as necessary, communication with both leadership and staff may help mitigate compliance risks posed by investors new to the health care industry or specifically the MA industry.

[64] *See* MedPAC, *Report to the Congress: Medicare Payment Policy*, March 2024, pp. 394–397.

G. Submission of Accurate Claims

As a condition of receiving payment, MAOs must submit certifications that the data submitted to CMS are accurate.[65] Failure to submit accurate payment data may result in administrative actions or, if fraud is involved, civil liability.

The False Claims Act is a civil statute that imposes liability on an individual or entity who knowingly submits or causes to be submitted false or fraudulent claims for payment to the Government. There are several ways that MA Parties can have exposure under the False Claims Act, many of which overlap with the substantive risk areas identified in this ICPG. MA Parties have settled cases involving various allegations of false claims stemming from MA Parties' submitting or causing submission of inaccurate information or failing to correct inaccurate information submitted to the Government.

The GCPG provides a detailed overview of the civil False Claims Act.

This alleged conduct has taken various forms, including:

- participating, either as an MAO, provider, or vendor, in a scheme to submit false and fraudulent information (e.g., diagnoses for ailments that patients did not actually have) to CMS to increase the amount of reimbursement received from the Medicare program for MA enrollees;
- knowingly submitting and failing to withdraw inaccurate and untruthful diagnosis codes for MA enrollees to increase reimbursements from Medicare; and
- submitting unsupported diagnosis codes for certain patient encounters, such as visits to an individual's home for completion of health risk assessment forms.

[65] 42 CFR § 422.504(l).

SECTION III
Compliance Program Structure and Activities

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III. Compliance Program Structure and Activities

MAOs are required to adopt and implement compliance programs that include measures that prevent, detect, and correct noncompliance with CMS's program requirements, as well as measures to prevent, detect, and correct fraud, waste, and abuse. In its regulations, CMS identifies its expectations for core elements of the compliance programs, and its *Medicare Managed Care Manual* provides additional compliance program guidelines.

CMS regularly performs audits of MAOs to assess compliance with certain key requirements of their contracts with CMS. The program audits focus on certain program areas, including Compliance Program Effectiveness, and the Medicare requirements associated with access to medical services, drugs, and other enrollee protections.[66] CMS also more recently began performing program integrity audits of MAOs, focusing on fraud, waste, and abuse. The results of these audits can be useful tools for MAOs' compliance efforts.

The Medicare Advantage ICPG and the GCPG (which provide voluntary, nonbinding guidance) complement the regulatory requirements CMS imposes on MAOs. CMS's regulations provide the minimum requirements for compliance program structure and operation. The Medicare Advantage ICPG and the GCPG recommendations could help facilitate MA Parties' compliance with CMS's requirements as well as with other statutory and regulatory obligations.

The GCPG provides a discussion of the following seven elements of an effective compliance program that are applicable to the broad spectrum of organizations and entities involved in health care delivery: (1) Written Policies and Procedures; (2) Compliance Leadership and Oversight; (3) Training and Education; (4) Effective Lines of Communication with the Compliance Officer and Disclosure Programs; (5) Enforcing Standards: Consequences and Incentives; (6) Risk Assessment, Auditing, and Monitoring; and (7) Responding to Detected Offenses and Developing Corrective Action Initiatives.

Across the discussion of risk areas in this Medicare Advantage ICPG, some sections include recommendations that MA Parties should consider when implementing those seven elements of a compliance program (and these sections may reference some, but not all, of those elements). Other sections do not include specific recommendations. Because the risk areas and recommendations in the

[66] CMS publishes the audit protocols online, which include Compliance Program Effectiveness protocols.

Medicare Advantage ICPG are not exhaustive and are not specific to any particular entity, MA Parties should closely review it and the GCPG in light of their own organizations' risk profiles as they work to implement, evaluate, and update compliance program operations.

For ease of reference, OIG also has created the following chart, which provides specific compliance practices that MA Parties could consider when structuring an effective compliance program and complements the guidance provided elsewhere in this Medicare Advantage ICPG and in the GCPG.

