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Medicare Advantage and the False Claims Act

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Contents

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Executive Summary

The Medicare program is transforming its approach to delivering quality healthcare and reducing the rate of cost growth primarily through the use of reimbursement models that incentivize better healthcare outcomes. Greater emphasis on care coordination, efficient resource use, and payment models that encourage improved outcomes are key elements of this transformation. The Medicare Advantage program, which uses a capitated payment model, is an early and ongoing example of this transformation. Under a capitated payment model, the financial risk for delivering healthcare services is transferred from the Medicare program through a per-member, per-month payment to a private health plan that meets specific requirements set by the Centers for Medicare & Medicaid Services (CMS). No matter how much care is delivered to a patient enrolled in a Medicare Advantage plan, payment to the plan from the Medicare program will not exceed (or fall below) the per-member amount.

Capitation is materially different from fee-for-service (FFS) Medicare, the original payment model used by the Medicare program. The FFS model reimburses providers retrospectively on a per-service basis; naturally, this incentivizes the provision of as many services as possible regardless of whether those services are needed. This volume-based incentive is fundamentally different from the incentive in the capitation-based model used in Medicare Advantage, which encourages greater efficiency and reimbursement for care that improves enrollee health outcomes.[1] The Medicare Advantage model has been proven to successfully care for clinically-complex patients, prevent hospital readmissions, and lower the cost of care for beneficiaries.[2]

While the Medicare program is undergoing a transformation into a value-based system, enabling changes to the federal fraud and abuse framework that governs the Medicare program have lagged. The current framework was designed to penalize fraud and abuse in a FFS payment system, where volume is the primary payment incentive. This framework prohibits arrangements between and among providers and other industry stakeholders that, in a volume-based payment system, have the potential to encourage over-utilization of healthcare resources, inappropriately influence provider decision-making, decrease competition among competitors, and harm patients. The federal civil False Claims Act (FCA) is one of the most powerful mechanisms in the framework available to the federal government to punish and deter fraud and abuse and to sanction healthcare providers who knowingly attempt to defraud the federal

government. The FCA imposes civil liability and other penalties (including exclusion from federal healthcare program participation) on any individual or entity that knowingly submits a false claim to Medicare, Medicaid, or other federal healthcare program or retains funds it was not entitled to receive (e.g., an overpayment).

The FCA plays an important role in preventing and penalizing fraud and decreasing waste and abuse within the FFS Medicare program. However, the FCA lacks the clear enforcement application in Medicare Advantage that it has in the FFS Medicare context. The Medicare Advantage program is, by design, a more efficient and coordinated option with an entirely different payment structure than the FFS Medicare payment system, inherently eliminating many of the volume-based incentives the FCA is used to guard against. While the FCA has been used effectively to combat fraud and abuse in the FFS Medicare context, it is much more difficult to align its provisions with the structure of the Medicare Advantage program itself and the general concept of capitated payments.

As noted above, payments in FFS Medicare are made retrospectively per-service; this structure creates opportunities for FCA overpayments in the form of incorrect or fraudulent billing and service over-utilization. In contrast, capitated payments are made for a defined set of benefits for a specified set of enrollees, which eliminates per-service billing and the incentive for over-utilization, significantly reducing the scenarios in which an overpayment could occur. The prospective, risk-adjusted bid process through which capitated payment amounts are determined results in an agreement between CMS and the Medicare Advantage plan on the payment amount and benefit package before any service is ever used (or not used) by an enrollee. The various methods of risk adjustment and model calibration used by CMS ensure that these payments are as accurate as estimates of as-yet incurred costs can be.

While there are various theories of FCA enforcement in the context of Medicare Advantage, they lack the direct connectivity of the claims-based application to the FFS payment model. A per-member, per-month capitated payment is fundamentally different than a claims-based reimbursement system. Furthermore, the concerns that FCA enforcement is intended to address in the FFS context, such as overutilization (e.g., submitting claims for unnecessary services), are inherently eliminated in the capitated payment model context that shifts the financial risk for overutilization to the health plan.

As the Medicare program continues to move away from FFS Medicare towards expanded capitated payments to insurers such as Medicare Advantage plans and clinically and financially integrated organizations such as accountable care organizations (ACOs), FCA application will continue to be less clear. The focus on encouraging and financially incentivizing care management and coordination of the health of a population coupled with capitated payment models that shift financial risk to providers eliminates the volume-based incentives inherent under FFS Medicare in favor of outcomes-based incentives. This realignment of incentives does not align with the claims-based enforcement approach of the FCA.

There are several mechanisms through which the current interpretation and enforcement of the FCA could be modified to better ensure that actual fraud and abuse is identified and penalized while recognizing and encouraging innovation in care delivery and payment models that inherently reduce the opportunity for fraud and abuse. For example, Congress could legislatively exempt from FCA enforcement certain arrangements and payment models, such as capitated payment arrangements that meet specific criteria. Alternatively, or in addition, CMS could issue regulation based on industry feedback to address the misalignment of FCA enforcement in the context of Medicare Advantage, particularly as it relates to the concept of overpayments and risk adjustment. CMS also could address potential fraud and abuse in the Medicare Advantage program using other statutory authorities, such as its civil monetary penalty (CMP) authority,[3] as an enforcement mechanism to penalize health plans that have repeated high error rates. Whether these paths or others are pursued, stakeholders must recognize the need to modernize the fraud and abuse legal framework as the healthcare delivery and payment system transforms in ways that stretch beyond the current framework to achieve the shared goals of reducing costs to protect the sustainability of these programs and improving the quality of healthcare for Medicare beneficiaries.

A necessary precondition to effective stakeholder advocacy is a comprehensive understanding of the Medicare Advantage program's design, the FCA, and theories of FCA application. This paper begins with an overview of the role of Medicare Advantage in both payment and healthcare delivery, followed by a general comparison between payment methodologies in FFS Medicare and capitation. The paper then explores the Medicare Advantage program's care management-oriented payment

design in-depth, highlighting key differences from FFS' service-oriented design. The paper then transitions to a discussion of the FCA – its provisions, its history, its role in a FFS system, and recent changes – before exploring theories of its application to the Medicare Advantage program's payment design. The paper concludes with recommendations for what should come next, emphasizing the need for action on the misalignment between the FCA and the Medicare Advantage program. As the healthcare payment and delivery system continues to modernize in an effort to lower costs and improve the quality of care, the structure of the federal fraud and abuse framework and the approach to its application must similarly modernize to be workable in a value-based health care system.

I. Introduction

Since the inception of the Medicare program in 1965, rising healthcare costs have been an acute concern threatening the sustainability of the program (as well as other publicly and privately funded healthcare programs). The rate of cost growth was and continues to be due in part to the original payment model of the Medicare program, a fee-for-service (FFS) model that reimburses providers on a per-service basis. In the FFS Medicare payment model, providers are financially incentivized to provide as many services as possible, regardless of whether the services are needed.

Shortly after the Medicare program was created, Congress expanded the authority of the federal agency that administers the Medicare program (the Centers for Medicare & Medicaid Services (CMS)[A]) to penalize fraudulent and abusive billing, such as submitting claims for care not delivered, medically unnecessary care, or for non-patients, and other arrangements such as kickbacks and financial relationships between providers and other industry stakeholders that could lead to overutilization of healthcare services and compromise patient safety. One of the primary enforcement tools used by the federal government to combat fraud and abuse is the federal civil False Claims Act (FCA). While the FCA actually predates the Medicare program, the FCA makes it illegal to knowingly submit a false claim for reimbursement by the federal government. In healthcare, this means submitting a false claim for healthcare services paid for by a federal healthcare program such as Medicare. Financial penalties for violations are assessed on a per claim basis in direct alignment with the original claims-based FFS Medicare payment model.

As the rate of cost growth continued to increase, threatening the sustainability of the federally funded Medicare program, Congress expanded (and continues to expand) the authority of CMS to utilize different types of payment models in the Medicare program to better align reimbursement with the quality and outcomes of care delivered. One of the primary payment models CMS has used in addition to FFS is a capitated payment model in an effort to reduce the rate of cost growth and improve coordination of healthcare services. CMS gradually increased the use of a capitated payment model in various iterations that are now embodied by the Medicare Advantage program. Under capitation, CMS transfers the financial risk for delivering healthcare services in the Medicare program through a per-member per-month payment to a private health plan that

[A] Note that the original Medicare and Medicaid program administrator was the Health Care Financing Administration (HCFA), established in 1977. It was renamed the Centers for Medicare & Medicaid Services (CMS) in 2001. For purposes of this paper, "CMS" is used throughout, even where an activity would technically have been carried out when it was named the HCFA.

meets specific requirements set by CMS. In capitation, no matter how much care is delivered to a patient, payment will not exceed (or fall below) the per-member amount. If the cost of treatment falls below the per-member amount, the health plan retains the difference as profit and/or to improve the administration of the plan. If the cost of treatment exceeds the per-member amount, the health plan bears the risk of covering that cost.

