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Reimbursement and Payor Dispute Update

POLSINELLI REIMBURSEMENT TEAM NEWSLETTER

Federal Cases Offer Medicare-Enrolled Providers Possible Injunctive Relief from Recoupments While Awaiting Administrative Appeal

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On June 28, 2018, the United States District Court for the Northern District of Texas entered a judgment granting Family Rehab, a home health agency, a preliminary injunction against the Centers for Medicare and Medicaid Services (CMS), restraining the agency from withholding Medicare payments and receivables until Family Rehab's overpayment appeal could be heard in front of an Administrative Law Judge (ALJ).[2] While this decision ended a long legal saga between Family Rehab and CMS, the decision by the district court, and the 5th Circuit before it, has opened a Pandora's Box across the country in regards to how courts are treating similar cases. One year later, there is a divisive split among the circuit and district courts. Several courts have found that they have jurisdiction to hear motions for injunctive relief and often grant TROs and preliminary injunctions against CMS to stop recoupments. However, just as many have found that they lack jurisdiction and therefore cannot hear the issue, leaving providers to resolve their issues through the administrative process. Broken down even further, there appears to be one central issue at question: Do health care facilities possess a property interest in Medicare payments or Medicare agreements?

When a health care provider is notified by a CMS contractor that it has been overpaid by CMS, the provider may enter what the Fifth Circuit has described as "the harrowing labyrinth of Medicare appeals."[3] First, the provider may submit to a Medicare Administrative Contractor (MAC) a claim for redetermination of the overpayment.[4] Second, it may seek reconsideration from a Qualified Independent Contractor (QIC) hired by CMS.[5] If the QIC affirms the MAC's determination, CMS may,

[1] Robby Morris, Juris Doctorate Candidate, Georgetown University, 2020, assisted with the drafting of this article.

[2] *Family Rehab., Inc. v. Azar*, No. 3:17-CV-3008-K, 2018 WL 3155911, at *7 (N.D. Tex. June 28, 2018).

[3] *Family Rehab., Inc, v. Azar*, 886 F.3d 496, 499-500 (5th Cir. 2018).

[4] 42 U.S.C. § 1395ff(a)(3)(A).

[5] *Id.* § 1395ff(c), (g); 42 C.F.R. § 405.904(a)(2).

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and often does, begin recouping the alleged overpayment by garnishing future reimbursements to the provider.[6] Third, the provider may request a *de novo* review before an independent ALJ, where the provider presents testimony, cross-examines witnesses and submits statements of law and fact.[7] By statute, the ALJ "shall conduct and conclude a hearing ... and render a decision ... not later than" 90 days after a timely request.[8] Forth, a provider may request an appeal to the Medicare Appeals Council, who reviews the ALJ's decision *de novo* and is bound by a similar 90 day timeline.[9] If the ALJ does not issue a decision within the allocated 90 days, the provider may "escalate" the appeal to the Council, which reviews the QIC's decision.[10] However, the current backlog of appeals within the Department of Health and Human Services has created a delay of three to five years before a provider may get a hearing with an ALJ.[11]

Federal courts, under U.S.C. § 405(g) and (h), are vested with jurisdiction over claims "arising under" the Medicare Act only after a final decision has been rendered by HHS.[12] However, under the "collateral-claim exception," jurisdiction may lie over claims (a) that are "entirely collateral" to a substantive agency decision and (b) for which "full relief cannot be obtained at a postdeprivation hearing."[13] The Fifth Circuit was the first court to find that a provider met both exceptions, holding that, because Family Rehab only sought to have recoupment suspended until an ALJ hearing and the likelihood of irreparable harm if recoupment continued, their claims were collateral, and the court could exercise jurisdiction over them.[14] Prior to this ruling, similar cases were dismissed for failure to exhaust administrative remedies.[15]

In order for a due process claim to succeed, there needs to be an asserted property or liberty interest.[16] The Fifth Circuit, in deciding *Family Rehab*, did not declare whether Family Rehab actually possessed a property interest in Medicare payments. However, the court held that because Family Rehab only requested to suspend the recoupment until an ALJ hearing, rather than "wade into the

