



# THE HEALTH LAWYER

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## THE STORY SO FAR: WHAT WE KNOW ABOUT FCA LITIGATION ON THE SECOND ANNIVERSARY OF *UNIVERSAL HEALTH SERVICES, INC. V. UNITED STATES EX REL. ESCOBAR*

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On June 16, 2016, the United States Supreme Court issued one of the most important False Claims Act (“FCA”) decisions in recent history, *Universal Health Services, Inc. v. United States ex rel. Escobar*.<sup>1</sup> The decision changed FCA investigations and litigation in two significant ways.

First, *Escobar* confirmed the existence of the implied certification theory as a basis of liability under the Act. Under the implied certification theory, liability may be found when a person (entity or individual) submits a claim for payment to the federal government without meeting all of the statutory, regulatory, or contractual compliance standards associated with that claim. Under the implied certification theory, a person seeking the payment of

government funds is impliedly certifying compliance with all attendant laws, regulations, and rules. The implied certification theory expands the scope of potential FCA liability exposure exponentially relative to what would otherwise be explicit certifications in connection with claims for payment with government funds.

Second, *Escobar* requires that alleged implied certification violations be tested under a “rigorous” materiality standard that the Court set forth in its decision.<sup>2</sup> Under *Escobar*, a violation of a statutory, regulatory, or contractual obligation must be material to the government’s decision to pay.

Over the last two years, the materiality inquiry has become a bulwark against transforming run-of-the-mill breach of contract claims into FCA actions.

When *Escobar* was decided, it was unclear what was meant for an alleged violation to be material. In 2009, Congress passed the Fraud Enforcement and Recovery Act (“FERA”), which defined materiality for purposes of false statement liability<sup>3</sup> as “having a natural tendency to influence, or be[ing] capable of influencing, the

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## Chair's Corner

### What We Learned on Our Cuban Vacation—



Chair Hilary H. Young



Former Chair Paul DeMuro

From March 26 through 31, 2018, we were part of a group of eight who visited Havana, Cuba as a small delegation from the American Bar Association Health Law Section. Our group included an electrical engineer, a healthcare administrator, a law professor, a consultant, and in-house and private practice attorneys. We had six J.D.s and three Ph.D.s among us, and three of us have wielded the gavel as Chair of the Section, including our delegation leader, David Johnson. We met with several professionals to learn about the Cuban government and its commitment to healthcare; we toured three medical facilities; and we enjoyed wonderful meals in private restaurants. While our group had divergent opinions and interests, questions and skepticism, it is probably safe to say it was a fascinating visit for us all.

As a Caribbean island nation, Cuba presents beautiful features. Havana overlooks the Gulf of Mexico and boasts some striking Spanish-colonial architecture, particularly in Old Havana. The music is lively and the people friendly. Cars from the 1950s are picturesque. But problems and poverty are also evident. Restored mansions stand next to collapsed buildings. Laundry hangs from the balconies of buildings that evoke the Soviet era. Opportunities appear limited.

Our trip came at an historic time for Cuba. The country had just elected a new Parliament, which in turn would elect a new President. For the first time since 1959 the President of Cuba would not be a Castro. Since our return to the United States, on April 19, 2018, Raul Castro has stepped aside and 57-year-old Miguel Diaz-Canel assumed the presidential mantle. Whether the younger President will bring changes to the country remains to be seen.

The economy is clearly a major concern in this single-party nation controlled by the Communist Party. Until recently, the government owned all businesses. Although the Cuban Constitution commits to provide food, housing, education, and healthcare for free, it is

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## THE ABA HEALTH LAW SECTION

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## The Story So Far: What We Know About FCA Litigation

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payment or receipt of money or property.”<sup>4</sup> But the language used in the *Escobar* decision suggests that the Court was imposing a materiality standard on implied certification cases far more rigorous and demanding than the standard set forth in the FERA legislation.

As the second anniversary of the *Escobar* decision approaches, lower courts have confirmed that *Escobar* did in fact impose a materiality standard far more rigorous and demanding than the standard set forth in FERA. A violation is material under *Escobar* when the government decisionmaker responsible for paying claims would have refused to pay a claim had it known of the claimant’s alleged statutory, regulatory, and/or contractual violation. This view is confirmed by the *Escobar* decision itself, which defined the concept of materiality using what are generally considered to be five principles:

- 1. Government Knowledge/Government Treatment of Violations (A Subjective Test).** This principle is perhaps the most important: Whether the government knew of a claim’s falsity, but nevertheless paid the claim, which would tend to negate a finding of materiality.<sup>5</sup> This argument is also known as the so-called “government knowledge” defense. Conversely, “evidence that the defendant knows that the government consistently refuses to pay claims in the mine run of cases based on noncompliance” supports a finding of materiality.<sup>6</sup>
- 2. Option Not Relevant.** This is the converse of the government knowledge principle – it does not matter what the government could have done, it matters only what the government would have done. “Nor is it sufficient for a finding of materiality that the government would have the option to decline to pay if it knew of the defendant’s noncompliance.”<sup>7</sup>
- 3. Importance (An Objective Test).** A violation is material when the violation is important to the government decision maker. To quote from the decision, importance asks whether a “reasonable man [acting on the government’s behalf] would attach importance to [the representation] in determining his choice of action in the transaction.”<sup>8</sup> It follows that a reasonable person would not attach importance to a violation that is “minor or insubstantial.”<sup>9</sup>
- 4. Labels Used.** Before *Escobar*, some jurisdictions recognized implied certification cases only when the statute, regulation, or contract at issue identified compliance as an express condition of payment. Importantly, *Escobar* rejected the so-called “condition of payment” requirement. In doing so, however, the Court noted that such labels may be helpful in determining materiality. Thus, this principle asks whether the government has “expressly identifi[ed] a provision as a condition of payment,” although such identification is “relevant but not automatically dispositive.”<sup>10</sup>
- 5. Essence of the Bargain.** In certain cases, an alleged violation is so severe that it goes to the very heart of what the government was purchasing. Thus, this principle, which derives from the common law, examines materiality by asking whether the regulatory, statutory, or contractual violation goes to the “essence of the bargain.”<sup>11</sup>

In the last two years, a series of decisions applied these principles to cases involving healthcare entities. These decisions have made FCA litigation more predictable. These decisions will also continue to provide defendants with increased incentives to litigate, rather than settle, FCA cases.

## Government Knowledge of Violations Weighs Heavily Against Materiality

Perhaps the most interesting cases that have arisen in the wake of *Escobar* have been those dealing with government knowledge. The idea behind government knowledge is that a violation of a statutory, regulatory, or contractual requirement does not matter (*i.e.*, is not material) if the government agent responsible for paying claims knows of the violation and nonetheless pays the claim.

In *United States ex rel. Petratos v. Genentech, Inc.*,<sup>12</sup> the Third Circuit affirmed a district court’s dismissal of a FCA suit on the grounds that the relator failed to satisfy *Escobar*’s materiality requirement. The relator sued Genentech for allegedly suppressing data that caused doctors to certify incorrectly that Avastin, a Genentech cancer drug, was “reasonable and necessary” for certain at-risk Medicare patients. The court found that the relator disclosed “material, non-public evidence of Genentech’s [alleged] campaign of misinformation” to the Food and Drug Administration (“FDA”) and Department of Justice (“DOJ”) in 2010 and 2011.<sup>13</sup> And in the face of that disclosure, “the FDA has not merely continued its approval of Avastin for the at-risk populations that [the relator] claims are adversely affected by the undisclosed data, but has added three more approved indications for the drug. Nor did the FDA initiate proceedings to enforce its adverse-event reporting rules or require Genentech to change Avastin’s FDA label, as [the relator] claims may occur. And in those six years, the Department of Justice has taken no action against Genentech and declined to intervene in this suit.”<sup>14</sup> The court concluded that the government’s failure to take any action whatsoever in the face of its knowledge of the allegations against Genentech demonstrated

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that the alleged violations were not material to the government's decision to pay claims.<sup>15</sup> "After all," the court explained, "the False Claims Act is not 'a blunt instrument to enforce compliance with all . . . regulations.'"<sup>16</sup>

A similar result on government knowledge was reached by the Ninth Circuit in *United States ex rel. Campie*, which is currently pending certiorari at the United States Supreme Court. There, the Ninth Circuit reached the opposite conclusion of *Petratos*, holding that the FDA's drug approval is insufficient government knowledge, without more, to defeat materiality.

In *Campie*, a relator alleged that a pharmaceutical company made false statements about its compliance with FDA regulations, actively concealing its use of illicit products prior to FDA approval, resulting in government payment through Medicare, which conditions payment for drugs on FDA approval. Acknowledging proof of materiality can include whether "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated," the court cautioned against reading too much into the FDA's continued approval in this instance, because (1) doing so would allow the company to use the allegedly fraudulently-obtained FDA approval as a shield against liability; (2) there are many conceivable reasons why the FDA would choose not to withdraw drug approval; and (3) the company ultimately stopped using the drug in question, negating the significance of the government's decision to keep paying for compliant drugs.

Another critical blow to the defendant's government knowledge argument was the lack of evidence clarifying the government's "actual knowledge" of noncompliance. The court was reluctant to find "actual [government] knowledge" when the relator sufficiently pled allegations that

the defendant deliberately misled the government. The company's petition to rehear the case was denied by the Ninth Circuit on September 27, 2017. The company's certiorari petition is fully briefed and pending decision by the Supreme Court.

Perhaps the way to reconcile *Petratos* with *Campie* is to distinguish what the FDA (the regulating agency) knew from what the Centers for Medicare & Medicaid Services ("CMS") (the government payor) knew. The *Campie* court distinguished *Petratos* on this ground – explaining that there was no evidence that CMS actually knew of the alleged regulatory violations at issue in *Campie*. A similar line of reasoning was adopted in *United States ex rel. Brown v. Celgene Corp.*, in which the court rejected the importance of the FDA's knowledge of off-label use. The court explained "[t]he fact that the FDA knew generally about off-label use does not mean CMS knew about and agreed to reimburse particular off-label claims."<sup>17</sup> This distinction is important because it demonstrates that *Escobar's* government knowledge analysis focuses on the government agent or agency responsible for paying claims.

Another interesting post-*Escobar* case on government knowledge involving a pharmaceutical company is *City of Chicago v. Purdue Pharma, L.P.*<sup>18</sup> The City of Chicago brought an FCA action against several pharmaceutical companies, including Purdue, alleging that they provided misleading and fraudulent direct marketing to doctors seeking to create, promote, and control the unbranded marketing of opioids to treat chronic pain. The City alleged that the companies knowingly disseminated unbranded marketing messages that were inconsistent with information on defendants' branded marketing materials, thereby causing the City to spend over \$13 million on fraudulent claims

for opioid prescriptions. Although there were multiple theories of liability raised by the City, the relevant theory for *Escobar* purposes was implied certification. The court dismissed the implied certification claim, noting that the City continued to pay for claims despite the companies' alleged misrepresentations, but granted leave to the City to plead consistent with the standards set forth in *Escobar*.

In sum, when the government agency responsible for paying claims has actual knowledge of the alleged violations and pays claims anyway, it is nearly impossible for a court to find such violations material. For this reason, the government knowledge inquiry is often the most critical question when examining materiality.

### It Is Not Enough That The Government Could Refuse Payment – The Question Is Whether The Government Would Refuse Payment

Another feature of *Escobar* is its explanation that it is not enough that the government could refuse payment. Rather, what matters is whether the government would have refused payment had it known of the alleged violations. This principle was recognized in *Petratos*, where the court explained:

*Petratos* does not claim that Genentech's safety-related reporting violated any statute or regulation. He acknowledges that the FDA would not "have acted differently had Genentech told the truth." And as we have explained, he does not dispute that CMS would reimburse these claims even with full knowledge of the alleged reporting deficiencies.<sup>19</sup>

This aspect of *Petratos* is particularly important in cases where

deposition testimony of government officials or other record evidence shows that the government would not have acted differently regardless of whether the defendant actually violated a statutory, regulatory, or contractual requirement. Following *Escobar*, such evidence has taken on a new level of importance and will continue to do so in future litigation.