At its core, capitation incentivizes health plans to reduce costs by increasing efficiency although it may also incentivize underutilization and compromise care quality if plans take on too many enrollees or select cheaper and less effective treatment options.[B] Thus, the incentive to provide more services in a FFS payment model is fundamentally different from the incentive in capitation arrangements like Medicare Advantage that ideally encourage greater efficiency and reimbursement of care that improves enrollee outcomes.[4] This also fundamentally alters the interaction with the FCA. While there are various theories of FCA enforcement in the context of Medicare Advantage, they lack the direct connectivity of the claims-based application in the FFS payment model. A per-member, per-month capitated payment is fundamentally different than a claims-based reimbursement system. Furthermore, the concerns FCA enforcement is intended to address in the FFS context such as overutilization (e.g., submitting claims for unnecessary services) are inherently eliminated in the capitated payment model context that shifts the financial risk for overutilization to the health plan.

This paper provides a comparison of the two primary payment models used in the Medicare program, FFS and capitation in the managed care context, and an overview of the Medicare Advantage program (Medicare managed care). This discussion provides the background and context for an exploration of the interaction of the FCA with the capitated payment model of the Medicare Advantage program, the inherent misalignment of FCA enforcement in Medicare Advantage, and alternatives to eliminate this misalignment that would still stifle fraud and abuse without stifling innovation in care delivery and payment models designed to achieve improved healthcare outcomes.

[B] Due to the potential for underutilization and potentially compromised quality, capitated payments are paired with quality reporting requirements and quality incentives for health plans participating in the Medicare Advantage program to help ensure quality of care is not impacted adversely.

II. Medicare Advantage: Role as a Healthcare Delivery and Payment Model

Medicare Advantage is a federally funded health insurance program administered by private health plans and offered to Medicare beneficiaries as an alternative to FFS (i.e., traditional or original) Medicare. Under FFS Medicare, a beneficiary may choose any Medicare-participating provider, and healthcare services provided to a beneficiary are billed and paid for as they occur (i.e., fee-for-service payment model). In contrast to FFS Medicare, under the Medicare Advantage Program a beneficiary may choose to enroll in a private health plan to receive Medicare-covered benefits. CMS contracts with different types of private health plans, such as health maintenance organizations (HMOs), to offer "all-in-one" coverage to Medicare beneficiaries for a fixed monthly amount per enrollee (i.e., a capitated payment model) paid by Medicare.

Medicare Advantage combines the separate types of coverage offered under FFS Medicare into a single plan that includes Medicare Part A (hospital insurance), Part B (medical insurance), and often Part D[c] (prescription drug coverage). Enrollees also are responsible for premiums and other out-of-pocket costs depending on the health plan they select. Conversely, FFS Medicare requires enrollees to sign up for each of these Parts separately and potentially pay different premiums, deductibles, and coinsurance amounts for each Part in which they are enrolled. Medicare Advantage plans are required to cover the same services covered in FFS Medicare, provide enhanced consumer protections (such as annual out-of-pocket spending limits and care coordination), conduct more expansive quality reporting, and may also offer supplemental benefits (e.g., vision, hearing, and dental coverage) or reductions in enrollee out-of-pocket costs. In 2018, approximately 36% of the 60 million Medicare beneficiaries chose to enroll in a Medicare Advantage plan,[5] and payments to Medicare Advantage plans accounted for 29% of total Medicare program spending.[6] The share of beneficiaries choosing Medicare Advantage has tripled since 2004 (13% in 2004).[7]

[c] Because Medicare Part D is not a FFS Medicare benefit (FFS beneficiaries may choose to enroll in Part D from a private plan), Part D benefits are considered a separate benefit prepaid to MA plans.

Medicare Advantage plans are functionally similar to plans offered through employer-based health insurance, which enables them to leverage private-sector expertise in care management and coordination, provider engagement, customer satisfaction, and process efficiency. The structure of the traditional FFS Medicare benefit was designed to mirror the structure of insurance in the 1960s, and segments care delivery and payment into setting-based silos (inpatient/hospital, outpatient/ambulatory, physician, pharmacy) that can lead to care fragmentation and higher costs.[8] Conversely, the Medicare Advantage program offers beneficiaries integrated coverage across settings of care and providers along with payment options and protections that make it a simpler and more coordinated option for enrollees.[9]

The capitated payment structure of Medicare Advantage incentivizes plans to avoid unnecessary utilization of potentially high-cost healthcare services and improve health outcomes through preventive measures and care coordination. Various federal requirements and flexibilities specific to Medicare Advantage plans have produced more consumer-centric features such as out-of-pocket spending caps, performance transparency, lower premiums, easier to navigate cost-sharing (such as co-pays, rather than co-insurance), and access to expanded benefits and services beyond FFS Medicare (such as new supplemental benefit options[10]).

Medicare Advantage has proven to be successful at caring for clinically complex patients, preventing hospital readmissions, and lowering costs for beneficiaries.[11] The benefits of Medicare Advantage plans extend into the larger healthcare environment as well. In markets with higher Medicare Advantage plan enrollment, FFS Medicare spending growth is lower than in markets with limited Medicare Advantage plan penetration[12] without reductions in care quality.[13] This trend is attributed to providers adapting their practice patterns across their patient population to align with Medicare Advantage plans' resource utilization strategies, which "spillover" to all patients.[14]

III. How Payment Models Impact Healthcare Reimbursement in Medicare

A Closer Look at FFS Medicare and Capitation in Medicare

One of the primary challenges facing CMS (as well as other public and private sector payers) is identifying and implementing sustainable payment model(s) to incentivize and support the delivery of high-quality, coordinated care while controlling the rate of cost growth. In the Medicare program, the FFS Medicare payment model, which primarily incentivizes volume (i.e., the more services billed, the more payment provided), has led to material cost growth despite numerous efforts to curb this growth. From 2000 to 2005, spending on FFS Medicare beneficiaries grew at an average annual rate of 7.1%.[15] While rate of cost growth in FFS Medicare has slowed since 2007, this is due to numerous factors including changes in payment rates and regulatory requirements, in beneficiary demand and the way providers deliver care, and in the rising share of beneficiaries choosing to enroll in Medicare Advantage plans instead of FFS Medicare.[16] FFS Medicare does not inherently include any mechanisms to incentivize higher quality of care or improved outcomes at the individual and population levels, although CMS has added quality reporting and related initiatives to address this. However, the managed care model and its use of capitated payments in the Medicare Advantage program is specifically designed to address these issues. CMS is also implementing other models of payment and care delivery to address these issues. For example, Accountable Care Organizations (ACOs) and Patient-Centered Medical Homes are designed and financially incentivized to coordinate the care of their patient population. CMS is using these and other alternate payment models to shift away from the FFS Medicare payment system that incentivizes volume of services towards inclusive payment models that incentivize quality and better health outcomes.

Fee-for-Service

CMS has traditionally used a retrospective claims-based FFS payment model to pay for health care provided to Medicare beneficiaries. Medicare Parts A (hospital insurance) and B (medical insurance) were created as a FFS payment and delivery system, like the standard employer-sponsored plans that were dominant in the insurance marketplace in 1965. In a standard FFS (or indemnity insurance) payment system, providers are required to submit claims for reimbursement and are reimbursed on a per-service or claim basis. As such, in the FFS Medicare program, a provider

(physician, hospital, skilled nursing facility, etc.) delivers healthcare services and/or supplies to a beneficiary and then submits a claim(s) to CMS after the services are delivered. The provider supplies procedure codes on the claim, which align with the service delivered during the beneficiary's hospitalization, same-day-procedure, or outpatient visit.

As volume and costs continued to grow, CMS made several efforts to control FFS Medicare reimbursement rate growth, but despite these attempts, healthcare expenditures continued to increase rapidly.[17] Among continued efforts to standardize charges and control costs, CMS introduced:

- Fee schedules for physicians, or a list of the maximum rates CMS would allow for services;[D] [18]
- An inpatient hospital prospective payment system based on diagnosis related groups (DRGs) that provides hospitals a flat "per-stay" payment that varies based on diagnosis, severity, and procedures performed;[19] and
- Prospective payment systems applicable to different care settings[E] that provide a fixed payment for a defined group of services.[20]

For most payment systems in FFS Medicare, CMS determines a base rate for a specified unit of service and that base rate is then adjusted based on beneficiaries' clinical severity, geographic market area differences, and other specific policies, such as covering costs associated with graduate medical education (GME).

The per-service, per-claim, or per-case FFS payment model still exists in Medicare today, with 64% of total Medicare beneficiaries enrolled in the FFS Medicare program in 2018.[21] Under FFS Medicare, providers are paid for treating a patient regardless of that patient's clinical outcome, thus incentivizing higher levels of service delivery volume and making CMS the sole bearer of insurance risk.