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[6] *Family Rehab, Inc.*, 886 F.3d at 500.
[7] *Id.*
[8] 42 U.S.C. § 1395ff(d)(1)(A).
[9] *Family Rehab, Inc.*, 886 F.3d at 500.
[10] *Id.*
[11] Infinity Healthcare Servs., Inc. v. Azar, 349 F. Supp. 3d 580, 584 (S.D. Tex. 2018); see also Family Rehab, 886 F.3d at 500 ("an ALJ hearing is not forthcoming--not within 90 days, and not within 900 days. According to Family Rehab--and effectively conceded by the government--it will be unable to obtain an ALJ hearing for at least another three to five years. And based on HHS's own admissions to a federal judge, the logjam of Medicare appeals shows no signs of abating anytime soon.").
[12] *Family Rehab., Inc.*, 886 F.3d at 500 (noting that Although § 405(g) is a provision of the Social Security Act, it has been made applicable to Medicare by 42 U.S.C. § 1395ff(b)(1)(A)).
[13] *Id.*, citing *Mathews v. Eldridge*, 424 U.S. 319, 326–32, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976).
[14] *Id.* Note that while the court did claim jurisdiction on the procedural due process and *ultra vires* claims, they did not extend jurisdiction under 28 U.S.C. § 1331 or mandamus jurisdiction, as the Plaintiff was not requesting the government provide it with a timely ALJ hearing.
[15] *See Affiliated Prof'l Home Health Care Agency v. Shalala*, 164 F.3d 282, 285-86 (5th Cir. 1999); *Haro v. Sebelius*, 747 F.3d 1099 (9th Cir. 2014).
[16] *Sahara Health Care, Inc. v. Azar*, 349 F. Supp. 3d 555, 572 (S.D. Tex. 2018) ("a due process claim fails when there is no property interest."); *PHHC, LLC v. Azar*, No. 1:18CV1824, 2018 WL 5754393, at *7 (N.D. Ohio Nov. 2, 2018) ("in order to prevail on either a substantive or procedural due process claim, Plaintiff must establish a protectable liberty or property interest.")

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Medicare Act or regulations," it raised collateral claims. Further, they raised a "colorable claim" that erroneous recoupment would "damage [it] in a way not recompensable through retroactive payments."[17] Therefore, the Fifth Circuit held, the court had jurisdiction to hear Family Rehab's procedural due process and *ultra vires* claims.[18] On remand, the District Court, without explanation, held that Family Rehab held a property interest in "Medicare payments for services received."[19] Additionally, the court granted Family Rehab's TRO because the court found that Family Rehab had a substantial likelihood of success on the merits of its procedural due process claim and faced a substantial threat of irreparable injury if the recoupments continued.[20] Shortly thereafter, the Southern District of Texas followed, holding that an ambulance service also had a property interest, again without explanation.[21] In September of 2018, the Western District of Tennessee granted a preliminary injunction for a medical equipment company, after finding that it possessed liberty and property rights in Medicare payments for supplies provided to patients.[22] At the same time, the District of South Carolina held that the private interest affected by recoupment before an ALJ hearing is the Plaintiff's "very existence and financial stability."[23] Quoting the Supreme Court, the court declared that "[i]t is a purpose of the ancient institution of property to protect those claims upon which people rely in their daily lives, reliance that must not be arbitrarily undermined."[24]

On the opposite side of the argument, many courts have held that medical providers do not possess a property interest in Medicare payments. The District of Kansas has held that the patient, rather than the provider, is the intended beneficiary of the Medicare program, and a provider's interest is on "uninterrupted payments."[25] Even within the Fifth Circuit, courts are split on the issue.[26] The court in *Angels of Care Home Health* held that the provider had a property interest in Medicare payments for services rendered, while the court in *Sahara Health* found that the unprotected interest was in the reimbursement of "bad claims."[27] The Northern District of Ohio reasoned that, because CMS determines the amount to be paid to providers and has the authority to make adjustments to payments, there can be no protected property interest in the overpayments.[28] Quoting the Northern District of Ohio, the Middle District of Florida quickly followed.[29] Finally, in June of 2019, the Southern District of California held that because a plaintiff submitted only the underlying claim to CMS, rather than the due process claim, they had not exhausted their administrative remedies. The court also acknowledged that Medicare Act's channeling requirement "comes at a price, namely, occasional individual, delay-related hardship."[30]

These cases suggest momentum is building amongst courts, which are beginning to understand certain providers should be offered injunctive relief as they await the backlog of Medicare appeals. While this offers providers a framework for obtaining injunctive relief, they still have significant hurdles to prove while seeking a TRO, including financial ruin of their businesses if recoupment payments continue. Nevertheless, these cases provide a precedent that was not previously available to providers and, if used correctly under the right circumstances, may shelter needy providers and their employees while they await their day in court.