## Whether a Reasonable Person Would Consider the Violated Requirement “Important” Goes to Materiality

In a case where the government does not know of an alleged violation, how can materiality be determined? *Escobar* answered in objective terms, explaining that materiality can be determined by asking whether a “reasonable man [acting on the government’s behalf] would attach importance to [the representation] in determining his choice of action in the transaction.”<sup>20</sup> As one lower court explained, it is not enough for the government to simply issue a regulation.<sup>21</sup> That fact alone does not speak to importance. Rather, the court will examine the relationship between the alleged violated requirement and the transaction at issue to determine whether the requirement was important.

For example, in *United States ex rel. Emanuele v. Medicor Assocs.*,<sup>22</sup> the court found that the failure to adhere to a Stark Law exception’s writing requirement was not “minor or insubstantial.” The Stark Law generally prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician maintains a financial relationship. Many exceptions to that general prohibition require the financial relationship at issue to be “set out in writing.”<sup>23</sup> In finding that the writing requirement was not “minor or insubstantial,” the court explained, “[c]ompliance with the writing requirement permits a reviewer to analyze the timeframe,

rate of compensation, and the identifiable services contemplated in the arrangement to determine whether any portion is based on the volume or value of physician referrals.”<sup>24</sup> The requirement, therefore “plays a role in preventing fraud and abuse.”<sup>25</sup> Because of the writing requirement’s role in preventing fraud and abuse, the *Emanuele* court held that the writing requirement was material.

This element of *Escobar*’s decision is important because there will always be cases in which the government does not know whether a violation occurred. In those cases, this objective test of whether a “reasonable man [acting on the government’s behalf] would attach importance to”<sup>26</sup> the representation becomes critical in determining whether the alleged violation was material.

## Labels Matter: Pre-Escobar Dichotomy of “Conditions of Payment” Versus “Conditions of Participation” Remain Relevant, But Not Dispositive, Following Escobar

Prior to *Escobar*, some courts held that implied certification cases could survive a motion to dismiss only if the statute, regulation, or contractual provision that was allegedly violated was a “condition of payment,” as opposed to a “condition of participation” in a government program. Because liability under the FCA attaches only to the submission of claims for payment, the theory went that only violations of provisions integral to the payment of those claims could result in liability under an implied certification theory.

*Escobar* eliminated this distinction, noting that the labels used are no longer dispositive of liability, but are still relevant. *Petratos* provides a good example of how post-*Escobar* courts deal with the labels used by a statute, regulation, or contractual provision. In *Petratos*, the court observed that section 1395y of the Social Security Act is one such express condition

of payment, but nevertheless held that “[t]he mere fact that § 1395y is a condition of payment, without more, does not establish materiality.”<sup>27</sup> *Brown*<sup>28</sup> reached a different result from that reached in *Petratos*. There, the labels used were Medicare regulations that stated Medicare Part D may reimburse only “covered part D drugs,” which must be “used for a medically accepted indication.”<sup>29</sup> The court explained that although this language, which rendered a medically accepted indication “an explicit condition of payment under the program,” was not “automatically dispositive,” it was nevertheless “highly ‘relevant.’”<sup>30</sup>

These holdings are significant because they demonstrate that what matters in the post-*Escobar* world is only whether the violation was material to the government’s decision to pay, not the labels used by a statute, regulation, or contract. That a statute, regulation, or contractual provision renders compliance a “condition of payment” is certainly relevant to whether the government would pay a particular claim, but it may not be dispositive in light of evidence showing that the government agency pays claims despite the “condition of payment” label and despite its knowledge that a violation likely occurred. This represents a significant movement away from *per se* rules about what labels are used to a common sense view that the only things that matter for purposes of the FCA are those things that actually mattered to the government payor responsible for approving claims.

## Violations of Regulations That Speak to the Essence of the Bargain Between the Government and the Healthcare Industry are Likely to be Material

*Escobar* held that regulations that go to the “essence of the bargain” between a contractor and the government are

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likely to be material to the government's decision to pay. A good example of how this plays out took place in *Brown*, described above. In *Brown*, recall that the regulation at issue was one that conditioned reimbursement under Medicare Part D to only "covered part D drugs," which must be "used for a medically accepted indication." The court described this regulation as speaking to the "essence of the bargain" because it was "an essential feature of the Medicare Part D program – a coverage limitation that is central to the balance Congress struck between expanding prescription drug coverage and containing costs."<sup>31</sup> This type of reasoning will likely play out in favor of materiality in cases with particularly damning facts – e.g., cases in which the government contracts for security services in a warzone and the security guards cannot shoot straight or cases, like *Escobar*, in which reimbursement from Medicare and Medicaid is sought for medical treatment provided by unlicensed professionals.

### **Escobar's Demanding Materiality Standard Demonstrates it is Difficult to Prove Implied Certification Cases at Summary Judgment and Trial**

The cases above suggest it is one thing for a relator or the government to allege materiality in its complaint to survive motions to dismiss, but it is a wholly different thing for the relator or the government to establish materiality on summary judgment or even following trial.

No healthcare case demonstrates this better than *United States ex rel. Ruckh v. Salus Rehabilitation, LLC*.<sup>32</sup> In *Ruckh*, the relator alleged that the defendant owners and operators of specialized nursing facilities violated

the FCA by submitting implied false statements in support of false claims by (1) failing to maintain comprehensive care plans as required by Medicaid and (2) upcoding Resource Utilization Group ("RUG")<sup>33</sup> levels.<sup>34</sup> The court, applying *Escobar's* holding and reasoning, set aside the jury verdict, holding that the relator "offered no meaningful and competent proof" that the responsible government agencies would have regarded the disputed practices as material to their payment decision, nor evidence that defendants knew or should have known the governments would have refused to pay the claims if they had known of the practices.<sup>35</sup> Importantly, the court added that both the United States and Florida have, in fact, continued to pay defendants despite the ongoing litigation:

In fact, both governments were – and are – aware of the defendants' disputed practices, aware of this action, aware of the allegations, aware of the evidence, and aware of the judgments for the relator – but neither government has ceased to pay or even threatened to stop paying the defendants for the services provided to patients throughout Florida continuously since long before this action began in 2011.<sup>36</sup>

The court's decision carefully traced the Supreme Court's analysis to hold that a defendant's misrepresentation or false omission supports liability only if "material to the other party's course of action."<sup>37</sup> Conversely, the court pointed out that *Escobar's* "rigorous" and "demanding" materiality and scienter requirements preclude FCA liability "based on a 'minor or unsubstantial' or a 'garden variety' breach of contract or regulatory violation."<sup>38</sup> FCA liability "rests comfortably on proven and successful principles of exchange – fair value given for fair value received."<sup>39</sup> The court noted

the unfairness of a system that imposes "essentially punitive" consequences of FCA's liability. Liability "requires proof that a vendor committed some non-compliance that resulted in a material deviation in the value received and requires proof that the deviation would materially and adversely affect the buyer's willingness to pay."<sup>40</sup>

Put plainly, "Escobar rejects a system of government traps, zaps, and zingers that permits the government to retain the benefit of a substantially conforming good or service but to recover the price entirely – multiplied by three – because of some immaterial contractual or regulatory non-compliance."<sup>41</sup> Adding force to this view, the court noted that the FCA is not the only remedy available to the government for a contractor's non-compliance. The government has alternative and more measured remedies, including providing notice of the deficiency and demanding a cure, administrative remedies, or a price adjustment, and proving materiality may require showing that the government would not have chosen one of those more measured remedies.<sup>42</sup> The decision reinforces the principle established in *Escobar* that FCA liability cannot be premised on mere allegations or post-payment rationalizations. Rather, liability depends on proof of the parties' agreement, conduct, and knowledge.

### **Materiality is an Increasingly Difficult Hurdle for Relators to Overcome in Implied Certification Cases**

*Ruckh*, like many of the other decisions discussed above, illustrates *Escobar's* likely effect on FCA litigation and summary judgment. Although *Escobar* raises the bar for **pleading** materiality, it is a bar that the government and relators will be able to clear in many cases. To succeed at **summary**

**judgment** and **trial**, however, the evidentiary hurdle is much, much higher. Consider the following:

- First, claims at issue will have been paid long before litigation is commenced, often years before. Thus, the material facts are set and the government or a relator will have little meaningful ability to shape (or re-shape) them.
- Second, the nature of agency regulation, practice, and decision-making is characteristically (although not invariably) more flexible than civil or criminal enforcement, and agency decision-makers often have greater discretion over how to address non-compliance. In fact, agency officials are generally expected and required to consider programmatic needs when deciding the appropriate response to non-conforming goods, services, or regulatory paperwork. Proving that the administering agency has elected not to deny payment in favor of a more measured remedy may be a decisive defense.
- Third, among agency contractors, some agencies are notorious for giving vague, little, or no guidance concerning what they expect from contractors in terms of regulatory compliance or how the agency will respond to non-compliance. Indeed, it is the dearth of agency guidance that has spawned an entire industry of compliance consultants. This reality of agency practice will likely make it difficult for the government to show that a contractor knew or should have known a particular non-compliance would be material to the agency's decision to pay.
- Fourth, defendants' employees will often be well-versed in the range of responses the regulatory agency makes to instances of non-compliance. If an agency routinely pays a particular deficient claim, a government contractor or healthcare entity would reasonably expect that deficiency was immaterial to the government's decision to pay claims.

## The Take Away: Escobar Opens the Door to More FCA Litigation, But Its Demanding Materiality Standard Will Block Increased Recoveries

By validating the implied certification theory, *Escobar* has certainly opened the door to more FCA litigation. But its imposition of a rigorous materiality standard gives the healthcare industry a solid platform from which to defend cases that are nothing more than mere regulatory violations. In this vein, *Escobar* rebalances FCA jurisprudence to prevent well-intentioned companies from being subjected to the Act's Draconian penalties based on technical regulatory non-compliance or post hoc rationalizing.



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## Endnotes

- <sup>1</sup> 136 S. Ct. 1989 (2016).
- <sup>2</sup> "Moreover, other parts of the False Claims Act allay Universal Health's concerns. '[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent,' concerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements.' SAIC, *supra*, at 1270. Those requirements are *rigorous*." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002, 195 L. Ed. 2d 348 (2016).
- <sup>3</sup> Compare 31 U.S.C. § 3729(a)(1)(A) (no materiality requirement to establish liability for one who "knowingly presents, or causes to be presented, a false or fraudulent claim"), with 31 U.S.C. § 3729(a)(1)(B) (liability for one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim").
- <sup>4</sup> 31 U.S.C. § 3729(b)(4) (defining "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property").
- <sup>5</sup> *Escobar*, 136 S. Ct. at 2003.
- <sup>6</sup> *Id.*
- <sup>7</sup> *Id.* at 2003.
- <sup>8</sup> *Id.*
- <sup>9</sup> *Id.*
- <sup>10</sup> *Id.* at 2002.
- <sup>11</sup> *Id.* at 2003 n.5.
- <sup>12</sup> 855 F.3d 481 (3d Cir. 2017).
- <sup>13</sup> *Id.* at 490.
- <sup>14</sup> *Id.*
- <sup>15</sup> *Id.* (citing *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016) (dismissing FCA complaint on materiality grounds because "federal agencies in this case have already examined [the claims] multiple times over and concluded that neither administrative penalties nor termination was warranted" (citations and internal quotation marks omitted))).
- <sup>16</sup> *Petratos*, 855 F.3d at 490 (citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 307 (3d Cir. 2011)).
- <sup>17</sup> 226 F. Supp. 3d 1032 (C.D. Cal. 2016). In the interest of full disclosure, David T. Fischer, one of the co-authors of this article, was a counsel of record for the relator in this matter.
- <sup>18</sup> 211 F. Supp. 3d 1058 (N.D. Ill. 2016).
- <sup>19</sup> *Petratos*, 855 F.3d at 490.
- <sup>20</sup> *Escobar*, 136 S. Ct. at 2003.
- <sup>21</sup> *U.S. ex rel. Schimelffenig v. Dr. Reddy's Labs Ltd.*, 2017 WL 1133956 (E.D. Pa. Mar. 27, 2017).
- <sup>22</sup> 242 F. Supp. 3d 409 (W.D. Pa. 2017).