[D] Services are defined based on code sets, including Current Procedure Terminology (CPT) for physician services and HCFA Common Procedural Coding System (HCPCS) for products, supplies, and services not included in the CPT codes.

[E] The Balanced Budget Act of 1997 required prospective payment systems for: Inpatient rehabilitation hospitals or units; Skilled Nursing Facilities (SNFs); home health; hospital outpatient departments; and outpatient rehabilitation. The Benefits Improvement and Protection Act of 2000 created prospective payment systems for Federally Qualified Health Centers and Rural Health Clinics (FQHCs/RHCs) (https://www.cms.gov/About-CMS/Agency-Information/History/Downloads/Medicare-and-Medicaid-Milestones-1937-2015.pdf).

Capitation and Managed Care

In an effort to manage rising healthcare costs often associated with a FFS payment system,[22] Congress enacted the Social Security Amendments of 1972, permitting Medicare beneficiaries to choose to have all Part A and Part B services provided or arranged for by a Health Maintenance Organization (HMO). HMOs are medical insurance groups that provide a specified range of health services to enrolled populations in exchange for a fixed payment that is determined in advance of care delivery (i.e., a capitated fee).

Unlike in a FFS payment system, capitated payments are made to plans regardless of whether each enrollee ultimately needs or chooses to obtain certain (or any) healthcare services. However, plans are not provided additional reimbursement if actual costs of care delivery for any given enrollee exceed the pre-determined (i.e., prospective) capitated fee. As such, the plans bear the full responsibility (or risk) for the costs of their enrollees' care. HMOs were expected to contain costs and restrain cost growth in several ways:

- Decreasing hospital utilization by requiring the provision of preventive care as part of the basic health services package;
- Incentivizing efficiency with capitated payments; and
- Streamlining healthcare systems and resources through group practice collaboration.[23]

Today, CMS pays participating private health plans (HMOs and other types of health plans) a fixed, per-member per-month (i.e., capitated) rate that covers all healthcare services provided over a defined time period. The capitated rate is adjusted for each enrollee's known healthcare status (i.e., it is risk-adjusted for the level of expected healthcare needs of the enrollee) and holds the Medicare Advantage plan responsible for the actual cost of providing care to each enrolled beneficiary. If the cost of care exceeds the capitated payment, the Medicare Advantage plan is responsible for the additional costs. If the cost of care, including administrative costs, is lower than the capitated amount for any single enrollee, the Medicare Advantage plan may use those funds to offset costs across the enrollee population in the health plan. In Medicare Advantage, the capitated payment shifts the responsibility and risk of the amount, form, and cost of care for enrolled beneficiaries away from the Medicare program to the Medicare Advantage plan.

IV. What is Medicare Advantage?

Historical Context

The original Medicare legislation authorized group practice prepayment plans to contract with CMS for the prospective payment of Part B services on a reasonable charge or reasonable cost basis.[24] However, concerns were raised that CMS was not taking advantage of cost savings that may be generated under a prospective payment system. As such, the Social Security Amendments of 1972 amended the Medicare statute to permit HMOs to enter into either a cost-[F] or risk-based (capitated) contract[G] to provide Medicare Parts A and B benefits to beneficiaries who chose to enroll.[25]

Through the 1980s, various amendments to the Medicare statute and pilot programs expanded the role of HMOs[26] and the definition of organizations eligible to enter into risk-based contracts with CMS.[27] In 1997, these modifications were formalized as the Medicare+Choice program (Part C), which offered beneficiaries the option to enroll in a staff- or group-model HMO, an independent practice association (IPA), or one of three other plan types[H] as an alternative to Medicare Parts A and B enrollment.[28] In 2003, this program was renamed Medicare Advantage and it added additional plan types as options,[I] though HMOs still account for the majority of total Medicare Advantage enrollment.[29] In addition, legislation created the Medicare prescription drug benefit (Part D) program and allowed Medicare Advantage plans to offer prescription drug coverage.[30]

[F] Cost-based contracts reimburse HMOs the "reasonable cost" actually incurred in providing Parts A and B services to enrollees; HMOs received a monthly interim capitated payment for each enrollee – adjustments at the end of the contract period are made to reflect actual costs incurred in service provision.

[G] Risk-based contracts reimbursed HMOs a prospective monthly cost based on the estimated cost of treating a typical FFS beneficiary in the enrollee's county (i.e., the average area per capita cost, or AAPCC). At the end of the contract year, the HMO's reasonable costs were compared to the retrospectively determined AAPCC incurred for the year – if the HMO's costs were less than the AAPCC, the HMO shared in 50% of the savings (up to 10% of the AAPCC) as a bonus. If the HMO's costs were higher than the AAPCC, the HMO was required to absorb the difference.

[H] These three types are: PPO, POS, PFFS. Note that Medicare Part C PFFS plans do not restrict enrollees to a plan network (unlike HMOs, IPAs, PPOs, and POS plans) but only cover care if the provider accepts the plan's restrictions on service provision and payment rate.

[I] New plan types were Regional PPOs and Special Needs Plans (SNPs).

Payment Model

CMS pays Medicare Advantage plans a per-enrollee, or capitated, fee to provide Parts A and B benefits as medically necessary to Medicare Advantage plan enrollees. CMS also pays an additional per-enrollee fee for providing Part D, or prescription drug, benefits for Medicare Advantage Prescription Drug (MA-PD) plans. The payment a Medicare Advantage plan receives from CMS is expected to cover all care for its enrollees, even if an enrollee receives a covered service from an out-of-network provider (in some circumstances).[J] Medicare Advantage plans generally contract with providers to form a network through which the providers deliver care to enrollees at negotiated rates. The plans negotiate specific payment rates with the providers in their networks, but the Medicare Advantage plans retain the overall financial risk under the capitated payment from CMS.

Prior to the creation of the Medicare+Choice program in 1997, CMS reimbursed HMOs 95% of the average FFS Medicare costs in each county,[K] under the assumption that these plans were able to provide more efficient (and thus less expensive) care than could be provided in FFS Medicare.[31] This reimbursement rate incentivized managed care plans to enroll healthy people who did not utilize as many services (and thus did not cost as much), but it did not attract enough plans to operate in rural and underserved areas. Payment formulas were revised in the late 1990s and early 2000s to attract more managed care plans to participate in Medicare+Choice and to enroll and treat less healthy beneficiaries (thus increasing insurance risk). These revisions included the adoption of a diagnosis-based risk-adjusted payment system wherein Medicare Advantage plans were paid more for higher-risk enrollees expected to have higher costs than the average beneficiary (and less for lower-risk enrollees expected to be less costly).[32]

In 2006, CMS began paying Medicare Advantage plans using a bidding process. Under this approach, managed care plans submit annual, prospective bids to CMS that are estimates of what it will cost the plan to provide Parts A and B services to anticipated enrollees in the counties in which the plan will offer coverage. Bids are compared to county-level benchmark amounts set by statutory formula (basically a bidding target), although payment rates ultimately will vary based on county-specific FFS

[J] A Medicare Advantage plan must cover out-of-network providers if it offers out-of-network coverage (PPO, PFFS, MSA, HMOPOS); all Medicare Advantage plans must cover out-of-network providers to the extent that the provider practices in a specialty required for network adequacy and the Medicare Advantage plan does not have an adequate network of that specialty in the county in which the enrollee resides.

[K] The AAPCC for a given beneficiary, adjusted for demographic factors and county.

Medicare spending. If a plan's bid exceeds the benchmark amount, plan enrollees must pay the difference between the benchmark and the bid amount as a monthly premium. If the bid falls below the benchmark amount, the plan retains part of the difference (referred to as the "rebate").[L] This rebate must be used to provide plan enrollees with supplemental benefits not covered under FFS Medicare (e.g., vision, dental), to buy-down enrollee premiums, or reduce cost-sharing amounts for enrollees.

The Affordable Care Act (ACA) also authorized quality-adjusted payments in the Medicare Advantage program in an effort to incentivize investments in quality improvement.[33] CMS uses a five-star quality rating system to assign each Medicare Advantage plan a score (on a scale of 1-5, with 5 being the highest) to indicate the quality of care the plan provides to enrollees. Prior to the ACA, plan quality ratings were provided online as a service to beneficiaries choosing a Medicare Advantage plan. With the introduction of the ACA's quality-adjusted payments, the Star Ratings continue to be publicly available for beneficiary review and now are also used to adjust Medicare Advantage plan payments via an increase to the plan's benchmark. In order to earn a quality bonus that increases the benchmark amount[M] (and thus have more room to generate rebates), plans must earn at least a 4-star rating.[N]

In an effort to decrease the amount of consumer premiums spent on plan administration and overhead costs and ensure Medicare beneficiaries receive value from their Medicare Advantage plan, the ACA required all plans to report data on their Medical Loss Ratio (MLR), the proportion of premium revenues spent on clinical services and quality improvement activities. If a Medicare Advantage plan does not have an MLR of at least 85%, it can be subject to financial and other penalties including repayment to CMS, a prohibition on enrolling new members, or contract termination.[34]

[L] The beneficiary rebate amount was 75% of the difference between the bid and the benchmark until the ACA modified it so that the Medicare Advantage rebate percentage varies by Star Rating (70% for 4.5- or 5-Star plans; 65% for 3.5- or 4-Star plans; 50% for 3-Star or less plans).