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[17] *Family Rehab., Inc.*, 886 F.3d at 504.
[18] *Id.*
[19] *Family Rehab., Inc. v. Azar*, No. 3:17-CV-3008-K, 2018 WL 3155911, at *4 (N.D. Tex. June 28, 2018).
[20] *Id.*
[21] *Adams EMS, Inc. v. Azar*, No. CV H-18-1443, 2018 WL 3377787, at *4 (S.D. Tex. July 11, 2018)
[22] *A1 Diabetes & Med. Supply v. Azar*, No. 218CV02612JTFCGC, 2018 WL 7283329, at *4 (W.D. Tenn. Sept. 21, 2018)
[23] *Accident, Injury & Rehab., PC v. Azar*, No. 4:18-CV-02173-DCC, 2018 WL 4625791, at *7 (D.S.C. Sept. 27, 2018)
[24] *Id.*, quoting *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972).
[25] *Blue Valley Hosp., Inc. v. Azar*, 322 F. Supp. 3d 1149, 1167 (D. Kan. 2018), aff'd, 919 F.3d 1278 (10th Cir. 2019).
[26] *See Angels of Care Home Health, Inc. v. Azar*, 2019 WL 1101286, at *2 (N.D. Tex. Feb. 13, 2019), report and recommendation adopted, No. 3:18-CV-3268-S-BK, 2019 WL 1099028 (N.D. Tex. Mar. 8, 2019) ("[p]recedent makes clear that [Plaintiff] has a valid property interest in receiving Medicare payments for services rendered."); *but see Sahara Health Care, Inc. v. Azar*, 349 F. Supp. 3d 555, 572 (S.D. Tex. 2018)("Plaintiff's claim and related arguments fail because they are based on the existence of a property interest Plaintiff does not have").
[27] *Id.*
[28] *PHHC, LLC v. Azar*, 2018 WL 5754393, at *8 (N.D. Ohio Nov. 2, 2018).
[29] *Alpha Home Health Sols., LLC v. Sec'y of United States Dep't of Health & Human Servs.*, 340 F. Supp. 3d 1291, 1302 (M.D. Fla. 2018)
[30] *Id.*

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CMS Finalizes Expansion of Provider Enrollment Disclosure Requirements and Expansion of its Revocation and Denial Authorities

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On September 10, 2019, the Centers for Medicare and Medicaid Services (CMS) released a long awaited Final Rule that greatly expands the provider enrollment disclosure requirements for the Medicare, Medicaid and Children's Health Insurance (CHIP) Programs and enhances the ability of CMS to deny and/or revoke enrollment of any provider or supplier participating or seeking to participate in the Medicare program. The Final Rule takes effect on November 4, 2019, despite CMS's requests for continued comments regarding certain aspects of the Final Rule and ongoing development of the forms and processes necessary to fully implement it. The major provisions of the Final Rule are highlighted below.

Disclosure of Affiliations for Medicare, Medicaid and CHIP

The most anticipated (or dreaded) provision of the Final Rule requires any provider or supplier initially enrolling in or revalidating its enrollment in the Medicare, Medicaid or CHIP programs to identify any affiliations that it (or any owning or managing individuals or organizations of the provider or supplier) has with (or within the previous five years has had) any currently or formerly enrolled provider or supplier that has experienced a so called "disclosable event", which includes: (a) uncollected debt to Medicare, Medicaid or CHIP (regardless of amount, repayment status or any pending appeals); (b) payment suspension under a federal health care program (regardless when it occurred or was imposed); (c) exclusion from Medicare, Medicaid or CHIP (regardless of when it occurred or the status of any pending appeals); and (d) denial or revocation of Medicare, Medicaid or CHIP billing privileges (regardless of when imposed, the reasons for such action or status of any appeals). Once a reporting obligation for an affiliate is triggered, the disclosure of "disclosable events" is unlimited in duration and affords CMS (or a state Medicaid or CHIP program, as applicable) the ability to deny or revoke enrollment of a provider or supplier based on its determination whether the affiliation and disclosable event(s) poses an "undue risk" of fraud, waste, or abuse to the Medicare (or Medicaid or CHIP) program.