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- <sup>23</sup> See, e.g., 42 C.F.R. § 411.357(d).  
<sup>24</sup> *Emanuele*, 242 F. Supp. 3d at 431.  
<sup>25</sup> *Id.* (quoting 80 Fed. Reg. 70886, 71333-71334).  
<sup>26</sup> *Escobar*, 136 S. Ct. at 2003.  
<sup>27</sup> *Petratos*, 855 F.3d at 490.  
<sup>28</sup> 226 F. Supp. 3d 1032 (C.D. Cal. 2016).  
<sup>29</sup> *Id.* at 1049 (citing 42 C.F.R. § 423.100).  
<sup>30</sup> *Id.* (citing *Escobar*, 136 S. Ct. at 1996).  
<sup>31</sup> *Id.*  
<sup>32</sup> No. 8:11-CV-1303-T-23TBM, 2018 WL 375720 (M.D. Fla. Jan. 11, 2018).  
<sup>33</sup> Resource Utilization Groups is a way of defining the level of care required for a particular nursing facility patient and is spelled out in the Minimum Data Set (“MDS”), which is used to, among other things, determine the amount of reimbursement to the nursing home for that patient’s care.  
<sup>34</sup> *Ruckh*, at 1-2.  
<sup>35</sup> *Id.* at 2.  
<sup>36</sup> *Id.* at 2.  
<sup>37</sup> *Id.* at 6 (quoting *Escobar*, 136 S. Ct. at 2001).  
<sup>38</sup> *Id.* at 7 (quoting *Escobar*, 136 S. Ct. at 2003).  
<sup>39</sup> *Id.* at 8.  
<sup>40</sup> *Id.* at 8-9.  
<sup>41</sup> *Id.* at 8.  
<sup>42</sup> See *id.* at 12-13.

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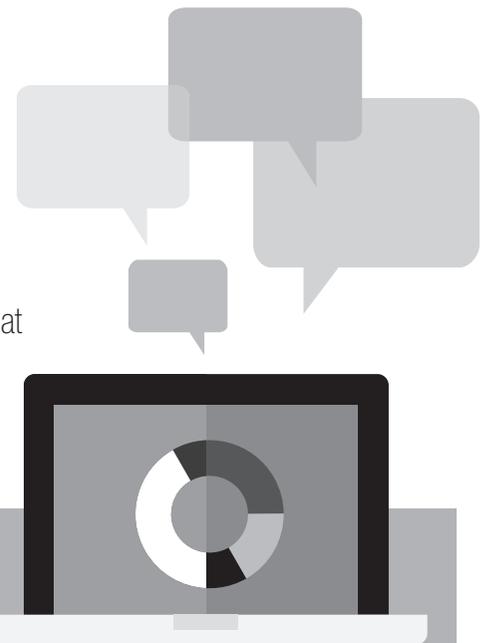
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# MEDICARE ADVANTAGE PLAN LITIGATION CHALLENGES CMS INTERPRETATION OF 60-DAY OVERPAYMENT RULE

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Despite years of being promised clarity and consistency in how the 60-Day Overpayment Rule (“60-Day Rule”) would be applied to Medicare and Medicaid, providers still face different standards for reporting and returning overpayments depending on the government program involved, as well as possible fraud exposure for conduct that may not satisfy the longstanding “knowledge” requirement of the False Claims Act (“FCA”). Passed by Congress in the Patient Protection and Affordable Care Act of 2010 (“PPACA”), the 60-Day Rule imposed a new obligation on Medicare and Medicaid providers to report and return overpayments within limited timeframes, or face liability under the FCA for failure to do so. The statute and subsequent implementing regulations continue to cause confusion and anxiety as the 60-Day Rule’s scope shifted and expanded through agency rule-making and federal court decisions seeking to fill in gaps in the rule-making.

In an effort to impose clarity on these issues as they apply to Medicare Advantage providers, UnitedHealthcare Insurance Company and its Medicare Advantage plans (collectively, “UHC”) initiated a must-watch declaratory judgment action against the United States under the Administrative Procedure Act (“APA”), 5 U.S.C. § 706(2)(A) and (C), to square agency rulemaking under PPACA with the FCA’s “knowledge” requirement, among other issues.<sup>1</sup> The United States unsuccessfully sought an early dismissal of the case and instead received an

unfavorable district court ruling recognizing the potential validity of UHC’s concerns.<sup>2</sup> Judicial review in this APA case based on an administrative record of the regulations at issue has moved forward to summary judgment. This article sets out the battle lines between UHC and the government in the declaratory injunction case. The article also briefly addresses the issue overlap with two FCA cases brought by the U.S. Department of Justice (“DOJ”) in the Central District of California.<sup>3</sup>

But first, a review of the current regulatory requirements and how the government got there.

## Background

The 60-Day Rule establishes a duty on providers to report and return any “overpayment” by the later of 60 days after the overpayment was “identified” or, if applicable, the date any corresponding cost report is due.<sup>4</sup> “Overpayment” is defined by PPACA as “any funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled.”<sup>5</sup> The government programs at issue are Medicare Part A (hospital insurance), Part B (medical insurance), Part C (Medicare Advantage (“MA”) organizations), Part D (prescription drug coverage), and Medicaid.<sup>6</sup>

The 60-Day Rule incorporates the FCA’s enforcement scheme by defining an overpayment not timely reported and returned as an “obligation” for which a provider is liable for FCA civil damages and penalties, typically under a “reverse” false claims theory.<sup>7</sup> Providers are understandably concerned about the scope and interpretation of “overpayment,” given that failure to return an identified

overpayment within 60 days can have serious consequences – fraud litigation exposure, highly punitive treble damages and civil penalties, and potential exclusion from participation in federal healthcare programs.

PPACA did not specify what it means to “identify” an overpayment for purposes of starting the 60-day clock for repayment. In response to uncertainty as to when the obligation to repay starts, the Centers for Medicare & Medicaid Services (“CMS”) committed to providing program-specific guidance regarding the application of the 60-Day Rule. CMS published a final rule applicable to Medicare Parts C and D in 2014 and to Medicare Parts A and B in 2016, both of which addressed the meaning of an “identified” overpayment. In 2015 case law emerged addressing the applicability of the 60-Day Rule to Medicaid providers.

The different rules applicable in each context, discussed further below, are summarized for ease of reference in the chart on the following page.

### Medicare Parts C and D

In May 2014, CMS finalized the first of these rules, publishing a final rule applicable to Medicare Parts C and D (“Part C/D Final Rule”).<sup>8</sup> The Part C/D Final Rule defined “identified” to include situations in which an MA plan or Part D sponsor “has determined, or should have determined through the exercise of reasonable diligence that [it] has received an overpayment.”<sup>9</sup> This articulation of an “identified” overpayment was a departure from CMS’s January 2014 proposed rule, which tracked the FCA knowledge requirement and stated that a payment was “identified” when the organization “has actual knowledge of the existence of the overpayment or acts in reckless

PAYOR	RULE REGARDING “IDENTIFYING” AN OVERPAYMENT
Medicare Parts C & D	A Medicare Advantage organization or Plan D sponsor has “identified” an overpayment when it “has determined, or should have determined through the exercise of reasonable diligence that [it] has <b>received</b> an overpayment.” (emphasis added)
Medicaid	No CMS rule proposed, but one federal court found a Medicaid provider’s overpayment is “identified” when the provider has been <b>put on notice</b> of a <b>potential</b> overpayment.
Medicare Parts A & B	A Part A/B provider has “identified” an overpayment when it “has, or should have through the exercise of reasonable diligence, determined that [it] has <b>received</b> an overpayment <b>and quantified the amount of the overpayment.</b> ” (emphasis added)

*disregard or deliberate ignorance of the existence of the overpayment.”*<sup>10</sup>

CMS did not explain why it shifted to a negligence-based mental state – *has determined or should have determined through the exercise of reasonable diligence* – for defining overpayments when negligence is not within the FCA’s long-established knowledge requirement of actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of information.<sup>11</sup> The Part C/D Final Rule Preamble states that MA plans and Part D sponsors have an existing obligation to submit accurate, complete, and truthful risk adjustment data under certification requirements, and CMS has always expected them to conduct payment evaluation procedures to meet the requirements of certifying the data.<sup>12</sup> Similarly, in CMS’s response to providers seeking clarification of the meaning of reckless disregard and deliberate ignorance, CMS explained that “reasonable diligence” comprised of proactive compliance reviews is simply the “flip side” of the agency’s long-standing requirement that providers submit complete, accurate, and truthful data and does not impermissibly lower the FCA knowledge standard to negligence.<sup>13</sup>

CMS, in effect, grafts the PPACA “overpayment” provision onto pre-existing regulatory requirements developed as part of the implementation of the Medicare+Choice (now MA) program, even though nothing in PPACA or its legislative history suggests this

was the intended interpretation of “overpayment.” By arguing that there is nothing new in its interpretation, CMS avoids a new notice and comment period for agency rule-making as required by the APA. Whether it has properly done so will be decided in the first instance in the UHC federal court litigation.

#### Medicaid

Limited federal case law developed in the FCA context has examined the issue of when the 60-day clock for overpayments begins to run for Medicaid claims, with the principle case decided in 2015 by the U.S. District Court for the Southern District of New York. In *United States ex rel. Kane v. Continuum Health Partners*,<sup>14</sup> the court held that the 60-day clock starts to run after the provider receives *notice of a potential overpayment*. Continuum Health Partners (“Continuum”), an owner and operator of non-profit hospitals, had inaccurately billed Medicaid as a secondary payor when its managed care organization had already received fixed payments for the services provided. The New York State Comptroller’s office raised the issue to Continuum, which assigned a team, including the relator,<sup>15</sup> to review its billing data. The relator subsequently sent Continuum management an email attaching a spreadsheet of more than 900 potential billing errors, explaining that further analysis was needed to confirm the accuracy of the findings.<sup>16</sup> Four days after sending the spreadsheet to

management, the relator was terminated; 60 days after he sent the spreadsheet, he filed a *qui tam* case. The government intervened after the Part C/D Final Rule was announced.

Continuum moved to dismiss, arguing that the United States failed to state a claim because Continuum had not *identified any overpayments* on the date it received relator’s spreadsheet. The district court disagreed, holding that “identified” is when a provider is put on *notice of a potential overpayment*, not when an error is conclusively established.<sup>17</sup> The court, acknowledging that its holding imposed an “unforgiving” timeline on providers, reasoned that the FCA’s legislative history suggested that Congress intended for FCA liability to attach where there is an established duty to pay money to the government, even if the precise amount due has not yet been determined.<sup>18</sup> The court noted that CMS had not issued regulations providing guidance to Medicaid providers, but found that its interpretation of “identified” was consistent with the Part C/D Final Rule and the proposed rule for Part A/B providers.<sup>19</sup>

*Kane*, though limited in precedential effect, is the most significant decision to date that analyzes the 60-Day Rule responsibilities of Medicaid providers.

