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Plans and Providers in the Changing Health Care Delivery Environment

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Much has been written regarding the legal and regulatory risks that First Tier, Downstream, and Related Entities (FDRs) providing administrative services can create for the plan sponsors (Plan Sponsors) of Medicare Advantage (MA) and Medicare Part D (Part D) plans (Plans). Plan Sponsor relationships with provider organizations and with contracted providers are equally critical to the success of Plans. Indeed, new Centers for Medicare & Medicaid Services (CMS) initiatives, such as Value Based Insurance Design (VBID), underscore the importance of Plan Sponsors' partnerships with provider organizations and contracted providers. Recent events, including a February 2015 federal grand jury indictment of a physician on eight counts of criminal health care fraud based on allegations that he systematically fabricated diagnosis codes for MA patients, however, have brought into focus the legal and regulatory risks that health care service providers can create for Plan Sponsors.

MA and Part D Plans and FDRs

Plan Sponsors contract with outside entities, often referred to as FDRs, to perform various administrative services and health care functions to satisfy their contractual obligations to CMS. Plan Sponsors often choose to deliver Plan services (e.g., call center support, care management) by engaging an FDR that can provide a turn-key solution rather than developing and managing internal processes. Among other benefits, this creates efficiencies when an external event, such as a change in guidance from CMS, necessitates a rapid operational response. Moreover, most Plan Sponsors rely on external, contracted providers to supply the items and services required to meet the health care needs of their members.[1]

Although CMS acknowledges and expressly approves of the engagement and use of FDRs by Plan Sponsors, CMS essentially disregards their existence on any issue relating to a particular Plan Sponsor's compliance with its obligations to CMS, focusing

[1] Although few MA plans have crossed over into the provider space, there are many health care providers, particularly larger hospital systems, that have developed their own MA products that rely primarily, if not exclusively, on their affiliated providers. *See e.g.,* www.hopkinsmedicine.org/news/media/releases/johns_hopkins_launches_all_new_medicare_advantage_product.

exclusively on the Plan Sponsor. Because CMS attributes the actions of FDRs to Plan Sponsors, FDRs can create a substantial amount of regulatory and compliance risk for the Plan Sponsors that engage them. Put differently, regardless of how a Plan Sponsor chooses to fulfill its contractual and regulatory obligations to CMS or whom it engages to do so, CMS holds the Plan Sponsor ultimately and absolutely responsible for the fulfillment of those obligations.[2] These subcontracting relationships also can create an additional layer of legal risk given the need for accuracy in payment data submitted to CMS and the potential for liability under the False Claims Act (FCA) for any inaccuracies in such data.

CMS has emphasized that Plan Sponsors must actively oversee and monitor their FDRs' compliance with MA and Part D regulations, CMS requirements, and the Plan Sponsor's contractual obligations with CMS.[3] To reinforce this point, CMS has expanded its use of penalties against Plan Sponsors for noncompliance by their FDRs by auditing plan oversight of FDRs and levying civil monetary penalties on plans for the failures of their FDRs.[4] Because of the breadth of risks that FDRs can create, Plan Sponsors should take great care in selecting their subcontractors and carefully assess the risks posed by any potential arrangement. Plan Sponsors should perform this due diligence process not only to confirm that an FDR is capable of performing the services at issue[5] and has a clear understanding of the regulatory environment surrounding the MA program, but also to understand how the vendor will perform the services, the risks that the vendor could create for the plan once the relationship is formed and the work begins, and how to mitigate those risks.

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[2] *See* Centers for Medicare & Medicaid Services, Medicare Managed Care Manual, Ch. 21, Compliance Program Guidelines, § 40.
[3] *Id*.
[4] *See e.g.,* 2015 Program Audit Protocols and Process Updates, HMPS Memo (Feb. 13, 2015); Part C and D Compliance Program Effectiveness, Audit Process and Data Request; *see also* Common Conditions, Improvement Strategies, and Best Practices Based on 2013 Program Audit Reviews, HPMS Memo (Aug. 27, 2014).
[5] When a plan sponsor is delegating to an FDR the fulfillment of a contractual obligation to CMS, the plan sponsor must conduct a pre-delegation audit of the FDR. *See* Medicare Managed Care Manual, Chapter 9, Section 110.2. In all other instances, CMS does not expressly require such audits.