Notably, unlike the proposed version of this Final Rule that

> *"The Final Rule takes effect on November 4, 2019, despite CMS's requests for continued comments regarding certain aspects of the Final Rule and ongoing development of the forms and processes necessary to fully implement it.*

was released in March 2016, the Final Rule limits the disclosure obligation to those providers and suppliers requested to so disclose by CMS. Moreover, for the vast majority of providers and suppliers participating in Medicare, Medicaid and CHIP programs, any such requests are likely to be delayed by several years while CMS and the states rush to develop a reporting process and new Form CMS-855 enrollment forms and state Medicaid/CHIP applications to capture such information. With regards to the Medicare program, the development of these processes and forms will be required to undergo the notice and comment rulemaking process. How and when such processes will roll out for the state Medicaid and CHIP programs is

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less clear as those programs were afforded two differing options for implementation of these new rules. For now, providers and suppliers in any of these programs should take the opportunity to identify any "affiliates" and determine whether those affiliates have any so-called "disclosable events" that would merit reporting, if requested to do so by CMS, especially considering the time and effort that process could take.

Expansion of CMS's Denial and Revocation Authorities Under the Medicare Program

The Final Rule also expands the ability of CMS to deny or revoke the enrollment of a provider or supplier seeking to enroll in or currently enrolled in the Medicare program. The provisions under this expanded authority include denying or revoking the enrollment of a provider or supplier that:

a. Fails to fully and completely provide a list of affiliates and disclosable events upon request by CMS. Commenters indicated to CMS the difficulty that would be encountered in identifying affiliates and obtaining information regarding disclosable events and in response CMS indicated it will evaluate providers and suppliers according to what it determines the provider or supplier "knew or reasonably should have known". Notably, states will hold similar authority to terminate a provider's enrollment in state Medicaid and CHIP programs;

b. Is currently revoked under a different name, numerical identifier or business identity, and the applicable reenrollment bar has not expired. Notably, this is an expansion on current similar authority retained by CMS because under this enhanced provision CMS now clearly has the ability to reach across complex corporate structures and different legal entities to determine whether to deny or revoke the enrollment of related corporate entities that it previously did not have;

c. Billed for services performed at, or items furnished from, a location that the provider or supplier knew or should reasonably have known did not comply with Medicare enrollment requirements;

d. Demonstrates a pattern or practice of ordering, certifying, referring or prescribing Medicare Part A or B services, items or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries or otherwise fails to meet Medicare requirements. Notably, this authority is reserved for physicians and other "eligible professionals";

e. Has an existing debt that CMS refers to the United States Department of Treasury;

f. Is currently terminated or suspended (or otherwise barred) from participation in a state Medicaid program or any other federal health care program;

g. Has a license that is currently revoked or suspended in a state other than that in which the provider or supplier is seeking to enroll in or already enrolled in;

h. Is currently under a Medicare or Medicaid payment suspension. Notably, this authority extends as well to include Medicare or Medicaid payment suspensions against any owning or managing employee or organization of the provider or supplier as well;

i. Voluntarily terminates its enrollment in the Medicare program in order to avoid a revocation action by CMS; or

j. Fails to timely report a change of information. Notably, while CMS already retains similar authority, CMS seems to be hinting that it may seek to crack down on untimely change of information filings by its indication that in determining whether to revoke a provider or supplier's enrollment in such instances CMS will weigh factors such as the materiality of the information being reported and how late the report is.

Extension of Medicare's Reenrollment Bar; Institution of Reapplication Bar

Currently, if a provider or supplier's enrollment in the Medicare program is revoked for any reason, CMS will institute a "reenrollment bar" for 1-3 years (depending on the underlying reason for the initial revocation) that prohibits the revoked provider or supplier attempting to enroll in the Medicare program for the duration of the bar. Under the Final Rule, CMS is expanding the standard reenrollment bar from 3 to 10 years (again, depending on the reason for the revocation action) and is expanding that bar out to 20 years for providers and suppliers who are revoked a second time. In discussing these expanded reenrollment bars, CMS emphasized that 10-year and 20-year bars will typically be reserved for more serious conduct and not be imposed unless determined to be warranted after careful consideration of all of the required factors. Lastly, CMS now has the

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ability to add up to three years to a provider's or supplier's reenrollment bar (even if such period exceeds the maximum 10-year period) if CMS determines that the provider or supplier is attempting to circumvent its existing reenrollment bar by enrolling in Medicare under a different name, numerical identifier or business identity.