#### Medicare Parts A and B

On February 12, 2016, four years after its proposed rule was published, CMS issued the long-awaited Final

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Rule for Medicare Part A and B providers (“Part A/B Final Rule”), which added some clarification to the requirements for reporting and returning Part A and B overpayments, possibly in response to provider concerns about the Part C/D Final Rule and *Kane* Medicaid decision.<sup>20</sup> The Part A/B Final Rule states that “[a] person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment.”<sup>21</sup> CMS explicitly states that “reasonable diligence” means both “proactive compliance activities” to check for overpayments and “reactive reviews” (*i.e.*, investigations upon receipt of “credible information” of an overpayment) of Medicare claims.<sup>22</sup> For Part A/B providers, the 60-day clock begins to run after the reasonable diligence period, which CMS explained may take “at most 6 months from the receipt of credible information, absent extraordinary circumstances.”<sup>23</sup> Providers, accordingly, have up to eight months for repayment (six months to investigate, plus 60 days to report and return the overpayment). But if the provider has credible information that an overpayment occurred and does not exercise reasonable diligence, the provider will not be afforded six months to investigate and any overpayment will be considered late after 60 days.<sup>24</sup>

## UHC Declaratory Injunction Litigation

In the midst of these evolving standards, in January 2016 UHC filed a declaratory injunction action against CMS in the U.S. District Court for the District of Columbia seeking relief under the APA. UHC’s complaints about the Part C/D Final Rule fall into two buckets – (1) the rule imposes FCA liability for reverse false claims based on a negligence

standard not included in the FCA’s knowledge requirement, and (2) the rule violates the statutory mandate of actuarial equivalence between traditional Medicare Fee-for-Service (“FFS”) plans and MA plans.

### UHC’s Allegations

#### *Negligence Standard*

UHC alleges that the Final Rule applies a negligence standard for FCA liability by specifying that an overpayment would be considered “identified” when a MA plan determined, or should have determined through reasonable diligence, that it had received an overpayment.<sup>25</sup> According to UHC, “should have identified through the exercise of reasonable diligence” (*i.e.*, negligence) is a new standard not contemplated by PPACA or the FCA, which contain a recklessness standard.<sup>26</sup> UHC also contends that this negligence standard exceeds CMS’s statutory authority under the APA<sup>27</sup> and is procedurally deficient because it was not a logical outgrowth of the proposed rule, which incorporated a “reckless disregard or deliberate ignorance” standard.<sup>28</sup>

#### *Actuarial Equivalence*

UHC devotes much of the Complaint to arguing that the Part C/D Final Rule violates the statutory requirement that MA plans be treated with “actuarial equivalence.”<sup>29</sup> As background, MA plans are compensated for the risk they assume in insuring health plan members.<sup>30</sup> Congress requires Medicare to calculate reimbursement for MA plan beneficiaries using the same methodology as it does for Medicare FFS plan beneficiaries.<sup>31</sup> To accomplish this objective (known as actuarial equivalence), CMS first calculates the average monthly expenditure for the average Medicare FFS beneficiary. It then adjusts these baseline repayments according to the beneficiary profile of particular MA plans. Adjustments are based on MA plan data provided to CMS of diagnostic

codes from physician medical records.<sup>32</sup> MA plans are required to certify “based on best knowledge, information, and belief” that the risk adjustment data they provide to CMS, including diagnostic codes, are accurate.<sup>33</sup> Despite this requirement, the Complaint alleges that CMS has not previously required MA plans to independently validate diagnosis codes. Instead, CMS had created a risk adjustment model for MA plans, which was built using unaudited FFS data, to account for anticipated errors in diagnosis codes in the MA plan data.<sup>34</sup>

UHC alleges that the Part C/D Final Rule violates the requirement of actuarial equivalence because it requires MA plans to independently verify diagnostic codes provided by third parties (physicians) and delete those unsupported in the medical records. UHC argues that the Rule requires MA plans for the first time to scrutinize and correct enrollee data (such as those diagnostic codes from physicians) used to establish CMS per patient, per month payment rates to the MA plans, and it puts MA plans at the risk of incurring FCA exposure if it fails to do so for each inaccurate entry.<sup>35</sup> The net effect, according to UHC, is that by imposing greater scrutiny on MA plans than CMS applies to its own enrollee data for FFS plans, CMS will systematically underpay for the care of MA beneficiaries.<sup>36</sup>

### UHC Survives Motion to Dismiss

CMS moved to dismiss the Complaint, arguing that UHC lacked standing and the court lacked subject matter jurisdiction. On March 31, 2017, the district court denied CMS’s motion, in large part because of the new Rule’s potential FCA impact.<sup>37</sup> In ruling on UHC’s standing to challenge the Part C/D Final Rule, the court had to first determine whether UHC was allegedly injured either because the rule imposed a *novel* or new legal obligation on UHC or it

simply restated *pre-existing* obligations.<sup>38</sup> The court acknowledged that MA plans are obligated to exercise “due diligence” to certify to the accuracy of risk adjustment data they submit to CMS under 42 C.F.R. § 422.504(l)(2) and that they are required to adopt effective compliance programs under 42 C.F.R. § 422.503(b)(4)(v).<sup>39</sup> The court disagreed, however, that the PPACA overpayment provision imposed a pre-existing obligation on MA plans to engage in due diligence of diagnostic codes entered in medical records.<sup>40</sup> The court focused on the Rule’s requirement that MA plans engage in “reasonable diligence,” which requires “at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor the receipt of overpayments.”<sup>41</sup> The court found the new requirement’s impact on potential FCA liability to be significant:

While the Secretary points to other requirements that [UHC] must exercise “due diligence,” CMS has pointed to no other regulations where the statute has been interpreted to apply such a standard, either to CMS or to Medicare Advantage insurers. *In essence, the Secretary would have the Court find that the CMS Rule’s insistence on ‘proactive compliance activities,’ under pain of a False Claims Act suit provable by negligence alone is meaningless. It is not; it imposes (for good reason or not) new obligations.*<sup>42</sup>

#### Key Issues at Summary Judgment

As directed by the court, UHC and CMS briefed cross-motions for summary judgment, which likely will be decided later in 2018.<sup>43</sup> The vast majority of the briefing detailed the workings of Medicare Part C from the viewpoints of UHC, as a Part C provider, and CMS, the regulator. The parties differ on two key points – whether complete and accurate medical records are necessary to determine an MA plan’s actuarial equivalence to

a FFS provider and whether a negligence standard has been incorporated into FCA violations for overpayments by the Part C/D Final Rule. This article focuses on the negligence issue because it has important implications for a broader audience – all Medicare and Medicaid providers subject to FCA liability for not timely returning overpayments – but also briefly summarizes the actuarial equivalence arguments.

#### *Negligence as a Basis for FCA Liability*

– UHC

UHC argues that CMS essentially pulled a “surprise switcheroo” by publishing a final rule requiring MA plans to return overpayments that were “identified” and those that “should have been identified” or be subject to potential FCA treble damages and penalties. UHC also contends that even if the public had been given an opportunity to provide comments on the “should have been identified” standard, it is inconsistent with PPACA’s legislative history and an unreasonable interpretation of the statutory text requiring overpayments to be “identified.”<sup>44</sup> UHC builds on the district court’s earlier comment in its denial of CMS’s motion to dismiss that the “should have been identified” language is a negligence standard not found in the FCA.<sup>45</sup>

First, UHC emphasizes that the plain and unambiguous definition of “identified” requires actual knowledge, not negligence.<sup>46</sup> UHC provides several noted dictionary definitions of “identified,” all of which use terms such as “determine,” “establish,” or even “indicate,” and none of which suggest that “identified” means “should have” determined, established, or indicated.<sup>47</sup>

Second, UHC contends that, even if the word “identified” was ambiguous, CMS’s interpretation incorporating negligence is unreasonable given PPACA’s legislative history and the well-established scope of FCA liability.<sup>48</sup>

UHC reviews the House and Senate versions of PPACA to demonstrate that the final legislation, adopting the Senate version, reflected Congress’s intent that the standard for “identify” was to be stricter, not looser, than the FCA’s knowledge requirement of actual knowledge, recklessness, or willful blindness.<sup>49</sup> According to UHC, the House’s initial version of PPACA’s overpayment provision required an overpayment to be reported within 60 days after it was *known*, which was to have the same meaning as the FCA’s knowledge standard.<sup>50</sup> UHC notes that the Senate version, ultimately adopted by Congress, substituted “identified” for “known,” reflecting Congress’s decision to require actual knowledge, not the more expansive FCA knowledge standard.<sup>51</sup> In no event, though, did Congress in PPACA incorporate a lesser negligence standard.

UHC goes on to argue that its interpretation of Congress’s intent is supported by its consistency with FCA case law that requires more than negligence for FCA liability to be found.<sup>52</sup> UHC states “[u]nder CMS’s new definition, MA plans potentially are subject to this punitive liability based on merely negligent *inaction* (*i.e.*, failing to proactively search for and find overpayments) – a stark departure from the normal rule that the False Claims Act does *not* allow liability based only on negligence.”<sup>53</sup>

Lastly, UHC objects that CMS violated the APA when it proposed a definition of “identified” in its proposed rule and then applied a significantly different definition in its final rule – the “surprise switcheroo” – without the required notice and comment period.<sup>54</sup>

– CMS

CMS’s approach to UHC’s argument regarding the new imposition of a negligence standard in the Part C/D Final Rule is to deny that “should have been identified” is a negligence standard; instead CMS asserts that the standard of “should have been identified” through the exercise of reasonable

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diligence” is the same as reckless disregard under the FCA.<sup>55</sup> By doing so, CMS inexplicably ignores the district court’s prior finding that “should have been” is a negligence standard. CMS also ignores that UHC argued that “identified” could mean actual knowledge, a higher standard than FCA knowledge incorporating reckless disregard.

Instead of addressing the “should have been identified” language of the Part C/D Final Rule, CMS discusses only the “reasonable diligence” portion of the rule requiring an MA plan to return an overpayment when it “has determined, or should have determined through the exercise of reasonable diligence that [it] has received an overpayment.”<sup>56</sup> CMS first states, seemingly without statutory authority, that the Part C/D Final Rule’s use of “reasonable diligence” incorporates the pre-existing duty of MA plans to undertake “due diligence” in submitting accurate, complete, and truthful encounter data under 42 C.F.R. § 422.504(1) (an implementing regulation of the Medicare+Choice program).<sup>57</sup> CMS then equates “reasonable diligence” in the overpayment regulation with “due diligence” under § 422.504(1) and, thereby, concludes that there has been no “surprise switcheroo” between the proposed rule and the final rule.<sup>58</sup>

Finally, again brushing aside UHC’s contention that the overpayment requirement’s “should have been identified” standard is a negligence standard, CMS cites the previously-discussed *Medicaid* FCA case – *Kane* – for the proposition that Congress intended “to subject willful ignorance of Medi[care] overpayments to the [False Claims Act’s] stringent penalty scheme.”<sup>59</sup>

*Kane*, however, may not be as supportive as CMS suggests. First, *Kane* is a Medicaid case, and the court’s ruling expressly applied to Medicaid overpayments. Second, CMS’s substitution of the word *Medicare* for *Medicaid* in a key quotation from the case was done

without explanation or qualification, in contrast to an explicit admonition by the *Kane* court about the limits of its look to Medicare standards for deciding a Medicaid case.<sup>60</sup> Third, CMS did not offer context for the dispute in *Kane* – defendants were asserting that actual knowledge was required for FCA liability, whereas DOJ asserted that willful ignorance applied. The court sided with DOJ but, importantly, *Kane* did not involve application of the “should have identified” standard to proactive compliance activities (such as those that the District of Columbia court expressed concern about in rejecting the government’s motion to dismiss). The exact opposite was true. *Kane* was a reactive situation – a provider was on notice of potential Medicaid overpayments but failed to take timely action to report and return the overpayments. With that backdrop, CMS’s reliance on the “willful ignorance” language in *Kane* may be misplaced at its peril.