	Medicare Advantage-Specific Considerations— Compliance Program Elements and Recommendations
Written Policies and Procedures	MA Parties should consider implementing policies and procedures that provide guidance for issues specific to the MA program. The following are examples: • A policy to assist with administering health benefits and avoiding improper denials of coverage. This policy could, for example, require the compliance department to direct the review and documentation of trends in denied claims for payment or for outcomes of prior authorization and to outline a procedure for making necessary and timely changes based on the results. • A reimbursement policy to ensure that data MAOs submit to CMS for reimbursement are accurate, complete, and truthful. • A network adequacy policy requiring MAOs to routinely review provider network information to ensure that it remains current and accurate. • A procedure for tracking marketing and enrollment payments to agents, brokers, and other TPMOs, along with a policy requiring routine training of delegated entities conducting marketing on behalf of the MAO. The policy should ensure that delegated entities adhere to CMS regulations and avoid abusive marketing and enrollment activities. • Policies and procedures setting forth standards for oversight of third parties, including FDRs, and articulating the MAO's processes for pre-contracting review, ongoing monitoring and auditing, and corrective action. Because legal requirements involving the MA program may change over time, it is imperative that all policies and procedures be reviewed and updated regularly to incorporate changes in applicable laws, regulations, and program requirements. MAOs should understand that this might require a more frequent review and refresh of policies and procedures than in non-managed care focused compliance programs.

	Policies and procedures should be distributed to FDRs so that FDRs have a clear understanding of the MAOs' compliance expectations. MAOs should have a procedure for ensuring that policies and procedures are distributed and reviewed. For example, MAOs could require FDRs to complete attestations that employees have been trained to understand compliance requirements.
Compliance Leadership and Oversight	MA Parties should appoint a compliance officer with sufficient compliance experience to oversee the day-to-day operations of the compliance program. The compliance officer position should have direct access to the entity's board of directors, not report to the general counsel, be full-time and—for MAOs (per CMS regulations)—cannot be delegated to an FDR. The compliance officer should be responsible for defining compliance expectations of all personnel and FDRs. MA Parties should consider the unique compliance challenges outlined above when determining leadership and oversight positions. Because of compliance issues that are unique to the MA program, an MA Party with multiple lines of business should consider having a compliance officer dedicated solely to its MA business. The compliance officer responsible for the MA business should have the experience and expertise to effectively oversee compliance with applicable laws related to the MA program and, among other things, may: • ensure departments charged with MA operations are compliant with CMS regulations and programmatic requirements; • chair the Medicare compliance committee, if the entity has one; • report fraud, waste, and abuse to the Medicare Drug Integrity Contractor (MEDIC) and others as appropriate; • serve as liaison to the regional CMS contact; and • conduct oversight activities of FDRs, including any investigation and auditing/monitoring; responding to any potential FDR fraud, waste, and abuse issues; and any other FDR compliance oversight activities. To keep current on CMS requirements and compliance, audit, and enforcement information, MA Parties may consider having an employee or committee dedicated to routine monitoring of various information sources (e.g., CMS's Health Plan Management System memoranda). The employee or committee can be responsible for distributing guidance within the organization and for

	tracking, managing, and implementing any new or revised guidance. It is important that such changes are also disseminated to FDRs.
Role of the Compliance Committee and Governing Body	The GCPG provides a discussion of the general purpose and duties of the compliance committee and governing body. MA Parties should ensure that their compliance committees consist of leadership with expertise in MA program issues who understand the relevant risks and vulnerabilities. Depending on the size and structure of the company, members should include senior executives of relevant departments, such as billing, clinical services, human resources, audit, and operations. Governing bodies for MA Parties should consist of independent, nonexecutive members. Compliance committees should assist the compliance officer in the analysis of risk areas and should oversee monitoring of internal and external audits and investigations. The compliance officer and compliance committee should periodically report directly to the MA Party's governing body on the activities and status of the compliance program. The committee should meet regularly to enable reasonable oversight of the compliance program and develop strategies to promote compliance and the detection of potential violations. The GCPG provides a discussion of board responsibilities and refers to the Practical Guidance for Health Care Governing Boards on Compliance Oversight. MA Parties should follow these guidelines and understand the heightened obligation to prioritize audits, assessments, and other types of compliance-related inputs that are particular to the MA program. The compliance department should have open and transparent communications and a means for reporting FDR-related compliance issues to the compliance committee and governing body. Internal audit findings and matters self-reported by FDRs, for example, should be reported and addressed so that all parties understand the underlying cause of the issue, the potential impact of the compliance deficiency, and methods for remediation.
Training and Education	MA Parties should follow the recommendations in the GCPG related to compliance program training and education. MA Parties also should implement general compliance training and fraud, waste, and abuse training to comply with the requirements in CMS's regulations.[67] For example, the compliance