In addition to the expansion of the reenrollment bar, CMS newly instituted a "reapplication bar." The reapplication bar will seek to prohibit a provider or supplier from enrolling in the Medicare program for up to three years if its initial enrollment application is denied because the provider or supplier submitted false or misleading information on or with (or omitted information from) its application in order to gain enrollment in the Medicare program.

What Next?

As you contemplate your next moves in relation to this new Final Rule, consider the following:

- The Final Rule seeks comments from the provider and supplier community in various places. To the extent you are interested in submitting comments those are due on or before November 4, 2019. Given the lack of comments submitted in connection with the March 2016 proposed rule, the provider and supplier community alike would be well advised to seriously consider submission of comments in effort to help shape any future developments, such as the reporting process for affiliates and disclosable events or development of new Form CMS-855s. While comments aimed at dissuading CMS from continuing with this Final Rule likely won't be fruitful, there still may be an opportunity to help shape future developments.
- Start reviewing for and identifying current and past "affiliates" and a process for requesting and identifying whether and if those affiliates have any "disclosable events" so if you get a knock on the door from CMS, you are prepared to respond in a timely fashion.
- If you are involved a transaction or considering one, think now about whether the sellers or any owning employees, managing employees or organizations affiliated with the sellers will trigger reporting as affiliates and whether they have any disclosable events. If so, how and when to request that information while you still maintain some degree of leverage over the seller.
- Keep a weathered eye on the horizon for future proposals and most notably the new Form CMS-855 applications.

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4TH ANNUAL

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Assignments of Benefits Contracts Not Airtight for Out-of-Network Providers

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When a patient sees a provider, the patient signs an "assignment of benefits" contract with the provider, assigning the patient's legal rights to recover benefits from the insurance company to the provider so that the provider can be directly reimbursed for the services rendered to the patient. When the provider is in-network, this process is executed with little fanfare. However, for an out-of-network provider, the road to reimbursement is not always as smooth. Not all states expressly permit assignment-of-benefits clauses, and as a result, insurers send the reimbursement to the beneficiary rather than the provider. The beneficiary is then supposed to forward the reimbursement onto the provider, which many of them do. However, if they do not, providers are put in the uncomfortable and difficult position of suing the patient, which has an uncertain likelihood of success. Given this arduous task, some providers contend that insurance companies have begun to utilize direct payment to patients in retaliation against providers for refusing to join the insurer's networks.

In fact, in 2015, providers of inpatient and outpatient substance abuse and/or mental health treatment to chemically-dependent individuals filed suit against a group of insurers that includes several Blue Cross entities for this exact practice. In *Dual Diagnosis Treatment Center, Inc., et al. v. Blue Cross of California, et. al.*, the providers alleged that defendants purposefully ignored valid assignments of benefits and instead directly reimbursed providers' patients in order to punish the providers for being a few of a small number of providers who had not joined the insurers' networks.

In their defense, the insurers stated that some of the plans contained anti-assignment provisions, prohibiting beneficiaries from entering into assignment-of-benefits contracts with providers. The original complaint sought to recover benefits, remove breaching fiduciaries and, against the Blue Cross insurers, injunctive and declaratory relief that Blue Cross' pattern of denying providers' assigned claims without reviewing the operative plan document or informing providers of the denial violates the Employee Retirement Income Security Act of 1974 (ERISA), the federal law that regulates employee-sponsored retirement and welfare benefit plans. The court granted insurers' motion to dismiss without prejudice, specifically to allow the providers to amend their complaint to demonstrate that waiver or estoppel would apply to the anti-assignment provisions.

The providers filed a second amended complaint, which was dismissed by the court with leave to amend, and the providers filed a third amended complaint in October 2017. The third amended complaint brought two claims: a claim for plan benefits under ERISA and a state law claim under California law alleging that the Blue Cross insurers misled providers about the assignability of benefits (specifically, misrepresenting that benefits were assignable when they were not and also representing that benefits were not assignable when they were). The insurers filed a motion to dismiss on the state law claim, which the court granted on the grounds of insufficient standing because the providers did not properly allege an economic injury. Specifically, the court held that collection costs, bad debt, preventing the providers from assisting their patients in the administrative appeals process and denying providers the opportunity to make alternate payment arrangements or collect additional money from their patients up front were insufficient to allege that the insurers' conduct resulted in economic injury to the providers. The providers' claim for benefits under ERISA still stands. However, there is no date set for hearing at this time.