## *Actuarial Equivalence*

### – UHC

UHC’s summary judgment briefing largely addresses its actuarial equivalence claim that CMS is required by statute to ensure that payments to MA plans are adjusted “using an apples-to-apples” comparison of the risk assumed by a MA plan in insuring a beneficiary and the risk that CMS incurs for an identical FFS beneficiary.<sup>61</sup> UHC argues that the Part C/D Final Rule’s interpretation of “overpayment” violates the MA statutory requirements “by measuring the health status of MA plan beneficiaries using one measure (diagnoses recorded in medical charts) and the health status of FFS beneficiaries using another (diagnosis codes in claims data), in a manner that produces different assessments of risk for identical patients.”<sup>62</sup>

### – CMS

CMS frames UHC’s arguments as a blatant attempt to get paid for

beneficiary healthcare claims that are not supported in the underlying medical charts.<sup>63</sup> CMS lays out a starkly different understanding of the requirements of actuarial equivalence, and CMS argues that interpreting claims for payment based on diagnoses unsupported by beneficiary medical records as “overpayments” is reasonable and not contrary to the requirements of “actuarial equivalence” or of using the same methodology to calculate the risk score for traditional Medicare beneficiaries as for MA plan beneficiaries.

As a preliminary point, CMS argues that defining “overpayment” to include claims for payment based on diagnoses unsupported by the medical record is plainly reasonable, given its long requirement that diagnosis codes be supported by medical records, as expressed in MA Program Manuals, training materials, and the certification requirement in 42 C.F.R. § 422.504(1) (2).<sup>64</sup> CMS claims that the Part C/D Final Rule did not change this underlying requirement, and that challenging the Part C/D Final Rule will not relieve MA plans of this obligation.<sup>65</sup>

CMS claims that UHC has fabricated a risk adjustment model that bears no resemblance to the one CMS created. It denies having created a system built on an acknowledgment that MA risk adjustment data contained numerous erroneous risk adjustment codes.<sup>66</sup> It further asserts that CMS has a complex process for ensuring actuarial equivalence, and that the court should defer to its expertise in this context, consistent with the broad discretion given to the agency under the MA statute.<sup>67</sup>

## California False Claims Act Cases

Prior to UHC filing its declaratory injunction action, DOJ unsealed and joined two whistleblower FCA

cases in California against UHC entities (and others) alleging, *inter alia*, overpayments arising from risk adjustment data that did not accurately reflect the health risk of patients due to inadequately documented diagnosis codes in medical records and false attestations of accuracy and truthfulness regarding risk adjustment data sent to CMS.<sup>68</sup>

Of current significance is *United States ex rel. Poehling v. UnitedHealth Group*,<sup>69</sup> which was significantly trimmed back by the Central District of California on February 12, 2018 to leave only the “reverse” FCA claims<sup>70</sup> for overpayments relating to the risk adjustment data. The *Poehling* court found that the false attestation claims did not pass the Supreme Court’s *Escobar* materiality test<sup>71</sup> because the complaint failed to allege that if CMS knew of the false attestation, defendants’ risk adjustment payments would have changed.<sup>72</sup> By contrast, and potentially opening a new front in FCA cases, the court refused to find that *Escobar*’s materiality bar applied to this “reverse” false claim arising from an overpayment because (1) *Escobar* addressed the typical false presentment of a false or fraudulent claim brought under 31 U.S.C. § 3729(a)(1)(A), (2) the Ninth Circuit had previously held that provider cost reports were material because they had the effect of increasing or decreasing a defendant’s overpayment obligation, and (3) the government had sufficiently alleged materiality in its “reverse” false claims allegations.<sup>73</sup> Although the court dismissed the false attestation claims with leave to amend, DOJ on February 26, 2018 advised the court that its complaint would not be further amended, leaving it to proceed with the overpayment claims only.<sup>74</sup>

## Conclusion

Clearly, the two district courts involved in the UHC declaratory injunction and remaining FCA case have their work cut out for them. Applying standards for statutory and

regulatory interpretation and the APA, the court in the District of Columbia will decide whether CMS’s Part C/D Final Rule exceeds its statutory authority. Meanwhile, the court in the Central District of California, applying a preponderance of the evidence standard,<sup>75</sup> will likely need to decide whether risk adjustment data may contain inaccurate diagnosis codes and, if so, then has DOJ been able to demonstrate that all elements of the FCA are met, particularly defendants’ knowledge of the inaccurate codes. The Central District may wait for the District of Columbia to rule on the declaratory injunction before deciding the first issue.

The other issue before the District of Columbia court – whether “should have been determined through reasonable diligence” is a negligence state of mind – may be a foregone conclusion, given its earlier decision and CMS’s disregard of the court’s expression of concern about potential FCA liability for proactive compliance activities.

In any event, MA plans and other Medicare/Medicaid providers will be watching both litigation fronts closely.



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## Endnotes

- <sup>1</sup> *UnitedHealthcare Ins. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C., filed Jan. 29, 2016), Complaint (“Compl.”), ECF No. 1.
- <sup>2</sup> *UnitedHealthcare Ins. Co. v. Azar*, 248 F. Supp. 3d 192 (D.D.C. 2017).
- <sup>3</sup> *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. CV 16-08697 (C.D. Cal., transferred Nov. 8, 2016 from W.D.N.Y., filed Mar. 24, 2011); *United States ex rel. Swoben v. Scan Health Plan*, CV-09-5013 (C.D. Cal., filed Jul. 13, 2009).
- <sup>4</sup> 42 U.S.C. § 1320a-7k(d)(2).
- <sup>5</sup> 42 U.S.C. § 1320a-7k(d)(4)(B).
- <sup>6</sup> The PPACA 60-day Overpayment Rule does not apply to TRICARE or the Department of Veterans Affairs (the “VA”). However, TRICARE and the VA are subject to FCA liability under the “reverse false claims” provisions for retaining overpayments. See 31 U.S.C. § 3729(a)(1)(G) (creating FCA liability for avoiding an obligation to pay money to the government); 31 U.S.C. § 3729(b)(3) (defining an “obligation” to include retention of an overpayment). At least one healthcare provider has entered into a settlement with DOJ to resolve allegations that the provider failed to report and return overpayments from various federal payors, including TRICARE and the VA, as well as Medicare and Medicaid. See Press Release, Department of Justice, “Jacksonville Cardiovascular Practice Agrees to Pay more than \$440,000 to Resolve False Claims Act Allegations for Failing to Reimburse Government Health Care Programs,” (Oct. 13, 2017), <https://www.justice.gov/usao-mdfl/pr/jacksonville-cardiovascular-practice-agrees-pay-more-440000-resolve-false-claims-act>.
- <sup>7</sup> 42 U.S.C. § 1320a-7k(d)(3); 31 U.S.C. § 3729(b)(3)).
- <sup>8</sup> 2015 *Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefits Programs*, 79 Fed. Reg. 29,844-29,968 (May 23, 2014) (codified in pertinent part at 42 C.F.R. § 422.326).
- <sup>9</sup> 42 C.F.R. §§ 422.326(c), 423.360(c) (emphasis added). Note that in the Part C context, MA plans do not submit claims for services. Rather, they submit risk adjustment data composed of diagnosis codes for their beneficiaries in a given year that are included in CMS’s calculation of monthly per-beneficiary sums. See 42 U.S.C. § 1395w-23(a)(1)(A), (C)(i). Thus, in the Part C context, an overpayment

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would include retention of a monthly payment not supported by diagnosis codes.

<sup>10</sup> 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefits Programs, 79 Fed. Reg. 1918, 2055, 2066 (as proposed Jan. 10, 2014) (emphasis added).

<sup>11</sup> See 31 U.S.C. § 3729(b)(1)(A).

<sup>12</sup> 79 Fed. Reg. 29,923 (citing 42 C.F.R. §§ 422.504(l) and 423.505(k)).

<sup>13</sup> 79 Fed. Reg. 29,923-24.

<sup>14</sup> *United States ex rel. Kane v. Continuum Health Partners, Inc.*, et al., 120 F. Supp. 3d 370 (S.D.N.Y. 2015) (“Kane”).

<sup>15</sup> A “relator” is a private plaintiff who is permitted to bring a civil fraud action on behalf of the United States under the FCA. After an opportunity to investigate the relator’s allegations, DOJ may intervene and proceed with the action or it may decline to proceed, in which case the relator may continue the case on behalf of the United States. See 31 U.S.C. § 3730(b).

<sup>16</sup> *Id.* at 375-77.

<sup>17</sup> *Id.* at 388.

<sup>18</sup> *Id.* at 388-89.

<sup>19</sup> *Id.* at 392-93. The court pointed to CMS’s February 16, 2012 proposed Part A/B rule, stating that an overpayment is “identified” when the provider “has actual knowledge of the overpayment or acts in reckless disregard or deliberate ignorance of the payment.” *Reporting and Returning of Overpayments*, 77 Fed. Reg. 9179, 9187 (as proposed Feb. 16, 2012). This standard was changed in the Part A/B Final Rule, as discussed *infra*.

<sup>20</sup> *Reporting and Returning of Overpayments*, 81 Fed. Reg. 7654-7684 (Feb. 12, 2016) (codified at 42 C.F.R. pt. 401 and 405).

<sup>21</sup> 42 C.F.R. § 401.305(a)(2) (emphasis added).

<sup>22</sup> 81 Fed. Reg. at 7662.

<sup>23</sup> *Id.*

<sup>24</sup> 81 Fed. Reg. 7662-63.

<sup>25</sup> Compl. at ¶¶ 77-78 (emphasis added); 79 Fed. Reg. 29,923.

<sup>26</sup> Compl. at ¶¶ 5, 78, 95; 31 U.S.C. § 3729(b)(1) (defining “knowing” and “knowingly”).

<sup>27</sup> 5 U.S.C. § 706(2)(A) and (C).

<sup>28</sup> Compl. at ¶ 96.

<sup>29</sup> Compl. at ¶¶ 6-10.

<sup>30</sup> Compl. at ¶ 30.

<sup>31</sup> Compl. at ¶¶ 31-33.

<sup>32</sup> Compl. at ¶¶ 30-34.

<sup>33</sup> Compl. at ¶ 41 (citing 42 C.F.R. §§ 422.504(l)(2)).

<sup>34</sup> Compl. at ¶ 42-43.

<sup>35</sup> Compl. at ¶¶ 42, 52, 77-78.

<sup>36</sup> Compl. at ¶¶ 78, 80-81.

<sup>37</sup> *UnitedHealthcare*, 248 F. Supp. 3d 192 at 205.

<sup>38</sup> *Id.* at 200.

<sup>39</sup> *Id.* at 200-01. Both regulations address requirements for contracts between MA plans and CMS and predate the 60-Day Rule.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.* at 201 (citing 79 Fed. Reg. at 29,923).

<sup>42</sup> *Id.* (emphasis added).

<sup>43</sup> UHC Motion for Summary Judgment and Supporting Memorandum (“UHC MSJ”) (filed Oct. 17, 2017), ECF No. 47-1; CMS Cross-Motion for Summary Judgment and Opposition to Plaintiff’s Motion for Summary Judgment (“CMS Opp.”) (filed Dec. 4, 2017), ECF No. 58; UHC Memorandum in Opposition to Cross Motion for Summary Judgment (“UHC Reply”) (filed January 18, 2018), ECF No. 60; CMS Reply in support of Cross Motion for Summary Judgment (“CMS Reply”) (filed February 12, 2018), ECF No. 64.

<sup>44</sup> UHC MSJ at 42-44.

<sup>45</sup> *Id.*

<sup>46</sup> *Id.* at 42-43.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 43.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.* (citing H.R. 3200, 111th Cong. § 1641).

<sup>51</sup> *Id.* (citing Pub. L. No. 111-148, § 6402(a), 124 Stat. at 755).

<sup>52</sup> *Id.* at 43-44.

<sup>53</sup> *Id.* at 44 (citations omitted) (emphasis in original).

<sup>54</sup> *Id.* at 44-45.

<sup>55</sup> CMS Opp. at 43-45.

<sup>56</sup> *Id.* at 43-44; 42 C.F.R. § 422.326(c).

<sup>57</sup> *Id.* at 44.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* (citing *Kane*, 120 F. Supp. 3d at 391).

<sup>60</sup> The *Kane* court looked to Medicare regulations in considering the reasonableness of its outcome in the Medicaid context, but it also stated that it “considers” but “does not place significant weight on the interpretation” provided by CMS. 120 F. Supp. 3d at 391.