[M] The increase is referred to as a "Quality Bonus Payment" (QBP), which is added on to the applicable ACA-mandated benchmark percentage ("Specified Amount").

[N] For plans with high Star Ratings operating in certain urban counties with low FFS Medicare costs and historically high Medicare Advantage enrollment, these quality adjustments are doubled (up to a benchmark cap). The benchmark cap is the pre-ACA benchmark amount calculated for the same county in the same year.

Risk Adjustment

In order to better account for variation in beneficiary healthcare needs and adjust reimbursement rates accordingly to encourage health plans to enroll beneficiaries in poorer health or with more complex health needs (and who are thus more costly to insure), CMS adjusts Medicare Advantage payments based on enrollees' risk. In 2004, CMS began using the Hierarchical Condition Category (CMS-HCC) risk adjustment model, which incorporates inpatient and ambulatory diagnoses categorized into cost-predictive condition categories. Under the CMS-HCC risk adjustment methodology, Medicare beneficiaries are assigned a risk score (a Risk Adjustment Factor, or RAF score) based on diagnostic information and demographic factors; the more complex a beneficiary's health (represented through the number and severity of diagnosis codes in the beneficiary's medical record), the greater the beneficiary's risk score.[O]

Medicare Advantage plans submit diagnosis codes to CMS, which uses the risk adjustment model described above and built using Medicare FFS claims to create beneficiary RAFs. Thorough and accurate medical record documentation is required to identify every health condition falling within an HCC that a beneficiary may have. Capitated payments are adjusted based in part on each enrollee's RAF scores (which are in turn based on diagnoses submitted for that enrollee for the previous calendar year[P]) and will thus vary depending on the estimated costs of enrollees' health (i.e., enrollees' predicted level of financial risk to the plan).

In CMS' methodology, risk-adjusted payments to Medicare Advantage plans are estimated using unaudited FFS Medicare expenditures calibrated based on coding patterns in FFS Medicare. In response to concerns about calibrating Medicare Advantage plan payments to FFS Medicare coding patterns, which may produce Medicare Advantage risk scores that are "systematically different" than those risk scores would be in FFS Medicare,

[O] The CMS-HCC risk adjustment model is calibrated using data from FFS claims. CMS then estimates coefficients for condition categories based on total FFS expenditures and beneficiary demographic factors. CMS creates a relative factor for each demographic factor and HCC in the model – these risk factors are used to calculate an individual beneficiary's risk score. The average risk score is 1.0. A healthier Medicare Advantage enrollee would have a risk score of less than 1.0, while a sicker enrollee would have a risk score of greater than 1.0.

[P] As an example of the timing, CMS makes prospective payments for January 2019 through July 2019 based on July 2017 through June 2018 diagnoses submitted through mid-September of 2018. CMS then makes prospective payments for August 2019 through December 2019 based on January 2018 through December 2018 diagnoses submitted through early March 2019. Payments are retroactively adjusted based on the previous calendar year diagnoses to rectify any payment discrepancies; in this example, payments would be retroactively adjusted based on CY2018 diagnoses.

there have been several attempts to measure and adjust for "coding intensity."[35] Coding intensity is the difference between the scores that a group of beneficiaries would have if enrolled in FFS Medicare and their actual scores in Medicare Advantage. CMS has studied differences in coding patterns and concluded that a coding intensity adjustment should be imposed because Medicare Advantage plans code more completely than FFS providers.[36]

CMS first began measuring for coding intensity and adjusting payments to Medicare Advantage plans on this basis, cutting payments by -3.41% in 2010. CMS also began performing Risk Adjustment Data Validation (RADV) audits of the diagnosis codes reported by Medicare Advantage plans to confirm they are supported by medical documentation and that other CMS requirements are met. The ACA and the American Taxpayer's Relief Act of 2012 both required CMS to increase its coding intensity adjustment of Medicare Advantage plans beginning in 2014 and continuing through 2018 and beyond (currently a -5.90% reduction).[37] Since 2014, CMS also has made substantial changes to the risk-adjustment model, focusing in particular on diagnoses that may be subject to coding intensity efforts.[38]

Link between FFS Medicare Payments and Medicare Advantage Capitated Payments

While the payment methodologies in FFS Medicare and the Medicare Advantage program are different, capitated payment rates to Medicare Advantage plans are linked to the payments made to providers under FFS Medicare. In determining the capitated rate for Medicare Advantage plans, CMS is required by law to ensure that there is actuarial equivalence between the Medicare Advantage capitated rates and FFS Medicare payments. Actuarial equivalence means that CMS' risk-adjusted payment to Medicare Advantage plans must be equivalent to the expected cost that CMS would pay if the same enrollee received health benefits through FFS Medicare.[39] CMS' risk-adjustment methodology is intended to support actuarial equivalence.[40]

As noted above, CMS conducts RADV audits to ensure that the diagnosis codes submitted by the Medicare Advantage plans and used, in part, to determine risk-adjustment calculations, are accurate. CMS selects a subset of Medicare Advantage plans to audit, and then from these plans selects a stratified sample of enrollees using specific criteria. The selected Medicare Advantage plans are required to submit actual medical records for the sample of enrollees to support all HCCs included in the enrollees' risk scores. CMS then compares the diagnoses reflected in the risk scores with underlying medical records to identify whether there are any codes that

are not supported by the medical record and whether there is a difference between the original payment and the new payment determined based on the results of the RADV audit. If this comparison of sample enrollees yields a difference, referred to as an error rate, CMS plans to calculate a contract-level error rate (i.e., the entire error in payment if the errors found in the RADV audit were reflected in all similar cases for that contract).[41] CMS has indicated that it may use this error as a basis to extrapolate the results of RADV audits to entire contracts to calculate a potential overpayment that a Medicare Advantage plan must return to CMS.

One of the primary challenges with this process is the reliance on *unaudited* FFS Medicare claims data to determine Medicare Advantage payment rates, and the use of *audited* Medicare Advantage medical records to determine payment errors that may give rise to an obligation for the Medicare Advantage plan to return payments to CMS. This RADV formula and its reliance on only a sample of plan members represented a significant shift in CMS' approach to auditing Medicare Advantage payments. Previously, CMS only required plans to repay claims with errors that CMS had specifically validated. In order to address concerns related to the use of unaudited FFS Medicare claims in comparison to audited medical records, CMS previously announced that it would implement a "FFS adjuster" that would take into consideration the error rate in CMS payments in FFS Medicare.[42] Without a FFS adjuster, diagnosis data in FFS Medicare and Medicare Advantage are subjected to different documentation standards when Medicare Advantage plans are audited, in violation of the actuarial equivalence requirement.

A recent judicial decision highlights the disconnect between the data sources used for these audits (e.g., the unaudited FFS Medicare claims data and audited Medicare Advantage data). In *UnitedHealthcare Insurance Co. et al v. Azar*,[43] a Medicare Advantage plan alleged that CMS violated the statutory requirement of actuarial equivalence between FFS Medicare payments and Medicare Advantage payments by determining overpayments based on audited Medicare Advantage records while the underlying data to determine Medicare Advantage payment rates are based on unaudited FFS Medicare records. The court stated that the process for determining potential overpayments to Medicare Advantage plans "fails to recognize a crucial data mismatch" and "establishes a system where actuarial equivalence cannot be achieved."[44]

V. The False Claims Act

Background

The federal fraud and abuse legal framework penalizes arrangements between and among providers and other industry stakeholders that have the potential to encourage overutilization of healthcare resources, inappropriately influence provider decision-making, decrease competition among competitors, and/or harm patients. This framework was designed to penalize fraud and abuse in a FFS payment system where volume is the primary payment incentive. The federal civil False Claims Act (FCA) is one of the most powerful tools available to the federal government to sanction healthcare providers who knowingly attempt to defraud the federal government. The FCA imposes civil liability and other penalties (including exclusion from participation in federal healthcare programs) on any individual or institutional entity that submits a false claim to Medicare, Medicaid, or other federal healthcare programs.