FDR Relationships with Provider Organizations

Plan Sponsors sometimes delegate to their contracted providers administrative functions in addition to health care-related functions for their MA and Part D Plans.[6] The functions more commonly subcontracted to provider organizations (or to organizations that include providers) include utilization management, credentialing, disease management and medication therapy management (MTM) programs, quality improvement, and provider network management. Many of these Plan functions and programs help ensure that beneficiaries can receive quality care in an efficient manner. The provider organizations performing these functions can affect not just the quality of care provided to individual beneficiaries, but also how efficiently and effectively a Plan can function.

Plans, for example, receive annual Star Ratings, which assess plan performance on an array of measures, including 33 measures for MA and 13 measures for Part D Plans in 2015. Much of what these measures assess is often in the hands of provider organizations and sometimes even individual providers, including health screenings, tests, and vaccines; management of chronic or long term conditions; the member experience with the plan, member complaints, and customer service; and drug safety and accuracy of drug pricing.[7] Star Ratings affect Plans' ability to attract enrollees and whether Plans receive quality bonus payments, which factor into the capitated amount MA plans are compensated for each plan member.[8] Low Star Ratings, therefore, can limit a Plan's chance to succeed and can even lead to termination of a Plan Sponsor's contract with CMS.[9]

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[6] *See supra* note 2.
[7] 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Apr. 6, 2015).
[8] *Id.; See* Section 1853(o) of the Social Security Act, 42 USC 1395w-23(o).
[9] 42 CFR §§ 422.510 (a)(4)(xi); 423.509 (a)(4)(x).

Risks Created by Contracted Providers

In addition to the possibility of lower Star Ratings, providers can create legal and regulatory risk for Plan Sponsors based on the role they play in the risk adjustment process. Under the MA program, CMS pays Plan Sponsors a capitated amount for each enrolled Medicare beneficiary, which is adjusted based on the actuarial risk a particular member poses to the Plan. The second payment component varies depending on data collected and submitted by Plan Sponsors, including the diagnosis codes (previously ICD-9 and now ICD-10) reflected in the member's medical records.[10] Because a member's health care providers document such codes and generate such records, the accuracy of the risk adjustment payments that a Plan Sponsor receives from CMS are dependent on the accuracy and integrity of the work performed by those providers. Plan Sponsors, therefore, must structure and administer their provider relationships to ensure the accuracy and integrity of the records that they create.

A recent example from Florida illustrates some of the risks contracted providers can create for Plan Sponsors regarding risk adjustment payments. In February 2015, a federal grand jury in Florida indicted a physician on eight counts of criminal health care fraud based on allegations that he systematically fabricated diagnosis codes for MA patients in order to make them appear sicker than they actually were and thereby increase their risk adjustment scores.[11] Although providers do not normally have any financial incentive to report inaccurate diagnosis codes insofar as their reimbursement is typically dependent on the Healthcare Common Procedure Coding System/Current Procedural Terminology codes that they report, this physician had entered into capitated payment arrangements with MA plans under which at least a portion of his compensation was tied directly to the payments that the plans received from CMS. By reporting inaccurate diagnosis codes for his patients, the physician could increase the risk adjustment payments that the MA plans would receive from CMS and thereby increase his compensation from the MA plans.

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[10] *See* Centers for Medicare & Medicaid Services, Medicare Managed Care Manual, Ch. 7, §§ 10-60, 120.

[11] *See United States of America v. Issac Kojo Anakwah Thompson*, No. 9:15-CR-80012-WJZ (S.D. Fla. Feb. 3, 2015).

None of the MA Plan Sponsors that contracted with the physician were accused of any wrongdoing in that case,[12] and one of the Plan Sponsors has publicly disclosed a repayment that it made to CMS in connection with the physician. Nevertheless, these Plan Sponsors face the possibility of a targeted risk adjustment data validation audit by CMS, which could result in significant repayment requests, or civil litigation under the FCA related to the work that the physician performed on their behalf. Such risks flow from the nature of the compensation arrangement that the MA plans agreed to with the physician. The recent indictment in Florida, therefore, serves to underscore the importance of a Plan Sponsor understanding the risks in its relationships with contracted providers, including the incentives created by compensation arrangements, and ensuring appropriate oversight to safeguard against those risks.