The outcome of this case will set the stage for future litigation and out-of-network payment strategies. In addition to this and other pending cases, out-of-network providers or those considering an out-of-network strategy should closely monitor proposed legislation in their states of operation regarding direct-pay-to-patient methods. Some states, such as Indiana, have proposed legislation requiring insurers to directly reimburse out-of-network providers for certain services. These types of laws, in combination with litigation, will significantly influence the risk associated with pursuing an out-of-network payment strategy.

Federal Judge Overturns CMS's Unlawful Expansion of Site-Neutral Payments

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In another recent victory for hospitals, the U.S. District Court for the District of Columbia held that the Centers for Medicare and Medicaid Services (CMS) exceeded its statutory authority when it expanded Congress' site neutral payment mandate in Section 603 of the Bipartisan Budget Act of 2015 (BBA) to grandfathered sites under the BBA.[1] CMS's CY 2019 Outpatient Prospective Payment System (OPPS) Final Rule slashed reimbursement for "excepted" off-campus provider-based departments by applying the corresponding Physician Fee Schedule rate to Evaluation and Management (E&M) G-code services provided at such locations.[2] As a result, CMS essentially equalized the payment rate for E&M services provided at excepted off-campus provider-based departments (PBDs), nonexcepted off-campus PBDs, and physician offices alike, despite a statutory exception for grandfathered sites mandated under the BBA.[3] CMS opted to ignore the mandated exception in the BBA in favor of implementing a policy that, in CMS's view, was intended to curb growth in Medicare spending at excepted sites. Following challenges from numerous hospital organizations, the Court concluded that CMS was not authorized to ignore the statutory process for setting payment rates in the OPPS and simply lower payments for certain services performed by certain providers. Notably, the Court found that CMS's authority to control expenditures under the Medicare program did not authorize it to unilaterally set outpatient department service-specific rates under the OPPS without regard to their relative position or budget neutrality.[4]

> *"Notably, the Court found that CMS's authority to control expenditures under the Medicare program did not authorize it to unilaterally set outpatient department service-specific rates under the OPPS without regard to their relative position or budget neutrality.*

The Court ultimately vacated the applicable portions of the 2019 OPPS Final Rule but remanded the matter back to CMS to craft the appropriate remedy consistent with the Court's opinion.[5] While the Court recognized the complications associated with an order to vacate, it also noted that CMS did not apply the applicable portions of the Final Rule in a budget neutral manner and that this, among other considerations, should lessen the burden for the Agency on reconsideration.[6] Although the implementation of the full E&M cut was staggered over two years, CMS projected an estimated savings of $300 million in 2019 alone.[7] The parties submitted a joint

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[1] *Am. Hosp. Assoc. v. Azar*, No. 1:18-CV-2841-RMC, 2019 WL 4451998,at *12 (D.D.C. Sept. 17. 2019).
[2] 83 Fed. Reg. 58818, 58822 (Nov. 21, 2018).
[3] 42 U.S.C. § 1395l(t)(21)(B)(ii).
[4] *Am. Hosp. Assoc. v. Azar*, No. 1:18-CV-2841-RMC, 2019 WL 4451998, at *11 (D.D.C. Sept. 17. 2019).
[5] *Id.*, at *12.
[6] *Id.*
[7] *Id.*, at *5.

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status report on October 1, 2019,[8] however, the HHS has filed a motion requesting that the Court modify its order to remand the matter without vacatur or, alternatively, stay the portion of its order vacating the Final Rule for 60 days while HHS assesses whether to appeal the Court's decision.[9] Pursuant to the CY 2020 OPPS Proposed Rule, CMS will continue the phase-in of the reduction for certain services furnished in excepted off-campus PBDs.[10] However, it remains to be seen whether CMS will appeal the Court's decision and push its CY 2020 proposal forward, or back track from the proposal given the Court's recent opinion. Polsinelli believes that providers should expect CMS to appeal the Court's initial ruling due to the potentially widespread implications it could have on HHS' ability to administratively adjust payment rates for select items and services provided in certain hospital settings. It is also likely that CMS will continue to pursue the payment reduction in the CY 2020 OPPS Final Rule. As Polsinelli's reimbursement team noted in a previous article, CMS faced a similar roadblock recently when trying to unlawfully discriminate against 340B covered entities.[11] Pursuant to the CY 2020 OPPS Proposed Rule, CMS confirmed it will continue the 2018 and 2019 underpayment policy for certain 340B covered entities unless the D.C. Court of Appeals upholds the lower court's ruling that it is unlawful.[12] If history is any lesson, CMS will stay its course and appeal adverse determinations that impact its ability to pay different providers different rates while aggressively pursuing these unlawful payment policies in future rules. Polsinelli's reimbursement team will continue to monitor these developments and develop strategies to pursue legal challenges to prevent these adverse payment policies. If you have any questions or wish to discuss strategies moving forward, please feel free to contact the authors.