<sup>61</sup> UHC MSJ at 1-2 (citing 42 U.S.C. § 1395w-23(a)(1)(C)(i)).

<sup>62</sup> UHC MSJ at 12, 21, 27, 27-32. UHC explains the impact on the MA plan in the following example:

Suppose that when it calibrates the [risk adjustment model], CMS identifies four FFS beneficiaries with the diagnosis code for diabetes and determines that the aggregate incremental healthcare costs for the four beneficiaries the following year were \$12,000. CMS therefore concludes that the average per-patient cost associated with diabetes is \$3,000 and it sets the diabetes risk coefficient accordingly. But suppose further that one of these diagnosis

codes was a false positive; the beneficiary did not in fact have diabetes. That means that the \$12,000 was in reality attributable to just three beneficiaries, such that the true per-patient cost of diabetes was actually \$4000 (\$12,000 ÷ 3 beneficiaries). By averaging the cost over the four beneficiaries with the diagnosis code, rather than just the three beneficiaries who actually have diabetes, CMS’s model produces a lower average incremental cost (and associated risk coefficient) than it would have done if the diagnosis codes in the FFS data had been perfectly accurate. . . . If all beneficiaries actually have diabetes, this payment will undercompensate the plan for its presumptive incremental costs, which would be \$16,000 (\$4,000 per beneficiary who actually has diabetes).

UHC MSJ at 12.

<sup>63</sup> See, e.g., CMS Opp. at 24 (“But United has concocted an alternative history, in which payment on the basis of unsubstantiated diagnoses is an essential premise of everything the Secretary has done to implement the Medicare Advantage program, which the Overpayment Rule would now abruptly and arbitrarily abandon. . . . What United wants is not the vacatur of 42 C.F.R. 422.326, which it barely mentions in its brief, but something far more wide-reaching: a judicial declaration that Medicare Advantage insurers can lawfully claim payments for the costs associated with diseases their beneficiaries do not have.”).

<sup>64</sup> CMS Opp. at 24-27.

<sup>65</sup> CMS Opp. at 2-3.

<sup>66</sup> CMS Opp. at 1-2, 8-13.

<sup>67</sup> CMS Opp. at 14-20, 28-31, 36-40; 42 U.S.C. § 1395w-23(a)(1)(C)(i) (“The Secretary shall adjust the payment amount . . . for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence.”) (emphasis supplied).

<sup>68</sup> One case, *United States ex rel. Swoben v. Scan Health Plan*, CV-09-5013 (C.D. Cal., filed Jul. 13, 2009), was dismissed by the government on November 2, 2017 after eight years of investigation and litigation when the government chose not to further amend its complaint-in-partial-intervention after the court dismissed significant portions of its claims.

<sup>69</sup> *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. CV 16-08697 (C.D. Cal., transferred Nov. 8, 2016 from W.D.N.Y., filed Mar. 24, 2011).

<sup>70</sup> *Id.*, Civil Minutes at 11 (entered Feb. 12, 2018), ECF No. 212 (citing 31 U.S.C. § 3729(a)(1)(G) (knowingly concealing or knowingly improperly avoiding an obligation to pay or transmit money to the government)).

<sup>71</sup> *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996, 2003-04 (2016). In *Escobar*, the Supreme Court held, *inter alia*, that only material noncompliance with statutes, regulations, or contract requirements can trigger FCA liability, and the government’s payment of claims in full despite its

actual knowledge that certain requirements were violated is strong evidence that the requirements were not material.

<sup>72</sup> *Poehling*, No. CV 16-08697, Civil Minutes at 16. See also *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 764 (3d Cir. 2017) (upholding dismissal of *qui tam*

complaint in Medicare Part D case where court found CMS would have paid defendant PBM's Part D claims containing "dummy prescriber IDs" even if it had known of their use).

<sup>73</sup> *Id.*, Civil Minutes at 19-20 (citing, for the second point, *United States v. Bourseau*, 531 F.3d 1159 (9th Cir. 2008)).

<sup>74</sup> *Id.*, United States' Notice of Decision Regarding Amendment of Complaint and Request for a Scheduling Conference (filed Feb. 28, 2018), ECF No. 217.

<sup>75</sup> 31 U.S.C. § 3731(d).



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## Chair's Corner

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questionable how fully the government can afford to meet this commitment. It sounded as if the economy was more robust when the Soviet Union was involved in Cuba and subsidized the country's crops of sugar and tobacco. But our hosts described a terrible economic crisis the country went through from 1992 to 1997 after the fall and withdrawal of the Soviet Union – they refer to it as the “Special Period.” The United States’ reopening of diplomatic relations with Cuba in 2015 and a surge of tourism fueled some private enterprise and increased income for some. Small businesses emerged to cater to the tourist industry, including private restaurants, taxi companies, and guesthouses. The Trump administration has reversed course, however, and discourages tourism to Cuba. This has reportedly led to an abrupt reduction in the tourist business from the United States, although we heard that a significant number of tourists are still coming from Europe and Latin and South America. Meanwhile, the Cuban government reportedly acted to curtail entrepreneurship in 2017 by ceasing to issue new licenses for businesses such as restaurants.<sup>1</sup> Our group ate all of our meals in private restaurants that locals probably cannot afford, and not all of those establishments were full when we were there.

Against that backdrop, we met with a number of warm and hospitable professionals. Our delightful and knowledgeable in-country guide had been a professor at Havana University before refocusing his language and teaching skills on the more lucrative business of guiding tourists. We were hosted at the National Union of Cuban Jurists by Doris Quintana, who has a doctorate in international and public law, is a law professor at Havana University, and serves as secretary of the Scientific Society of International Law of the National Union of Cuban Jurists. In addition to Dr. Quintana, an environmental lawyer and a family lawyer from the General Prosecutor’s Office provided us with interesting information about the government, the Cuban Constitution, and the healthcare system. Dr. Jose Portilla, a former surgeon currently with the Ministry of Public Health, also discussed the Cuban healthcare system with us. They were welcoming and eager to share their country’s structure, ideals, and accomplishments. They were also clearly frustrated with the ongoing U.S. embargo and long for our countries to re-establish a relationship.

The focus of the Cuban healthcare system is different from ours in the United States. We have the right to life, liberty, and the pursuit of happiness, but not necessarily an express right to healthcare. Article 50 of the Cuban Constitution, in contrast, guarantees everyone a right to free healthcare as follows:

Everybody has the right to health protection and care. The State guarantees this right:

- by providing free medical and hospital care by means of the installations of the rural medical service network, polyclinics, hospitals and preventive and specialist treatment centers;
- by providing free dental care;
- by promoting the health publicity campaigns, health education, regular medical examinations, general vaccinations and other measures to prevent the outbreak of disease. All of the population cooperates in these activities and plans through the social and mass organizations.<sup>2</sup>

Cuba has a population of around 11.5 million people and much less to spend on healthcare than the United States has. Therefore, the Cuban healthcare system’s highest priority is preventive care, followed in order of priority by treatments for minor problems, chronic conditions, and finally serious illnesses. The Cuban healthcare system is often touted as a very good primary care system relying on preventive care that does much with less.<sup>3</sup> According to the United Nation’s World Health Organization, it is an example for countries of the world.<sup>4</sup> Further, it has been suggested that Cuba offers the best model for poor countries.<sup>5</sup> It is certainly quite different in approach from U.S. healthcare, with its greater emphasis on tests, tools, and equipment for diagnosing and treating illnesses than on prevention.

The front line of the Cuban healthcare system is the family physician. We learned that after completing the equivalent of our high school, would-be Cuban physicians attend school for six years to become doctors, followed by a two-year residency in a family physician’s office and in a multi-specialty outpatient facility called a polyclinic. The training is free, and every Cuban-trained physician starts out as a family physician. It sounds as if most continue to practice as family physicians, while a few pursue specialty training, and only where there is a particular need.

Family physicians work in the neighborhoods where they live, and we learned that there are approximately 12,883 family physician offices in Cuba. These physicians typically have their offices on the bottom floor of a house and live in the upper floor or floors. A nurse and a technician work with each physician to serve their community. Through a combination of home and office visits, the family physicians are charged with knowing all of the families in their neighborhood and seeing every patient at least once a year. The family physicians also reportedly know the teachers at the local school; this connection enables physicians, teachers, and parents to work together to help children who develop health or

behavioral problems. We visited a family physician who serves around 994 patients. His office and exam room were small and simple, and his records were kept on paper in vertical file cabinets, but he was proud to show them to us.

The next layer of the system is the polyclinic. Cuba has around 451 polyclinics, with approximately 18 family physician offices connected to each one. In addition to a small emergency department, the polyclinics offer radiology and laboratory services; gynecology, obstetrics, pediatric services, and psychiatric care; and more complicated treatments such as ozone therapy and minor surgeries performed with topical anesthesia such as lidocaine. Although the facilities of the polyclinic we visited were old and somewhat dilapidated, they appeared clean. We saw many patients sitting in waiting rooms or wandering through the halls. Our guide through the polyclinic was a family physician who had trained there 20 years before. She then stayed on at the polyclinic, treating patients and in turn training residents.

Inpatient care is provided in 151 community hospitals and numerous specialty institutes, of which there are 15 in Havana. While we did not visit a hospital, we spent some time visiting with the medical director at the National Institute of Oncology and Radiology. This delightful surgeon was very generous with his time and explained the principal services that his institute offered, including head and neck surgery and breast surgery. He also described a world of precision medicine in the future, that we too, in the United States, are pursuing. He noted that Cuba has about 300 oncologists, and that colon cancer and lung cancer were prevalent in the country.

Our hosts were understandably proud of Cuba's many achievements. In part by registering every pregnancy with the family physician, providing ongoing prenatal care, and requiring births to occur in hospitals, Cuba has lowered infant mortality from 60 per 1,000 in the 1950s to four per 1,000 today. This contrasts favorably to infant mortality in the United States, which the Centers for Disease Control and Prevention has reported as just under six per 1,000.<sup>6</sup> Over that same period of time, Cuba has raised life expectancy from 60 to an average of 79, comparable to life expectancy in the United States.<sup>7</sup> By requiring all children to receive 13 vaccinations, they have eradicated numerous diseases from polio to pertussis. In 2015, the World Health Organization validated Cuba as the first country to eliminate transmission of HIV and syphilis from mother to child.<sup>8</sup> And Cuban researchers have developed new treatments to prevent amputation of diabetics' feet and a lung cancer vaccine that is a promising form of immunotherapy.

At the same time, there are concerning drawbacks to the lack of resources in the Cuban healthcare system and its focus on prevention. Given the American embargo, it is difficult and expensive for Cubans to obtain pharmaceuticals and supplies for treatment because so many are produced in the United States and are unavailable to them. There is a striking lack of wireless access to the internet, and we saw no electronic health records. The medical director of the National Institute of Oncology and Radiology noted that his institute had fiber optics, but not all institutes did, and Cuba has digital records only for clinical trials. Colonoscopies are not provided to screen for colon cancer, only to diagnose individuals who are already symptomatic. High-risk women receive mammography screening beginning at 40, but other women do not receive screening until 55. Certain types of cancer treatment modalities, such as proton accelerators, do not exist on the island. There are no shock trauma units. Many of the facilities do not appear to be state of the art in nature. Thus, the presence of high tech equipment and treatment for serious conditions appears to be quite limited, particularly in contrast with the sophisticated range of tests and treatments available in the United States.

The Cuban government appears to have taken deliberate steps to establish a healthcare system that enlists the community to focus on health and prevention, and that tries to achieve maximum effect with limited resources. It was fascinating to learn about their system in contrast to ours, with its greater focus on individual choice and treatment of illnesses.