The FCA was originally passed in 1863 during the Civil War as a remedy against companies that sold faulty supplies and equipment to Union troops. The Act included civil damages provisions and provided for $2,000 in fines for each false claim. The Act also enabled individual citizens to bring an action on behalf of the government and receive a portion of the recovered funds. These whistleblower provisions were intended "to reach all fraudulent attempts to cause the government to pay out sums of money to deliver property or services… a false claim for reimbursement under the Medicare, Medicaid, or similar program is actionable under the Act."[45]

FCA Liability

Although initially used primarily for defense-related matters, the FCA now is an important part of the government's arsenal of criminal, civil, and administrative remedies against healthcare fraud. Since its first application in the healthcare context, the FCA primarily prohibited a provider from making a false claim directly to the U.S. government to obtain money. The primary way in which a claim is "false" under the FCA is if the claim contains factually false or incorrect information on its face (e.g., a claim for services not provided). An additional FCA violation occurs when an entity knowingly makes a false statement or uses a false record material to an obligation to pay money to the government. An example of this type of false claim would be reporting and returning only a portion of an overpayment while asserting that it is repaid in full.

Penalties for violating the FCA can be severe; for civil violations, the government can collect up to three times the amount it paid for each claim, plus an additional $11,000 - $22,000 penalty per each false claim. (Note that these penalty amounts are adjusted upward every year to account for inflation; in 2019, the penalties were $11,463-$22,927.) In addition, any entity violating the FCA can be excluded from participating in the Medicare or Medicaid programs. Given the volume of claims billed to the federal government for Medicare-covered healthcare services, violations of the FCA can result in massive fines.

Defining a "Claim" and the Intent Threshold

Prior to 1986, the FCA defined "claim" narrowly; an expanded definition was added in response to concerns that courts were improperly limiting the scope of FCA liability. For example, a "claim" under the FCA originally was interpreted by the Supreme Court as strictly limited to situations in which a demand or request for payment from the federal government was made (thus limiting the federal government's ability to sue state-level grantees and contractors for fraud). Now, a "claim" is defined as a request or demand for money or property made by the contractor, grantee or other recipient, if the U.S. government provides any portion of the money or property that is requested, or if the government reimburses the contractor or grantee.[46]

If a claim is submitted that is false (i.e., incorrect), liability is predicated on the claimant's intent. FCA liability attaches only if a claimant submits a claim knowing the claim to be false; a mere [undiscovered] error does not rise to the requisite level of intent. For purposes of the FCA, a claimant "knows" a claim is false if the claimant has actual knowledge of falsity, acts with "deliberate ignorance" of the truth or falsity of the information in a claim, or acts with "reckless disregard" for the consequences of one's actions. Acting with "deliberate ignorance" requires that one actually intended not to know or learn regulations or requirements. Proving "reckless disregard" requires a showing that the claimant's actions were a "gross deviation" from the actions of an average (or similarly situated) claimant (e.g., more severe than negligence).

False Certification

Courts apply FCA liability based not only on the submission of a facially false claim, but also where a claimant falsely certifies to compliance with a statutory, regulatory, or contractual provision. As a practical matter, this means that any regulatory non-compliance issue is subject to liability under the FCA if the requisite intent (discussed above) can be shown to exist. Federal circuit courts have historically been split on whether false certification must be express (i.e., an explicit promise to comply with certain provisions) or if it can also be implied (i.e., simply through the act of submitting a claim). The implied certification theory holds that when a provider submits a claim to CMS, there is an implied certification to compliance with all regulatory requirements governing delivery of that service. If the provider is not in compliance with a regulatory requirement relating to the service provided at the time of claim submission (even if those requirements are not expressly listed as conditions of payment), certification to compliance with all laws is "false" and thereby subject to FCA liability, even though the content of the underlying claim itself may not be false.

The Supreme Court resolved this circuit split in its 2016 decision in *Universal Health Services, Inc. v. US and Commonwealth of Massachusetts ex rel., Julio Escobar and Carmen Correa*.[Q] The Court held that implied certification is a viable theory of FCA liability if non-compliance with regulatory requirements renders the information in the claim a "half-truth" and if this misrepresentation is material to the government's decision to pay the claim (i.e., if government would not have paid the claim had it been aware that there was a violation of another healthcare law or regulation).[R] For example, if a provider submits a claim for services that are rendered in return for a fraudulent kickback (in violation of the federal Anti-Kickback Statute[47]), this claim could be considered to be an actionable false claim, even if the services were actually provided, since they were provided in return for an illegal kickback.

[Q] There is a pending writ of certiorari in Brookdale Senior Living Communities Inc. v. US ex rel. Prather on Escobar's materiality standard; if the US Supreme Court grants the petitioner's writ, it could clarify or reverse its holding in Escobar.

[R] The Court laid out a four-part test for application of the implied certification theory, limiting it to instances in which: (1) a defendant submits a claim that does not merely request payment, but also makes specific representations about the goods or services provided, (2) knowingly fails to disclose the defendant's noncompliance with statutory, regulatory, or contractual requirements, (3) this omission renders those representations misleading, and (4) the resulting misrepresentation is material to the Government's decision to pay the claim.

Recent Updates to the FCA

In the late 2000s, the Fraud Enforcement and Recovery Act of 2009 (FERA), the American Recovery and Reinvestment Act of 2009 (ARRA),[S] and the ACA (2010) all made substantial changes to the FCA, expanding its scope, increasing the severity of its penalties, and making it easier to bring a suit. FERA amended the FCA to expand liability and prohibit the making of false statements to anyone if the U.S. government pays some part of the claim (overturning *Allison Engine Co. v. US ex rel Sanders*,[48] a 2008 Supreme Court case);[49] this includes Medicare and Medicaid managed care plans, Medicare Part D plans, and Medicare contractors.

The FERA amendments also expanded the FCA by imposing civil liability for knowingly concealing or improperly avoiding an obligation to pay money to the government. When an entity has (or should have) identified an overpayment received from a federal healthcare program, the ACA requires health plans (including Medicare Advantage plans) to report and return the overpayment within 60 days of identifying the overpayment (or within 60 days after the date any corresponding cost report is due, whichever is later). An "overpayment" is any funds received or retained to which, after reconciliation, the person is not entitled. Under the ACA, an obligation to repay the claim arises once an overpayment is retained beyond this 60-day period. This obligation applies to providers and suppliers submitting claims under FFS Medicare as well as Medicare Advantage plans and Part D plans. Continued, knowing failure to return the payment is an FCA violation, known as "reverse false claims" liability. Providers subject to reverse false claims liability can incur penalties and treble damages under the FCA.

[S] ARRA significantly enhanced protections for FCA whistleblowers who are employees of a firm receiving 2010 Stimulus funds; section 1553 prohibits employers (i.e., non-governmental employers who receive stimulus funds) from reprisals against employees who disclose information related to a false claim. ARRA also provides increased damages and a lower threshold of proof for employee whistleblowers than other laws.

VI. Applying FCA in Medicare Advantage

A 1990 Florida district court case *(US v. CAC-Ramsay, Inc.)* held that the FCA applied to Medicare managed care plans. The case related to a Medicare Advantage plan's acceptance of an overpayment from the government, but did not elaborate on other contexts in which the FCA would apply to capitation arrangements. While the particular facts of this case are not particularly noteworthy for purposes of this discussion, it is relevant as this case has been used as the precedent-setting case for the application of the FCA to Medicare managed care plans. As discussed above, payments in FFS Medicare are made retrospectively per-service; this structure creates opportunities for FCA overpayments in the form of incorrect or fraudulent billing and service over-utilization. In contrast, capitated payments are made for a defined set of benefits, for a specified set of enrollees, which eliminates per-service billing, eliminates the incentive for overutilization, and significantly reduces the scenarios in which an FCA overpayment could occur. The prospective, risk-adjusted bid process through which capitated payment amounts are determined results in an agreement between CMS and the Medicare Advantage plan on the payment amount and benefit package before any service is ever used (or not used) by an enrollee. The various methods of risk adjustment and model calibration used by CMS ensure that these payments are as accurate as estimates of as-yet incurred costs can be.

Despite the less obvious fraud and abuse risk posed by capitated arrangements, there are theories of FCA application to capitation and Medicare Advantage plans. For example, submission by a Medicare Advantage plan of falsified enrollees for capitation payments implicates FCA liability. Similarly, if a Medicare Advantage plan or a provider in a Medicare Advantage plan's network submits inaccurate diagnosis information for risk-adjustment calculations to the Medicare Advantage plan, and the Medicare Advantage plan knows the information is incorrect and forwards that information to CMS, this could trigger FCA liability. Finally, if a Medicare Advantage plan fails to provide required or necessary care to enrollees, this could be a violation of the FCA.

However, the fundamental structure and design of the Medicare Advantage program does not naturally align with the structure and enforcement of the FCA. As described below, this is illustrated by the Medicare Advantage capitated payment model, the competitive bid process by which per-member per-month payment rates are set, and the risk adjustment methodology. Therefore, the FCA concept of overpayments also does not naturally align with a capitated payment model.