Recent CMS Initiatives and the Provider-Plan Relationship

Recent CMS initiatives to improve health outcomes and move toward VBID also turn attention to the plan-provider relationship, in particular the need for Plan Sponsors to deepen their understanding of the care delivery models of provider organizations with which they contract or include in their network. These CMS initiatives also may indicate the beginning of a new focus on if and how the relationship between Plan Sponsors and such providers, even point-of-service or point-of-sale providers, can affect plans' ability to comply with regulatory requirements, to meet CMS' expectations, and to serve their beneficiaries.

[12] The Thompson indictment, therefore, appears to differ from recent qui tam cases involving risk adjustment data, in which Plans have been accused of "rampant fraud" or "turning a blind eye to the truth" by former employees. *See* Complaint at ¶ 9, *U.S. ex. rel. Valdez v. Aveta, Inc., et al.*, 2:11-cv-03343 filed in U.S. District Court, Central District of California (Apr. 20, 2011). *See* Complaint at ¶ 40, *U.S. ex. rel. Silingo vs. Mobile Medical Examination Services, Inc.,* No. 8:13-cv-01348(C.D. Cal. Aug. 30, 2013).

Part D Enhanced MTM Model Test

Part D Plans and MA Plans with prescription drug coverage must offer MTM programs,[13] which aim to reduce the risk of adverse events, such as drug interactions, and improve therapeutic outcomes for beneficiaries with multiple chronic conditions who take multiple Part D drugs and who are likely to incur significant drug costs.[14] In doing so, MTM programs seek to improve health outcomes for beneficiaries and avoid additional costs associated with adverse events. CMS recently increased its emphasis on MTM as a measure of Part D Plan quality by making the completion rate for MTM comprehensive medication reviews, currently a Part D Star Ratings display measure, also a process measure for Part D Star Ratings.[15]

Not surprisingly, providers and pharmacists play an important role in MTM. MTM programs, for example, must be developed in conjunction with pharmacists and physicians and must include consultations to beneficiaries' prescribers to resolve medication-related problems.[16] Likewise, certain services required as part of MTM programs, such as annual comprehensive medication reviews, must be performed by pharmacists or other qualified providers.[17] These providers, however, are primarily employed by MTM vendors or are plan-sponsor or pharmacy benefit manager pharmacists, and are not necessarily those prescribing medications or filling prescriptions for individual beneficiaries.[18]

The recently announced Part D Enhanced MTM Model test, however, suggests that Plans and providers, including beneficiaries' prescribers and pharmacists, may need to forge closer relationships in order to meet CMS expectations.[19] Currently, an MTM

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[13] 42 C.F.R. § 423.153(a).
[14] The core chronic conditions used to identify beneficiaries for targeting for an MTM program include the following: hypertension, heart failure, diabetes, dyslipidemia, respiratory disease or chronic lung disorders, bone disease-arthritis, or mental health. 42 CFR § 423.153(d); Centers for Medicare & Medicaid Services, Prescription Drug Benefit Manual, Ch. 7, § 30.2.
[15] 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Apr. 6, 2015), at 88.
[16] *See* Centers for Medicare & Medicaid Services, Prescription Drug Benefit Manual, Ch. 7, § 30.
[17] 42 C.F.R. 423.153(d); Prescription Drug Benefit Manual, Chapter 7, § 30.
[18] *See* www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2015-MTM-Fact-Sheet.pdf.
[19] The initial model test will run for five years, from 2017-2021, in five regions: Region 7 (Virginia), Region

program must provide uniform offerings to all Plan beneficiaries that meet the program's criteria, leading, in CMS' estimation, to both an under- and an over-identification of beneficiaries who would benefit from MTM.[20] The MTM Model test would allow participating Plans, beginning in 2017, to stratify beneficiaries based on medication-related risk and to provide more individualized interventions as part of their MTM programs. In other words, Plans will be able to offer different participating beneficiaries different MTM services, directing more or different services to those most at risk.