[67] 42 CFR § 422.503(b)(vi)(C).

	department should require specialized training to marketing employees on the risks associated with marketing, enrollment, and the Federal anti-kickback statute. This could include a more detailed review of the MA-specific policies and procedures implemented by the compliance department. MAOs may also provide specialized training for key departments that have frequent contact with enrollees, such as customer service, claims, and clinical services. With respect to third-party relationships, MAOs should identify opportunities to directly train their FDRs rather than relying on FDRs to train themselves. Ultimately, it is the responsibility of the MAO to ensure through written arrangements that all applicable laws, regulations, and program requirements are followed by contractors, subcontractors, and related entities.[68]
Effective Lines of Communication	MA Parties should follow the recommendations in the GCPG regarding open and effective lines of communication. Because MA Parties have relationships, partnerships, and arrangements with numerous entities, it is critical that MA-focused compliance programs have access to top leaders in the parent organization. MA Parties should train employees on how to report suspected or detected noncompliance and other concerns. A hotline or other system for reporting is essential to ensure that employees, enrollees, and other personnel can report concerns and potential violations of compliance policies or MA program requirements. Reporting mechanisms and direct lines of communication should also extend from MAOs to providers and FDRs, who should be protected from retaliation or retribution when making good faith reports of concerns. MA Parties should consider reporting mechanisms that allow for confidential and anonymous reporting of compliance and fraud, waste, and abuse concerns and ensure that such reports are appropriately conveyed to MAOs or others as needed.
Auditing and Monitoring	MA Parties should develop and implement an effective system for routine monitoring and identification of compliance risks, including internal and external monitoring and audits to evaluate compliance with applicable laws, regulations,

[68] CMS has developed and provided a standardized fraud, waste, and abuse training and education module available through the CMS Medicare Learning Network that meets CMS's fraud, waste, and abuse training requirements.

and program requirements. This includes FDRs' compliance with applicable requirements.

MA Parties should keep abreast of OIG audit and evaluation findings, particularly for high-risk areas, and consider incorporating that information into their internal controls.

To monitor for risk, MA Parties should tailor their methods to specific MA program risk areas. For example, in connection with quality of care, MA Parties should review service areas and collect information such as the number of primary care physicians available in the service area, the number of specialists available in the service area, and whether MA payments are being made only to eligible providers. MA Parties should maintain this information and use it to generate statistical data and analysis that can inform MA Parties on how to address any barriers to access or quality of care. MA Parties' auditing and monitoring should focus on the risk areas identified in section 2 of this ICPG.

MA Parties should pay particular attention to data and information that affect payments by Medicare. It is important for MAOs to monitor and audit claims submitted by providers to ensure that the MAO submits accurate data to CMS. In addition, MAOs should identify rendering, referring, and billing providers' National Provider Identifiers for such claims to monitor for fraud, waste, and abuse. When such monitoring and auditing result in the identification of an overpayment, MAOs are obligated to report and return the overpayment.[69] MAOs should pay close attention to the guidance in the Risk Adjustment section of this ICPG and provide significant oversight over the risk adjustment process.