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[8] *See* Joint Status Report, *Am. Hosp. Assoc. v. Azar*, No. 1: No. 1:18-CV-2841-RMC, No. 1:19-CV-00132-RMC (D.D.C Oct. 1, 2019)
[9] *See* Defendant's Motion to Modify Order, *Am. Hosp. Assoc. v. Azar*, No. 1: No. 1:18-CV-2841-RMC, No. 1:19-CV-132-RMC (D.D.C Sept. 23, 2019); see also Defendant's Reply in Support of Motion to Modify Order, *Am. Hosp. Assoc. v. Azar*, No. 1: No. 1:18-CV-2841-RMC, (D.D.C. Oct. 7, 2019)
[10] 84 Fed. Reg. 39398, 39401 (Aug. 9, 2019).
[11] *Am. Hosp. Assoc. v. Azar*, 385 F.Supp.3d 1 (D.D.C. May 6, 2019).
[12] 84 Fed. Reg. 39398, 39401 (Aug. 9, 2019).

Along Came Escobar: Are Medicare Conditions of Participation Now Material to Payment?

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Prior to the 2016 United States Supreme Court decision in *Universal Health Services v. United States ex rel. Escobar*, False Claims Act (FCA) liability could largely be assessed by determining whether there was an underlying violation of a Medicare Condition of Participation or Condition of Payment related to a payment in connection with Federal health care programs. Under the implied certification theory, a provider could be liable under the FCA if it submitted a claim to the federal government that implicitly certified compliance with applicable statutes, regulations, and contract requirements, because the "act of submitting a claim for reimbursement itself implies compliance."[1] Nevertheless, there was little risk of FCA liability due to a failure to comply with a Condition of Participation, whereas such liability was more likely due to non-compliance with a Condition of Payment.

Following Escobar, assessment of FCA liability has shifted to a determination of whether non-compliance with applicable statutes, regulations, and contract requirements would be *material* to

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[1] *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001).

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the government's payment decision, as opposed to whether non-compliance related to a Condition of Participation or Condition of Payment. This is to say that the non-compliance would be material if the government agency would not have paid the claim had it known of non-compliance. However, although the implied certification theory for FCA liability remains post-Escobar, the Supreme Court described the materiality standard as "rigorous" and "demanding," ensuring that the FCA does not become "an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract."[2]

So, should providers review applicable statutes and regulations, particularly the Conditions of Payment and Conditions of Participation, to determine the specific basis for non-compliance and associated FCA liability? Or, should providers instead focus on the likelihood that the government agency would have paid a claim even if it had knowledge of the specific instance of non-compliance (i.e., the non-compliance was insubstantial and not material)?

The answer is both. When evaluating materiality under the FCA, a statute or regulation expressly identifying a condition of payment is relevant, but not automatically dispositive. Proof of materiality can include evidence that the government agency consistently refuses to pay claims based on non-compliance with a particular statutory, regulatory or contractual requirement. Conversely, if the government agency regularly pays a particular claim in full despite its actual knowledge that certain requirements were violated, such certain Conditions of Participation, it is likely such requirements were not material.

Consequently, providers should:

Be aware of and comply with all applicable statutes, regulations and contract requirements that apply to their operations, including the Conditions of Payment and Conditions of Participation.

Incorporate the Escobar materiality standard in their compliance programs to ensure that non-compliance isn't merely identified, but also analyzed to determine whether such non-compliance is substantial and would affect a government agency's willingness to pay a claim.

Confirm that they hold proper licenses or authorizations necessary to provide the services which are billed to government programs.

Ensure that employed and contracted personnel are licensed or otherwise authorized to provide services within their facilities.

Be aware of the findings that have been issued by district and appellate courts given the lack of consistency in the application of Escobar and the interpretation of "materiality."

Train their workforce on regulations that courts have found material, Conditions of Payment and Conditions of Participation, and the compliance plan and program.

If non-compliance is identified in a Plan of Correction issued by CMS, correct deficiencies, challenge inaccuracies, but do not admit non-compliance.