Medicare Advantage Payment Model

Any payment system that rewards volume (even outside the healthcare context) creates an attendant risk that payers will be charged for services not warranted, necessary, or even provided. The FFS Medicare payment system is a clear example in that it incentivizes the submission of as many claims as possible in order to maximize payments regardless of whether care was actually delivered or necessary. As such, the FCA has been applied directly and effectively to the claims-based system of FFS Medicare with an enforcement focus on overpayments to providers that either should not have been made or were for a higher monetary value than warranted (e.g., submission of claims for unnecessary services or a higher level of service than was provided).

In its Part A and B Final Rule clarifying FCA liability for overpayments, CMS listed common examples of overpayments. The examples include payments for non-covered services, payments in excess of allowable amounts (e.g., due to upcoding or miscoding services provided), duplicate payments, errors and non-reimbursable expenditures in cost reports, payment received when another payer had the primary responsibility for payment (i.e., where the Medicare program is the secondary insurer), and billing for services that are inadequately documented. It is noteworthy that these examples are mostly unique to a retrospective FFS Medicare payment system (or per-service payment methodology) and are not and cannot be, by definition, issues in a capitated system. Capitated payments are made prospectively on a per-member per-month basis and are intended to pay for all covered services an enrollee may utilize in a given time period. There is no claim submitted for a particular service or services, but rather an obligation on the Medicare Advantage plan to manage (and carry the financial risk of managing) all of the services the population of enrollees needs over a defined period of time under the per-member per-month payment model. Because Medicare Advantage plans do not bill CMS on a per-service basis, there is no "claim" to be false as there is under a FFS Medicare payment system. As such, applying the FCA to Medicare Advantage plans is not a straightforward exercise and challenges the notion of a claims-based calculation of liability.

Medicare Advantage Bid Process

The bid process by which Medicare Advantage per-member per-month payments are set is further evidence of the material structural difference between Medicare Advantage and FFS Medicare that eliminates the incentive for over-utilization that FCA is designed to penalize. Medicare Advantage payments reflect the competitive bids health plans submit to participate in the Medicare Advantage program, which are reviewed, adjusted, and accepted by CMS before any healthcare services are ever provided to an enrollee. A bid is not a claim for services delivered nor is it derived from a set fee schedule. Rather, it is a reflection of the cost a health plan projects it will incur on average to provide healthcare services to its enrollees, as discussed above.

Medicare Advantage bids are also compared to county-specific benchmarks that are a reflection of the average monthly cost for a FFS Medicare beneficiary, and the resulting capitated payment amount is further adjusted for risk. Thus the per-member per-month payments that a Medicare Advantage plan receives for caring for its population of enrollees is the compilation of the plan's anticipated costs, the average cost determined by CMS of providing services to an enrollee population in a specific county and further adjusted by the anticipated health needs (risk) of that population. This competitive bid process that informs the capitated payments completely shifts financial risk to the health plan, eliminates the incentive for overutilization, and further challenges the notion of claims-based FCA enforcement. These unique attributes of the Medicare Advantage program payment methodology significantly reduce the opportunities for fraud and abuse as compared to the FFS Medicare program and do not align with the environment in which "overpayment" (as it is understood in FFS) occurs.

Medicare Advantage Risk-Adjustment Methodology

A key component of the calculation of the capitated per-member per-month payments to Medicare Advantage plans is the risk adjustment of those payments to reflect the severity of the enrollee and, ultimately, financial risk to the health plan (in terms of the scope of healthcare services anticipated to be needed). CMS has established a risk model that uses data from claims in the FFS Medicare program to assign relative values for health care conditions (e.g., diabetes, chronic kidney disease, congestive heart failure), and other factors such as age and gender. An individual beneficiary's risk score in one year is based on diagnoses from the prior year and reflects the beneficiary's predicted health costs compared to those of an average Medicare beneficiary, as discussed above. Medicare Advantage plans are required to submit diagnosis and encounter data to CMS that are used to

generate risk scores. However, these risk scores are based on factors that represent the relative costs (on average) of enrolling a beneficiary with a particular condition(s) that become relative payments for enrolling the beneficiaries. Medicare Advantage plans remain at risk for actual costs that may exceed or be less than anticipated costs.

When a Medicare Advantage plan submits diagnosis data to CMS for risk adjustment purposes, it must attest that the data is accurate, complete, and truthful. Intentionally inflating diagnosis codes (i.e., submitting codes that are unsupported by the record) in the risk adjustment data is an example of a false claim that could be subject to FCA liability. This, however, is not the same as coding intensity, which is the difference between a Medicare Advantage enrollee's risk score and the same enrollee's risk score in FFS Medicare.[50] Medicare Advantage plans are incentivized to identify and treat conditions in early stages to enable care coordination; as such, diagnosis information may appear earlier for a Medicare Advantage enrollee than a FFS Medicare beneficiary. Furthermore, FFS Medicare claims data is not subject to the same level of audit and review as Medicare Advantage data. To account for coding pattern differences due to the inherent structural differences between FFS Medicare and Medicare Advantage, CMS reduces per-member per-month risk-adjusted payments using a coding intensity adjustment when calculating MA plans' risk scores.

Coding in the FFS Medicare payment system is "known to be incomplete and variable,"[51] and payment is associated with each service provided. Thus, coding differences between the two programs may be attributable to FFS Medicare under-coding (and more accurate coding by Medicare Advantage plans) and not fraud. This issue exemplifies the differences in the structure of FFS Medicare and Medicare Advantage particularly as it relates to the identification of diagnoses and the primary reliance on FFS Medicare claims data to determine risk scores that are used to adjust payments to Medicare Advantage plans that are then further adjusted by a Medicare coding intensity adjustment. This, in turn, makes applying the FCA to Medicare Advantage plans materially problematic as the concept of an overpayment does not organically exist in the capitated payment context of Medicare Advantage. What is an overpayment when the elements of the payment model are based on averages (e.g., risk scores are based on average FFS Medicare costs for the "average" beneficiary with a particular condition) and data that is collected in one year and used to determine payment amounts in the following year? This use of averages (based on a prior year's data) is paired with the assumption that Medicare Advantage plans will enroll beneficiaries across a spectrum of health needs such that some beneficiaries with a particular condition may be more expensive than their risk score would predict and others less expensive, thus balancing out overall, on net.

The Concept of Overpayments

There was much confusion in the wake of FERA and the ACA's changes to the definition of "overpayment" and the tolling of the 60-day period described above. In particular, it was unclear from the language of the ACA when an overpayment was considered "identified." CMS sought to clarify these issues through regulation, issuing Final Rules applicable to Medicare Advantage plans in 2014,[T] and to FFS Medicare providers in 2016.

The Medicare Advantage Plan Overpayment Final Rule subjected Medicare Advantage plans to FCA liability for submitting any diagnostic code with inadequate documentation in an enrollee's medical chart if identified by the plan and the overpayment (due to inadequate diagnosis information) is not repaid within 60 days. The Final Rule defined "identification" as when a plan "has, or should have through the exercise of reasonable diligence, determined that the [plan] has received an overpayment." The FFS [Medicare] Final Rule defined "identification" similarly but added that the obligation to repay the overpayment (i.e., the 60-day "return" window) does not start until the provider has also "quantified the amount of the overpayment." This distinction is significant, as the time between discovering (or otherwise being notified) that one received overpayments and conducting a sufficient financial audit to determine the exact amount of the overpayment may be substantial.

With such a short (60-day) report and return window, this clarification eases the otherwise significant "reverse false claims" burden on providers operating in the FFS Medicare payment context. However, no such caveat exists with respect to the Medicare Advantage plan obligation to report and return an overpayment. This creates a heavier burden on Medicare Advantage plans because the definition of a false "claim" for a Medicare Advantage plan may encompass use of incorrect information in connection with complex actuarial tools and processes (e.g., risk-adjustment data, bid generation) and the amount of time it would take to quantify the full amount of the overpayment could take much longer than 60 days from identification. This issue (with respect to Medicaid managed care plans[U] as well as Medicare Advantage plans) has been brought before several courts, with mixed results.

[T] Note that CMS issued the Final Rule applicable to Medicare Advantage Plans without providing for the notice or comment period required in the Administrative Procedure Act. (See, e.g., *UnitedHealthcare Insurance v. Azar*)

[U] *Kane et al v. HealthFirst, Inc.* effectively created a loophole in the "60-day obligation to repay" standard in a case regarding a Medicaid managed care plan; the court held that while the negligence standard for intent was appropriate with respect to overpayment identification, it is "only when an obligation is knowingly concealed or knowingly and improperly avoided or decreased that a provider has violated the FCA."