Special Investigation Units (SIUs) are composed of individuals tasked with detecting, investigating, and potentially reporting and resolving claims of fraud, waste, or abuse. SIUs can, independently from the compliance department, conduct surveillance, interviews, and other methods of investigation to detect potential fraud, waste, and abuse. Similar to compliance program reporting, SIUs should be accessible, and there should be a process in place for anonymous reporting to the SIU. If the compliance department or the SIU identifies potential fraud or misconduct related to the MA program, including provider fraud, OIG recommends reporting the conduct to the MEDIC or, where

[69] Section 1128J(d) of the Act, 42 U.S.C. § 1320a-7k(d); 42 CFR § 422.326.

	appropriate in situations such as when the MAO and provider share risks or common ownership, through OIG's Health Care Fraud Self-Disclosure Protocol. MAOs are responsible for auditing and monitoring FDRs to ensure that FDRs comply with applicable laws, regulations, and program requirements. MAOs should consider routine review of key performance metrics and audits of FDRs and require additional or more frequent audits based on results of compliance risk assessments. MAOs should consider using risk assessment results to develop a work plan detailing monitoring and auditing oversight activities. Results and reports of internal monitoring and auditing activities should be shared within the compliance department, to relevant organization personnel, and to appropriate business stakeholders. When FDRs perform their own audits, MAOs should receive, at a minimum, a summary of the audit work plan and audit results relating to the services performed by the FDR.
Well-Publicized Disciplinary Guidelines	MA Parties must enforce standards through well-publicized disciplinary guidelines and procedures that encourage and incentivize good faith participation in the compliance program. Best practices include identifying disciplinary standards in both onboarding and annual trainings, as well as in any employee handbooks and on intranet sites. Methods for reporting compliance or fraud, waste, and abuse concerns can be publicized through the use of posters, table tents, mouse pads, computer lock screens or other electronic means, and other prominent displays throughout MA Parties' physical and online infrastructure (e.g., intranet sites).
Corrective Action	MA Parties must use effective measures to respond promptly to noncompliance and undertake appropriate corrective action. MA Parties should follow the recommendations in the GCPG regarding implementing corrective action initiatives. The compliance officer, with assistance from the compliance committee, should be responsible for the oversight and performance of internal investigations; incident and violation reporting under applicable laws, regulations, and program requirements; and development and implementation of corrective action plans. It is also important to ensure that FDRs identify and correct deficiencies. MAOs should track, measure, and document the effectiveness of their compliance program. When violations occur, compliance departments should

	consider collaborating with the impacted business areas to perform a root cause analysis and to ensure timely and appropriate corrective action. For example, if fraud, waste, or abuse has occurred, remediation could include suspending payments to a provider, referral to relevant agencies or authorities, or both. MAOs must also ensure that FDRs have corrected deficiencies. Corrective actions for fraud, waste, and abuse or program noncompliance by FDRs should include ramifications if the FDR fails to satisfactorily implement corrective actions. Compliance violations may warrant disciplinary measures such as employment or contract termination.

SECTION IV
Conclusion

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IV. Conclusion

The Medicare Advantage ICPG—together with the GCPG—provides an updated and centralized resource to advance the MA industry's compliance efforts to prevent fraud, waste, and abuse. It provides a compilation of guidelines that MA Parties should consider when implementing, evaluating, and updating their compliance programs. OIG recognizes that most MA Parties are dedicated to providing high-quality and cost-effective services to MA enrollees. The recommendations and practical considerations in the Medicare Advantage ICPG—if implemented by MA Parties—may further the goals of ensuring that MAOs and other entities meet their legal obligations, avoid pitfalls, and ultimately advance the objectives of the MA program to provide high-quality, cost-effective services to enrollees.

Because compliance is an evolving discipline, and given continuing changes to MA rules, business operations, and health care delivery, OIG may update this Medicare Advantage ICPG periodically to address newly identified risk areas and compliance measures, ensure timely and meaningful guidance from OIG, and respond to stakeholder feedback. MA Parties should consult governing laws and regulations for the most up-to-date legal information.

OIG welcomes written and specific feedback from the health care community and other stakeholders in connection with the Medicare Advantage ICPG and the GCPG. We have designated an email inbox at Compliance@oig.hhs.gov to which any such written, specific feedback can be submitted.

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