## Endnotes

- <sup>1</sup> *Cuba Leaves Castro Era With Slim Prospects for Change*, José de Córdoba, Wall Street Journal, April 17, 2018, <https://www.wsj.com/articles/cuba-leaves-castro-era-with-slim-prospects-for-change-1523957400>.
- <sup>2</sup> Oxford University Press, Inc. Translated by Pam Falk, Milagros M. Gavilan and Anna I. Velive Torras, *Cuba's Constitution of 1976 with Amendments through 2002*, Constitute Project.
- <sup>3</sup> Warner, Rich (PhD Candidate), Anglia Ruskin University, *Is the Cuban healthcare system really as great as people claim?*, The Conversation, November 30, 2016.
- <sup>4</sup> Lamrani, Salim, *Cuba's Health Care System, a Model for the World*, The Blog, August 8, 2014.
- <sup>5</sup> Fitz, Don Synthesis/Regeneration, RATB Writes, *Why is Cuba's Health Care System the Best Model for Poor Countries?*
- <sup>6</sup> <https://www.cdc.gov/nchs/fastats/infant-health.htm>.
- <sup>7</sup> <https://www.cdc.gov/nchs/fastats/life-expectancy.htm>.
- <sup>8</sup> *WHO validates elimination of mother-to-child transmission of HIV and syphilis in Cuba*, World Health Organization press release, June 30, 2015, <http://www.who.int/mediacentre/news/releases/2015/mtct-hiv-cuba/en/>.

## Montgomery & Andrews and University of New Mexico School of Law Award Four EMI Scholarships

**Montgomery & Andrews, P.A.**, a New Mexico firm with offices in Santa Fe and Albuquerque partnered with the **University of New Mexico School of Law** to establish a scholarship fund to enable law students with an interest in health law to attend the Emerging Issues in Healthcare Law (EMI) Conference in Scottsdale, Arizona from February 21-23, 2018. This year's recipient was **Lenaya Montoya**.

M&A attorneys **David H. Johnson**, **Deborah Mann**, **Stefan R. Chacón** and **Jesse Hale**, in collaboration with faculty and staff from the law school, started the annual scholarship in 2016. In addition, the law school

was able to raise additional funds to enable three more students, **Alison Goodwin**, **Joshua Hasyniec** and **Paul Martello**, to attend. The students enjoyed the educational experience at the conference, as well as the wealth of networking opportunities with healthcare attorneys from across the country. The Section hopes that other firms will seek similar opportunities with local law schools.

If you or your firm is interested in exploring a scholarship fund for students in your area, please contact the Section's Director, Simeon Carson at [simeon.carson@americanbar.org](mailto:simeon.carson@americanbar.org).



From left to right: David H. Johnson, Alison Goodwin, Lenaya Montoya, Jesse Hale, Joshua Hasyniec, Paul Martello and Stefan R. Chacón.

## Health Law Section Presents Five EMI Law Student Scholarships

The Health Law Section was pleased to present five law students with scholarships to attend the Emerging Issues in Healthcare Law (EMI) Conference in Scottsdale, Arizona from February 21-23, 2018. The recipients were:

**Lindsay J. Eaton**, University of Toledo College of Law, Toledo, OH;

**Maureen Iruke**, Thurgood Marshall School of Law, Houston, TX;

**Tatyana Krimus**, University of Miami School of Law, Miami, FL;

**Zoila Sanchez**, Maurice A. Deane School of Law at Hofstra University, Richmond Hill, New York; and

**Alexi Silverman**, University of San Diego School of Law, San Diego, CA.

The students were recognized by the conference Co-Chairs, **Kathy Poppitt** of King & Spalding, Austin, TX and **Diane Carter** of Husch Blackwell in Austin, TX.

The partial scholarships are intended for those who would not otherwise be able to attend the conference,

and those who have not previously received financial assistance from the Section to attend it.

For more information, please contact the Section's Director, Simeon Carson at [simeon.carson@americanbar.org](mailto:simeon.carson@americanbar.org).



From left to right: Zoila Sanchez, Kathy Poppitt, Maureen Iruke, Tatyana Krimus, Alexi Silverman, Lindsay Eaton and Diane Carter.

## Health Law Section Offers Publishing Opportunities

The Health Law Section is always interested in publishing material from our members and others. We strive to produce top quality, relevant and interesting articles, books, toolkits, and the like for the health law bar. Opportunities include:

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**ABA Health eSource** – Our electronic monthly newsletter is a perfect place to find and publish succinct, timely articles. Generally the articles for this monthly publication are not as long as the articles in *The Health Lawyer* but are every bit as important. Rachel Blakley is the staff person in charge of the *ABA Health eSource* and can be reached at 312/988-5468 or at [rachel.blakley@americanbar.org](mailto:rachel.blakley@americanbar.org).

**Book publishing** – Do you have a good idea for a single topic book? Contact Rachel Blakley to discuss your book project. Generally these are soft covered books of 200 to 300 pages; books in the Section's popular "What is..." series are typically less than 100 pages. Rachel can be reached at 312/988-5468 or at [rachel.blakley@americanbar.org](mailto:rachel.blakley@americanbar.org).

# COURTS STRUGGLE TO BALANCE BEDROCK PRINCIPLES OF ANTITRUST LAW WITH POLICY IMPLICATIONS OF NONPROFIT HOSPITAL MERGERS

Sean McGrath  
J.D. June 2018  
St. John's University School of Law  
Queens, NY

## Introduction

The 2016 Presidential Election brought with it an increased focus on the need for greater competition in the healthcare marketplace. A few months after the election, President Donald Trump issued an Executive Order “Promoting Healthcare Choice and Competition Across the United States.”<sup>1</sup> The Executive Order states that the Trump Administration “will . . . continue to focus on *promoting competition in healthcare markets and limiting excessive consolidation throughout the healthcare system.*”<sup>2</sup> The political spotlight on healthcare competition comes in response to the myriad hospitals that have consolidated or formed integrated delivery systems (“IDS”), either by merging or acquiring other hospitals and physician practice groups.<sup>3</sup> An IDS “owns one or several hospitals and also employs physicians across multiple specialties.”<sup>4</sup>

Many proponents of hospital consolidation are in favor of lenient antitrust enforcement for the healthcare industry, arguing that these IDSs are “not only better for patients but also reduce duplication and avoid unnecessary services, thus lowering costs.”<sup>5</sup> Opponents argue that consolidation does not lower prices and increase value, but in many cases actually increases costs for healthcare consumers; thus antitrust law should be strictly construed in order to foster greater competition and reduce prices for patients. While there is no one cause of the consolidation of the healthcare market, this article focuses on nonprofit hospital mergers and the

favorable treatment hospitals received by the courts despite overwhelming statistical evidence that the merger would be anticompetitive.

Although the executive branch historically and under the Trump Administration has taken a strong stance on competition in the healthcare market, the judicial branch has not been as clear. Unsuccessful government challenges to hospital mergers in the 1990s and early 2000s suggest that courts disagreed with the executive branch in regard to the consolidation of nonprofit hospitals.<sup>6</sup> Despite strong statistical evidence of potential anticompetitive effects, courts continuously ignored government warnings that a nonprofit hospital merger would result in a highly concentrated marketplace and substantially lessen competition.<sup>7</sup> Instead, courts believed that the charitable nature of the nonprofit hospitals and the proposed efficiencies of the merger would pass cost-savings onto consumers.<sup>8</sup> This harsh streak of “eight straight government losses” in the 1990s and early 2000s sent a clear message in favor of consolidation and resulted in “a long hiatus in hospital-merger enforcement” by the Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”) in the mid-2000s.<sup>9</sup> Although many factors contributed to the decline in the number of hospitals in the United States, there is no denying that favorable court treatment toward hospital mergers cleared a path for the mass consolidation.<sup>10</sup> Since 1975, the number of hospitals in the United States decreased from 7,156 to the 5,534 hospitals in the country today.<sup>11</sup>

Despite the general application of antitrust laws to “any line of commerce . . . in any section of the country,”<sup>12</sup> many scholars have debated

whether these laws should apply to the unique nature of the healthcare industry, and in particular to nonprofit hospitals. On one hand, courts seek to “prevent economic concentration in the American economy by keeping a large number of small competitors in business,” while on the other hand recognize the need to eliminate duplicate resources and waste.<sup>13</sup> Regardless of the policy arguments on both sides, empirical studies have shown that “that hospital mergers that create market power do lead to higher prices, and that *this is true for both for-profit and nonprofit hospitals.*”<sup>14</sup> Thus, absent legislation exempting hospital mergers, the courts should put policy aside and strictly adhere to the bedrock principles of antitrust law. In other words, courts should not ignore strong statistical evidence of potential anticompetitive effects and blindly rely on the charitable nature and promises of nonprofit hospitals to pass cost savings onto consumers.

Part A of this article analyzes the policy arguments both in favor of lenient antitrust enforcement for hospitals in the healthcare market and in favor of strict antitrust enforcement. It assesses the unique framework of the healthcare market, including the product differentiation, imperfect information in the third party payor system, and the significant number of nonprofit hospitals. Part B looks at the legal framework of an antitrust claim, explaining the procedure for government challenges and the legal analysis courts apply. Part C considers the trend of harsh judicial treatment to government challenges brought against nonprofit healthcare mergers. It explores how the courts ignored overwhelming evidence that the result of the merger would allow the hospitals to raise prices. In particular, courts

relied on the proposed efficiencies of the merger and the charitable nature of nonprofit hospitals to pass cost savings onto consumers, downplaying strong statistical evidence offered by the government that the mergers were presumptively anticompetitive. Part D illuminates empirical evidence suggesting that nonprofit hospitals do exercise their market share in highly concentrated markets, resulting in higher prices; anticompetitive mergers give hospitals more leverage, and the hospitals use this leverage to raise prices. Part E briefly examines the recent success of FTC challenges against hospital mergers. Finally, the article suggests how courts should apply antitrust laws to nonprofit hospital mergers more stringently, and continue down its recent path of more favorable treatment to FTC challenges.

## Part A: Policy Considerations for Exemption or Application of Antitrust Law to the Healthcare Market

“The economic justification for antitrust enforcement is that competition maximizes social welfare.”<sup>15</sup> However, “[w]hile in most industries the link between competition and social welfare is (or seems to be) direct, it is not obviously so in health care.”<sup>16</sup> Healthcare markets contain a number of “imperfections,” which largely derive from “the uncertainty and asymmetry of information between buyers and sellers that are inherent in the nature of health and medical care.”<sup>17</sup> Thus, proponents for lenient antitrust enforcement and exceptions for nonprofit hospital mergers believe that healthcare markets are “so fundamentally different from other markets that meaningful competition is either an impossibility or counterproductive.”<sup>18</sup> Proponents in favor of strict antitrust application concede that healthcare markets are not textbook competitive markets, but “few real

world markets” actually are.<sup>19</sup> Most if not all markets have imperfections, and “while competition in health care markets should be examined in light of its special character, so should competition in any other market.”<sup>20</sup> Three major imperfections in healthcare markets that provide the foundation for this debate include healthcare as a differentiated product, imperfect information in the third party payor system, and the large number of nonprofit hospitals.<sup>21</sup>

### Product Differentiation

One main argument in favor of lenient antitrust law enforcement regarding hospitals is that healthcare is a differentiated product.<sup>22</sup> Healthcare is a service and cannot be traded among consumers. Unlike other industries, healthcare is never the same thing twice.<sup>23</sup> Each time someone is sick, his distinct characteristics and medical history render his diagnosis and/or treatment different from another patient. Further, patients tend to stay loyal to their physicians.<sup>24</sup> This “inherently heterogeneous and non-retradable” product results in many healthcare providers, such as nonprofit healthcare systems, having substantial market power.<sup>25</sup> This is problematic for competition because “[t]he less substitutable are sellers for one another, the greater degree of market power.”<sup>26</sup> Proponents for lenient antitrust enforcement argue that since the healthcare market is a highly differentiated product and inherently anticompetitive, there is no need for judicial intervention.<sup>27</sup>