FCA Liability, Overpayments, and the Role of Intent

CMS clarified in its rulemakings that "[t]he 60-day time period begins when either the reasonable diligence is completed or [if the person failed to conduct reasonable diligence] on the day the person received credible information of a potential overpayment…" The Final Rules define "reasonable diligence" as "at a minimum… proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments and investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment." Under these definitions, a Medicare Advantage plan or a FFS Medicare provider could be subject to FCA liability simply for failing to conduct proactive compliance activities. A negligence standard for reverse false claims liability (i.e., "has determined or should have determined through the exercise of reasonable diligence") is much less stringent than the knowledge requirement for standard false claims submission (i.e., actual knowledge, deliberate ignorance, or reckless disregard) and it is unclear why CMS elected to assign a lower threshold of intent for reverse false claims liability.

Changes to the Overpayment Final Rule(s)

In 2018, the U.S. District Court for the District of Columbia vacated the Medicare Advantage Plan Overpayment Final Rule in *UnitedHealthcare Insurance v. Azar*. In the *Azar* decision, the Court held that CMS had [improperly] applied a simple negligence standard (described above) to FCA liability. Because the FFS [Medicare] Overpayment Final Rule utilizes the same simple negligence standard as the vacated Medicare Advantage Plan Overpayment Final Rule, it is unclear whether CMS' definition of the intent required for overpayment liability will remain in effect for FFS Medicare providers.

The decision to vacate the Overpayment Final Rule was also based on two other key findings. The *Azar* Court held that CMS did not comply with actuarial equivalence requirements in the Medicare Advantage Overpayment Final Rule because it would have used a sample of Medicare Advantage plan member records to extrapolate an overall error rate for the Medicare Advantage plan without accounting for the fact that the data sources from FFS Medicare and from Medicare Advantage are not compatible. CMS proposed to use audited medical charts to determine overpayments to Medicare Advantage insurers, while using unaudited FFS Medicare records to determine payments to Medicare Advantage plans, thus systemically devaluing payments to Medicare Advantage plans. The Court found that CMS applied "a more searching form of scrutiny than CMS applies to its own enrollee data."

The *Azar* Court held that CMS failed to comply with Administrative Procedure Act (APA) requirements, which govern the regulatory rulemaking process. For these three reasons, the Court vacated the overpayment rule.

While the *Azar* decision theoretically prevents CMS from proceeding with its overpayments rule for Medicare Advantage as planned, CMS issued a proposed rule addressing a number of policy issues for Medicare Advantage, including an updated RADV audit methodology, a few months after the *Azar* decision. In the proposed rule, CMS reverses its 2012 reasoning and states that a FFS adjuster would be inappropriate. Instead, CMS proposes to extrapolate the results of RADV audits to entire contracts without adjusting for differences between FFS and MA data.[52] In addition, the government has appealed the *Azar* ruling; the appeal is currently pending U.S. District Court for the District of Columbia.[53]

VII. Looking Ahead

The FCA plays an important role in preventing and penalizing fraud and decreasing waste and abuse within the Medicare program generally. However, that role lacks the clear parameters in Medicare Advantage that it has in the FFS Medicare context, forcing courts to construe the structure of the Medicare Advantage program as simply a version of FFS Medicare.

This construction is not accurate when the role Medicare Advantage plays in the Medicare program is to be a more efficient and coordinated option with an entirely different payment structure than the FFS Medicare payment system, which inherently eliminates many of the incentives the FCA is intended to guard against. The federal government has long recognized that Medicare Advantage plans should be treated differently under the fraud and abuse laws because they assume full financial risk for their enrollees. For example, the Department of Health and Human Services (HHS) Office of Inspector General (OIG), primarily responsible for enforcement of the federal anti-kickback statute (AKS), recently noted that "managed care arrangements do not present the same risks of overutilization or increased Federal health care program cost that exists with many fee-for-service payment arrangements"[54] in its interpretation of one of the three AKS exceptions that protect various managed care arrangements with providers and other contractors.[55]

While the FCA has been used effectively to combat fraud and abuse in the FFS Medicare context, it is much more difficult to align its provisions with the structure of the Medicare Advantage program itself and the concept of capitated payment. Novel theories of FCA application to managed care have been tested, but few cases have resulted in clear outcomes. Instead, most such cases are brought by whistleblowers (with the government declining to intervene and provide the resources necessary to effectively pursue a case against a large insurance plan) and dismissed for procedural reasons.[56] Where the government has elected to pursue a case against a managed care arrangement, the result is often a deferred prosecution agreement, a settlement, or similar vehicle that does not result in a court decision and thus does not offer precedent for similar scenarios.

For example, CMS' RADV audits on a diagnosis code-by-diagnosis code basis and overpayment scrutiny do not acknowledge that capitation is designed to pay accurately on average (not per claim). A risk score may over-predict costs for one enrollee and under-predict costs for another, but on average, the capitated payment gets it approximately right for a population of enrollees. Furthermore, where a plan mistakenly reports a diagnosis code in error for one enrollee (that could be used to extrapolate

an overall error rate on which an overpayment could be predicated based on CMS' interpretation), the plan also may mistakenly report a diagnosis code that is lower than the actual diagnosis and level of services provided or fail to report a diagnosis code at all. In this case as well, the capitation model is designed to set a payment rate for an overall population rather than an enrollee-by-enrollee rate, and as such, the enrollee-by-enrollee accounting is at odds with the fundamental nature of capitated payments and with the bidding model used in Medicare Advantage. It is arguable that Medicare Advantage plan payments are only overpayments if the total amount that CMS pays to the plan is too high across its entire enrollee population. This distinction is not a concern in a FFS Medicare payment system, where each service billed stands on its own. Even if defining overpayment in this manner is the applied application of the FCA to Medicare Advantage plans, it still does not provide clarity on how CMS could efficiently and effectively determine that its entire payment to a Medicare Advantage plan was "too high." Given the *Azar* decision, CMS' use of data sampling and error rate extrapolation (without applying similar scrutiny to all FFS Medicare claims) is, at the very least, an unsettled issue.

As the Medicare program continues to move away from FFS Medicare towards expanded capitated payments to insurers such as Medicare Advantage plans and clinically and financially integrated organizations such as accountable care organizations (ACOs), application of the FCA will continue to be less clear. The focus on encouraging and financially incentivizing coordination of the health and well-being of a population coupled with capitated payment models that shift financial risk to providers and organizations eliminates volume-based incentives inherent under FFS Medicare in favor of outcomes-based incentives. This re-alignment of incentives does not align with the underlying claims-based enforcement approach of the FCA.

There are a number of mechanisms through which the current interpretation and enforcement of FCA could be modified to better ensure that actual fraud and abuse is identified and penalized while innovation in care delivery and payment models that are inherently designed to reduce the opportunity for fraud and abuse are recognized and encouraged (rather than stifled). For example, Congress could modify the statutory text of the FCA to clarify the types of arrangements and payment models, such as capitated payment arrangements that meet certain criteria, that would be exempt from prosecution (similar to the exceptions and safe harbors found in other fraud and abuse statutes). Alternatively, or in addition, CMS could issue a request for information (RFI) soliciting industry feedback on these issues and incorporate the findings into a proposed and final Medicare Advantage rule that would address the issues particularly surrounding

the concept of overpayments and risk adjustment methodologies (or incorporate these issues into the annual rulemaking process). Furthermore, CMS could use other statutory authorities to address potential fraud and abuse in the Medicare Advantage program. For example, rather than attempting to apply the FCA to capitated payment arrangements, CMS could use its civil monetary penalty (CMP) authority[57] as an enforcement mechanism to penalize health plans that have repeated high error rates. Health plans that fail to correct their processes would face increasing financial penalties and possible exclusion from the Medicare Advantage program. As described above, the courts also play a role in the interpretation of the FCA as it relates to Medicare Advantage and could continue to provide guidance through their decision-making authority on the scope and enforcement of FCA in the Medicare Advantage context. These decisions could be incorporated into future rulemaking or demonstrate a need for legislative and/or regulatory action.

Whether these paths or others are pursued, stakeholders must recognize the need to modernize the legal and regulatory framework as the health-care care delivery and payment system transforms in ways that stretch beyond the current legal framework to achieve the shared goal of reducing costs to protect the sustainability of these programs and improving the quality of health and healthcare for Medicare beneficiaries.

Endnotes

[1] *See, e.g.,* Avalere Health (2018). "Medicare Advantage achieves cost-effective care and better outcomes for beneficiaries with chronic conditions relative to fee-for-service Medicare." Available from: http://go.avalere.com/acton/attachment/12909/f-0571/1/-/-/-/-/BMA%20Report.pdf?nc=0&ao_optin=1.