CMS specified that Plans cannot meet the goals of the MTM Model test on their own, but will need to work closely with their network-pharmacy providers and their beneficiaries' prescribers to identify all their beneficiaries who would benefit from enhanced MTM and to stage effective, more individualized interventions.[21] For example, CMS recommended Plans place "[g]reater reliance on local pharmacists to identify at-risk individuals (consistent with plan protocols) and to [provide] targeted counseling and other MTM services at teachable moments and in 'small bites'" and to rely on prescribers to identify beneficiaries who should be referred for MTM services.[22] CMS cautioned that both Plans and MTM vendors will need to involve prescribers and treating physicians more extensively in their MTM programs and will need to increase communications with and the flow of information between Plans and prescribers.[23] In short, Plans cannot succeed without the full cooperation of providers.

VBID

The recently announced CMS VBID initiative likewise underscores the plan-provider relationship and the increasing interdependence between Plans and provider organizations even with regard to plan design. The MA VBID model, starting January 1,

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11 (Florida), Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona). Announcement of Part D Enhanced Medication Therapy Management Model Test, HMPS Memo (Sept. 28, 2015), at 1.

[20] Announcement of Part D Enhanced Medication Therapy Management Model Test, HMPS Memo (Sept. 28, 2015), at 2.

[21] *Id.* at 3.

[22] *Id.* at 5.

[23] *Id.* at 11-12.

2017, will allow participating MA Plans in seven states[24] to implement health plan design elements, including member cost-sharing, to encourage the use of high-value clinical services and the most cost-effective care by targeted enrollees.[25] Such clinically nuanced plan design recognizes that the value of a service can vary based on a beneficiary's underlying health status and marks a significant shift in MA's uniformity requirement, which prohibits different plan design based on an enrollee's health status.[26]

Plans are not given carte-blanche over plan design in the VBID model test. Interventions must fall into one of the following four categories: (1) reduced cost-sharing for high-value services; (2) reduced cost-sharing for high-value providers; (3) reduced cost-sharing for enrollees participating in disease management or related programs; or (4) clinically targeted additional supplemental benefits.[27] Eligible enrollees include those with diabetes, congestive heart failure, chronic obstructive pulmonary disease (COPD), past stroke, hypertension, coronary artery disease, mood disorders, or combinations of these conditions, as determined by ICD-10 code.[28] While Plans can vary their interventions among targeted populations (i.e., offering one intervention to enrollees with COPD and another to those with diabetes), all must be benefit enhancements, or "carrots," and not "sticks" that might reduce a targeted enrollee's benefits or lead to higher cost-sharing. Similarly, Plans can require only that enrollees meet participation milestones, not achieve clinical goals.[29]

Plans participating in the VBID model test will need to look closely at the providers in their networks to understand which providers should be designated as high-value providers and which can provide high-value services. Providers also must be vested in the success of the VBID model, both in encouraging their patients to enroll in clinically nuanced interventions and in providing clinically appropriate, high-value services. The

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[24] These states are Arizona, Indiana, Iowa, Massachusetts, Oregon, Pennsylvania, and Tennessee. Announcement of Medicare Advantage Value-Based Insurance Design Model Test, HPMS Memo (Sept. 1, 2015), at 1.
[25] *Id*.
[26] 42 C.F.R. §§ 422.2 (definition of an MA plan), 422.100(d)(2) & 422.254(b)(2).
[27] *Supra* note 24 at 7-10.
[28] *Supra* note 24 at 6.
[29] *Supra* note 24 at 9-10.

success of the VBID model also depends on beneficiaries being motivated to seek high-value services from high-value providers and to meaningfully participate in the VBID interventions. While Plans can provide an incentive for participation with reduced cost-sharing and other "carrots," some motivation will come down to the power of the individual provider-patient relationship.

Conclusion

Plan Sponsors have long partnered with FDRs to fulfill the complicated operational challenges of sponsoring an MA or Part D Plan. In so doing, however, Plan Sponsors have learned that they must diligently oversee and police their FDRs. The changing health care delivery environment, marked by initiatives such as VBID and the Enhanced MTM Model test, means that Plan Sponsors must work more closely with provider organizations and individual providers to deliver quality care to beneficiaries and to steward health care resources. Even under these new models, however, Plan Sponsors will need to remain watchful for and safeguard against the legal, regulatory, and compliance risks created by their FDR relationships with provider organizations and sometimes even their contracted providers.

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