Consider whether refunds are necessary due to non-compliance with applicable statutes, regulations, and contract requirements.

The ruling in Escobar likely will result in new and different bases for FCA violations due to the ambiguity of the implied certification theory. Therefore, providers must be diligent in identifying and immediately addressing non-compliance in order to avoid or limit FCA liability.

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[2] *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2003 (2016).

Managed Care Issues in Corporate Transactions

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For most organizations furnishing reimbursable health care services, commercial third party payors (Payors) likely constitute the single largest source of revenue for the organization. This trend is likely to continue as the Centers for Medicare and Medicaid Services (CMS) transitions more and more Medicare beneficiaries into Medicare Advantage and as states look to Payors to manage Medicaid benefits. Given their key role in the financial potential of an organization, managed care contracts with Payors should be carefully reviewed during the course of a corporate transaction to identify and correct potential pitfalls early in the process to ensure a seamless transition at closing.

The list of essential managed care issues to analyze will depend on the type of transaction, whether the organization is the buyer or the seller, the nature of the organization's managed care contracts, and the timing of the transaction. We outline four issues here that warrant special attention in any corporate transaction.

I. Identify Missing Documentation

The diligence process for every transaction will involve identifying missing documentation. But gathering and reviewing documentation for managed care contracts can be particularly challenging. Many managed care contracts provide that the Payor may unilaterally amend the contract, including its reimbursement rates – contractual posture that is anathema in other types of contracts.

To make things more difficult, the amendment may not be transmitted in the form of a formal, standalone, written contract amendment. Instead, some amendments may be transmitted by a Payor via email or even simply posted on Payor websites. These amendments need to be gathered and reviewed because of their potential to materially affect reimbursement or the fundamental relationship between the parties.

II. Beware Antitrust Liability

Unlike most of an organization's contracts, managed care contracts likely include competitively sensitive information. In 2018, the Federal Trade Commission (FTC) warned parties to take steps to avoid creating antitrust liability by improperly exchanging competitively sensitive information during premerger negotiations, due diligence, or the integration planning process. The FTC offered a number of suggestions to reduce antitrust liability, but one of the most common in health care transactions is the use of internal "clean teams." Clean teams are limited groups of individuals from both parties to a transaction that have access to competitively sensitive information but, importantly, are not involved in day-to-day operations. The best practice is for managed care contracts to be shared only with and reviewed only by clean team members.

III. Observe Payor Notice or Consent Requirements

Contractual restrictions on assignment are routinely tracked during due diligence for all of an organization's written agreements, from real estate leases to employment arrangements. For managed care contracts, assignment by the health care provider is commonly prohibited without the written consent of the Payor. Occasionally, these provisions even define an "assignment" to include stock transactions. For many transactions, a plan is needed for the seller and buyer to jointly approach Payors prior to closing to seek consent.

In addition, there are other notice or consent requirements that are fairly unique to managed care contracts. It is not uncommon for Payors to require notice of or the right to consent to certain changes within the health care

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provider organization including, for example, changes in ownership (even indirect ownership), changes of directors or other key employees, or material changes to the health care provider's scope of services. These additional notice or consent requirements may be triggered regardless of the structure of the transaction.

IV. Other Communication and Coordination with Payors

Even when not required by law or managed care contract, it is often a good idea to communicate early with Payors regarding a transaction to ensure a smooth transition. Many transactions require Payors to make changes in their systems in response to the transactions to address things such as health care provider name, tax identification number, national provider identification number, electronic funds transfer information, facility location information or any other demographic or credentialing information of the health care provider. Notice of these types of changes to the Payors may not be required by contract or law but the practical reality is that failure to update any of this information in the Payors systems may affect payment. The fact is that many Payors are large bureaucracies, slow to respond to health care provider requests. Early communication and coordination with Payors on these smaller details may be critical to a smooth transition after the transaction closes.

Conclusion

Managed care contracts are not just another group of contracts to be handled by the normal corporate due diligence process. In corporate transactions involving health care organizations both the buyer and the seller have an interest in paying special attention to the managed care contracts. The buyer wants to know that the numbers it sees on financial statements are supported by reliable managed care contracts that can be transferred at closing without a delay or negative impact on cash flow. The seller wants to provide sufficient documentation of its managed care contracts to avoid a reduction in purchase price or any hiccups that might jeopardize closing. Since they are often the most important source of revenue for an organization, managed care contracts warrant special attention well in advance of the transaction closing.

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