[2] Barrette E and McGraves-Lloyd K (2016). "Data brief #5: Medicare Advantage health care utilization: Hospital readmissions," Health Care Cost Institute. Available from: https://www.healthcostinstitute.org/images/easyblog_articles/108/MA-readmissions---data-brief-5.pdf; Baicker K, Chernew M, and Robbins J (2013). "The spillover effects of Medicare managed care: Medicare Advantage and hospital utilization," J. Health Econ; 32(6): 1289-1300.

[3] 42 C.F.R. § 1003.101 (2019).

[4] Supra n.1.

[5] CMS.gov (2019). "Contract summary: 2019-05," Centers for Medicare & Medicaid Services. Available from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics- Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report.

[6] Id.; U.S. Department of Health and Human Services (2018). "Centers for Medicare & Medicaid Services: Medicare," pp. 51-56. Available from: https://www.hhs.gov/sites/default/files/Consolidated%20BIB_ONLINE_remediated.pdf.

[7] Kaiser Family Foundation (2019). "Fact Sheet: Medicare Advantage." Available from: https://www.kff.org/medicare/fact-sheet/medicare-advantage/.

[8] Barreto T, Bazemore A, Coffman M, Jabbarpour Y, and Liaw W (2017). "Bright spots in care management in Medicare Advantage," Washington, DC: Better Medicare Alliance and the Robert Graham Center. Available from: https://www.bettermedicarealliance.org/sites/default/files/2017-06/Bright%20Spots%20in%20Care%20Management%20Report.pdf.

[9] *See, e.g.,* Gold M and Casillas G (2014). "Report: What do we know about health care access and quality in Medicare Advantage versus the traditional Medicare program?" Washington, DC: Kaiser Family Foundation. Available from: https://www.kff.org/medicare/report/what-do-we-know-about-health-care-access-and-quality-in-medicare-advantage-versus-the-traditional-medicare-program/.

[10] Pub. L. No. 115-123, § 50322 (February 9, 2018); see also, CMS News (April 01, 2019). "CMS finalizes Medicare Advantage and Part D payment and policy updates to maximize competition and coverage." Available from: https://www.cms.gov/newsroom/press-releases/cms-finalies-medicare-advantage-and-part-d-payment-and-policy-updates-maximize-competition-and.

[11] Supra n.2.

[12] Johnson G, Figueroa JF, Zhou X, Orav EJ, and Jha AK (2016). "Recent growth in Medicare Advantage enrollment associated with decreased FFS spending in certain US counties," Health Aff; 1(35): 1707-15.

[13] Baicker K and Robbins JA (2015). "Medicare payments and system-level health-care use: The spillover effects of Medicare managed care," Am J Health Econ; 1(4): 399-431.

[14] Moffit RE, Numerof RE, and Buseman CM (2018). "Let the market compete: Learning from Medicare Advantage to move toward value-based care," Health Aff. Available at: https://www.healthaffairs.org/do/10.1377/hblog20180122.210298/full/.

[15] *See, e.g.,* Levine M and Buntin M (2013). "Working paper 2013-06: Why has growth in spending for fee-for-service Medicare slowed?" Washington, DC: Congressional Budget Office. Available from: https://www.cbo.gov/sites/default/files/44513_MedicareSpendingGrowth-8-22.pdf.

[16] Supra n.15 at pp. 3-6.

[17] *See, e.g.,* Langwell KM and Hadley JP (1986). "Capitation and the Medicare program: History, issues, and evidence," Health Care Financ Rev; 1986(Suppl.): 9-20; James BC and Poulsen GP. "The case for capitation," Harvard Bus Rev. (July/Aug 2016). Available from: https://hbr.org/2016/07/the-case-for-capitation.

[18] *See, e.g.*, Institute of Medicine (2000). "Chapter 4: Description of the current Medicare payment system and its historical roots," In Medicare laboratory payment policy: Now and in the future. Miller WD, Kalfoglou AL, and LeRoy L (eds). Washington, DC: Nat'l Academ Press. Available from: https://www.nap.edu/read/9997/chapter/6.

[19] CMS.gov (2019). "Design and development of the Diagnosis Related Group (DRGs)," In ICD-10-CM/PCS MS-DRG v.37.0 definitions manual. Baltimore, MD: Centers for Medicare & Medicaid Services. Available from: https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/Design_and_development_of_the_Diagnosis_Related_Group_(DRGs).pdf.

[20] Medicare Learning Network (2019). "MLN Fact Sheet: Hospital Outpatient Prospective Payment System," Centers for Medicare & Medicaid Services. Available from: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HospitalOutpaysysfctsht.pdf.

[21] *See, e.g.*, supra n.5.

[22] Congressional Record – Senate at S 20340 (December 16, 1970). Available from: https://www.ssa.gov/history/pdf/Downey%20PDFs/Amendments%20to%20the%20Social%20Security%20Act%20 1969-1972%20Vol.%208.pdf; Cromwell J. and Burstein P (1985). "Physician losses from Medicare and Medicaid discounts: How real are they?" Health Care Financ Rev;6(4):51-68.

[23] Uyehara E. and Thomas M (1975). "Health maintenance organization and the HMO Act of 1973." Santa Monica, CA: Rand Corp. Available from: https://www.rand.org/content/dam/rand/pubs/papers/2009/P5554.pdf.

[24] Bourdon T, Passwater K, and Priven M (1997). "An introduction to capitation and health care provider excess insurance," Casualty Actuarial Society Discussion Paper Program; 1997: 97-139. Available from: https://www.casact.org/pubs/dpp/dpp97/97dpp097.pdf.

[25] Centers for Medicare & Medicaid (2015). "Milestones 1937-2015." Available from: https://www.cms.gov/About-CMS/Agency-Information/History/Downloads/Medicare-and-Medicaid-Milestones-1937-2015.pdf.

[26] Id.

[27] Centers for Medicare & Medicaid Services (2015). "Report to Congress: Alternative payment models & Medicare Advantage." Available from: https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/Report-to-Congress-APMs-and-Medicare-Advantage.pdf.

[28] Supra n.25.

[29] Supra n.7.

[30] CMS.gov (2019). "Health plans – general information." Available from: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/index.html

[31] Supra n.25.

[32] Kronick R and Welch WP (2014). "Measuring coding intensity in the Medicare Advantage program," Medicare Medicaid Res Rev;4(2): E1-E19.

[33] Pub. L. No. 111-148 (March 23, 2010), § 3201 (*as modified by* §10318 of PPACA and § 1102 of Reconciliation Act).

[34] CMS.gov (2018). "Medical loss ratio." Available from: https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/MedicalLossRatio.html.

[35] Centers for Medicare & Medicaid Services (2007). "Advance notice of methodological changes for Calendar Year 2008 for Medicare Advantage (MA) capitation rates." Available from: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2008.pdf.

[36] Centers for Medicare & Medicaid Services (2008). "Advance notice of methodological changes for Calendar Year (CY) 2009 for Medicare Advantage (MA) capitation rates and Part D payment policies," at 12. Available from: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/advance2009.pdf.

[37] Supra n.32.

[38] Supra n.32.

[39] Brief of Defendant at 19, *United Healthcare Ins. Co. v. Azar*, 1:16-cv-0157-RMC, ECF No. 64 (D.D.C. Feb. 12, 2018).

[40] 42 CFR § 423.265 (2019).

[41] 83 Fed. Reg. 54982 (November 1, 2018).

[42] Centers for Medicare & Medicaid Services (2012). "Notice of final payment error calculation methodology for Part C Medicare Advantage risk adjustment data validation contract-level audits." Available from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.

[43] *UnitedHealthcare Insurance et al v. Azar*, 330 F.Supp. 3d 173 (2018).

[44] Id. at 187.

[45] S. Rep. No. 99-345: The False Claims Reform Act of 1985 (1986).

[46] 31 USC § 3729(b)(2) (2019).

[47] 42 U.S.C. § 1320a-7b (2019).

[48] *Allison Engine Co. v. United States ex rel. Sanders*, 128 U.S. 2123 (2008).

[49] 31 U.S.C. §3729(a)(1), (2) (*as amended by* FERA, Pub. L. No. 111-21, § 4 (May 20, 2009)).

[50] Supra n.32 at E4.

[51] Id.

[52] Supra n.42.

[53] *See, United Healthcare Insurance Co., et al. v. Alex Azar, et al.* Available from: https://www.pacermonitor.com/public/case/26194670/UnitedHealthcare_Insurance_Co,_et_al_v_Alex_Azar,_et_al.

[54] *See,* OIG Advisory Opinion No. 18-11 (2018). Available from https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-11.pdf.

[55] 42 C.F.R. § 1001.952 (l), (m), and (t) (2019).

[56] *See, e.g.*, Laemmle-Weidenfeld L (2015). "Managed care and the False Claims Act: A brief survey of cases." Available from: https://www.healthlawyers.org/Events/Programs/Materials/Documents/FC15/aa_laemmleweidenfeld.pdf.

[57] Supra n.3.