Those who believe that hospitals should be subject to strict compliance with antitrust law argue that allowing hospitals to merge without restraint or scrutiny would result in even more power to the sellers.<sup>28</sup> This argument was presented by the FTC and rejected by the court in *F.T.C. v. Butterworth*.<sup>29</sup> There, the FTC argued that patients would be unlikely to utilize other hospitals even if the merging hospitals

combined market power and raised prices.<sup>30</sup> The FTC surveyed consumers and found “outmigration would be resisted by patients due to physician loyalty, inasmuch as it could entail treatment in hospitals where their own treating physicians lack admitting privileges.”<sup>31</sup> Despite this testimony, the court held that the “dynamic evidence presented by the FTC [was] not conclusive.”<sup>32</sup>

### Imperfect Information in the Third Party Payor System

Another major argument against the strict application of antitrust law to healthcare markets is the competition for expensive medical equipment and resources due to the third party payor system. The third party payor system is “[a]ny organization, public or private, that pays or insures health or medical expenses on behalf of beneficiaries or recipients, such as commercial insurance companies, Medicare, and Medicaid.”<sup>33</sup> Patients usually pay a premium for coverage, and when a patient receives medical services the third party payor then pays the bills.<sup>34</sup> This can lead to a “decreased incentive for consumers to search for the lowest price.”<sup>35</sup>

Since patients often pay a little up front, and the insurance company covers the rest, patients often do not appreciate or even “see the total costs of the treatment that [they] receive.”<sup>36</sup> Unlike other goods or services, such as food in a restaurant, where “people are able to search online and elsewhere for customer reviews and prices,” “it is generally not possible to find out how much a treatment really costs.”<sup>37</sup> Therefore, “the consumer is left without valuable information as to which treatments are most cost effective.”<sup>38</sup> This results in an informational gap, sometimes referred to as the “third party payor problem,” where the supplier can take advantage of the misinformation.<sup>39</sup> For example, “a simple injection that would cost the care provider

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a mere seven dollars . . . could cost the patient and insurance company combined anywhere between \$150 and \$350.”<sup>40</sup> Moreover, since it can be difficult for patients to understand the nature and extent of their medical conditions, and since patients generally only focus on the reduced price of the treatment after insurance coverage, the inability to weigh the cost-benefit of treatment may lead to “excessive consumption.”<sup>41</sup>

Proponents for lenient antitrust enforcement argue that consolidation will reduce the third party payor gap and standardize the price paid for treatment.<sup>42</sup> Contrarily, advocates for stricter antitrust application argue that even if patients cannot fully comprehend which treatments are cost effective, managed care organizations are in a position to comprehend prices for care and negotiate on their members’ behalf.<sup>43</sup> Thus, managed care organizations need greater competition among hospitals to be able to leverage hospitals against other hospitals and negotiate lower prices. In *F.T.C. v. Tenet Health Care*, managed care organizations testified that they “negotiated substantial discounts and favorable per diem rates” from the hospitals that were seeking to merge by “playing the two hospitals off each other.”<sup>44</sup>

Additionally, some have claimed that because of insurance, hospitals do not compete on price to attract patients. Rather, hospitals “compete solely on quality of facilities to attract patients (or doctors who then bring patients with them).”<sup>45</sup> To that end, hospitals acquire an excessive amount of medical equipment to compete with other hospitals. This has been called the “medical arms race,” and could result in unnecessary, duplicative resources.<sup>46</sup> In *U.S. v. Long Island Jewish*, the hospitals argued that antitrust enforcement was not warranted because the merger would “eliminate duplication and facilitate pool purchases.”<sup>47</sup> So, too, in *F.T.C. v.*

*Butterworth*, one of the hospitals argued that it would save \$99.2 million by merging and combining resources as opposed to building its own replacement facility.<sup>48</sup> The hospital argued that this facility was necessary “to enable effective competition . . . in the ongoing ‘medical arms race.’”<sup>49</sup>

Proponents of strong antitrust enforcement in the healthcare market argue that even if a merger saves money in face of the medical arms race, any cost savings from consolidation will be retained by the hospitals rather than passed on to the consumers. In *F.T.C. v. Butterworth*, the FTC pointed to evidence that even board members of nonprofit hospitals “quickly develop institutional loyalty that may overcome their vigilance of community interests.”<sup>50</sup> The FTC unsuccessfully pointed to the above-average profit margins realized in recent years by the merging hospitals to demonstrate “that both boards have exercised market power to charge higher than necessary prices and realize above-average profits, which are not in the community’s best interests.”<sup>51</sup>

## Nonprofit Status

In the United States, the healthcare market is “dominated by not-for-profit firms.”<sup>52</sup> Out of the 5,534 total hospitals in the United States, 2,849 are nongovernment nonprofit community hospitals.<sup>53</sup> In theory, “not-for-profit hospitals seek to maximize the welfare of the community in which they are located, and thus do not exercise market power if given the opportunity.”<sup>54</sup> Therefore, such a large number of nonprofit firms reduced the need for enhanced competition.<sup>55</sup> This is precisely the argument proponents for lenient antitrust enforcement make. In *FTC v. Butterworth*, the court held that the charitable nature of the hospitals would prevent them from exercising market power in an anticompetitive fashion.<sup>56</sup> The court relied heavily on

the hospitals’ “nonprofit status” and that the boards of the merging hospitals were “comprised of community business leaders who have a direct stake in maintaining high quality, low cost hospital services.”<sup>57</sup> In contrast, proponents in favor of strict antitrust application to nonprofit hospitals believe that nonprofit status is not enough to prevent hospitals from exercising their market share and raising prices.<sup>58</sup> Such a view was taken by a more recent decision in *F.T.C. v. OSF Healthcare System*, where the court expressly rejected the nonprofit hospital defense, finding “that nonprofit hospitals do seek to maximize the reimbursement rates they receive.”<sup>59</sup>

Although the healthcare market is not the textbook competitive market, few markets actually are. Major imperfections, such as the differentiated product of healthcare, imperfect information in the third party payor system, and the domination of nonprofit hospitals in the market, as noted above, make it difficult to adhere to strict antitrust principles. This is demonstrated in the following cases, where the courts granted favorable treatment to the merging hospitals. Underlying the holdings of these cases is the court’s attempt to grapple with the policy implications of the unique nature of the healthcare market. Thus, the courts ignored the overwhelming statistical evidence of the government that the merger will be anticompetitive and relied on the nonprofit status of the hospitals in the belief that the hospitals will pass any efficiencies of the merger onto consumers. As described below, this trust in hospitals did not pan out.

## Part B: Legal Framework of an Antitrust Claim

The Sherman Act was originally enacted as a “comprehensive charter of economic liberty aimed at preserving

free and unfettered competition as the rule of trade.”<sup>60</sup> Congress then passed the Federal Trade Commission Act, which created the FTC, and the Clayton Act.<sup>61</sup> “[F]or over 100 years, the[se] [three core federal antitrust laws] have had the same basic objective: to protect the process of competition for the benefit of consumers, making sure there are strong incentives for businesses to operate efficiently, keep prices down, and keep quality up.”<sup>62</sup>

Section 7 of the Clayton Act prohibits mergers “in any line of commerce” when the effect “may be substantially to lessen competition, or to tend to create a monopoly.”<sup>63</sup> The Clayton Act requires merging parties to notify the FTC before commencing a merger that exceeds certain thresholds.<sup>64</sup> This triggers a waiting period where the FTC or DOJ investigate the merger and can request more information and consult with each other regarding the potential effects.<sup>65</sup> The inquiry focuses on “whether the proposed merger is likely to create or enhance market power or facilitate its exercise.”<sup>66</sup> Either agency can challenge the merger, but “[o]ver the years, the agencies have developed expertise in particular industries or markets.”<sup>67</sup> The FTC devotes most of its recourses to segments of the economy “where consumer spending is high,” such as healthcare.<sup>68</sup>

If the FTC or DOJ pursues a preliminary injunction in federal court, the motion may only be granted “if the Court finds, upon weighing the equities and considering the FTC’s [or DOJ’s] likelihood of ultimate success, that the injunction would be in the public interest.”<sup>69</sup> “[T]he Government has the burden of proof and seeks to: (1) define the relevant product market; (2) define the relevant geographic market; and (3) prove that the merger will be anticompetitive and will result in an increase in prices above competitive levels for a significant period of time.”<sup>70</sup>

The government may establish a prima facie case that the merger will

be anticompetitive through statistical evidence, including measures of post-merger market concentration and market share percentage. Courts have held “that a merger resulting in a single firm controlling at least 30% of the relevant market was sufficient to raise an inference that the effect of the contemplated merger . . . may be substantially to lessen competition.”<sup>71</sup>

Generally, courts use the Herfindahl–Hirschman Index (“HHI”) as a tool to calculate the increase in market concentration of hospitals.<sup>72</sup> “The HHI is calculated by summing the squares of the individual firms’ market shares, and thus gives proportionately greater weight to the larger market shares. High levels of concentration raise anticompetitive concerns, and the HHI calculation provides one way to identify mergers that are likely to invoke these concerns.”<sup>73</sup> Traditionally, courts held that “a post-merger HHI above 1800 [was] deemed to reflect a highly concentrated market, and a merger producing an increase in the HHI of more than 100 points [was] deemed likely to create or enhance market power or facilitate its exercise.”<sup>74</sup> Recent courts follow the FTC Merger Guidelines enacted in 2010, stating that the government presents a prima facie case of an anticompetitive merger when the resulting HHI of the hospital market is above 2500 points and the merger will result in an increase of 200 points.<sup>75</sup> However, in order for the government to establish a prima facie case, it must meet its burden of establishing the “relevant market,” consisting of the “the relevant product market and relevant geographic market.”<sup>76</sup>

The cases that follow are unusually harsh on the government’s attempt to establish a prima facie showing that a hospital merger would be anticompetitive. Despite evidence showing an HHI over 2500 and an increase in 200 points, the court in *F.T.C. v. Freeman Hospitals* refused to accept the government’s definition of the relevant market.<sup>77</sup> So, too, despite ample evidence

showing that the merger would result in an increase of “\$55,000,000 per year” for managed care organizations in *U.S. v. Long Island Jewish*, the court rejected the government’s definition of the relevant market.<sup>78</sup> Moreover, even when the court accepted the government’s prima facie showing of anticompetitive effects based on a highly concentrated HHI in *F.T.C. v. Butterworth*, the court relied on policy arguments in concluding that the resulting merger would not unduly enhance market power.<sup>79</sup> Underlying these decisions is the court’s belief in the policy ideals put forth by proponents of lenient antitrust enforcement in the healthcare market. The courts were ultimately persuaded that in the face of the medical arms race, the efficiencies of the merger and charitable nature of nonprofit hospitals would result in cost savings passed on to consumers that would result in greater benefit to consumers than strong competition in the marketplace.

## Part C: Trend of Courts Siding With Hospitals in the 1990s and Early 2000s

*F.T.C. v. Butterworth*, *F.T.C. v. Freeman Hospitals*, and *U.S. v. Long Island Jewish* are part of a “string of losses” where “courts reviewing proposed mergers of nonprofit hospitals have abandoned the bedrock principles of antitrust law.”<sup>80</sup> The courts engaged in a “faulty analysis,” avoiding the “hallmarks of socially beneficial competition.”<sup>81</sup> Rather than foster “competition in the health care sector,” the courts “entrust benevolent monopolists to act in the community’s best interest.”<sup>82</sup> Unfortunately, the courts underestimated the merged hospital’s market power “present[ing] some of the most serious and successful challenges to traditional economic presumptions that can be found anywhere in contemporary antitrust law.”<sup>83</sup> “For the most part, empirical work investigating the effect of hospital mergers on pricing finds that hospital mergers

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that create market power do lead to higher prices, and that this is true for both for-profit and nonprofit hospitals.<sup>84</sup> Thus, this trend, which apparently was in contravention of strict application of the antitrust laws for “over 100 years,” should act as a warning against relying on the promise of nonprofit hospitals to relay cost savings to consumers.<sup>85</sup>

In *F.T.C. v. Butterworth*, the court held that the FTC demonstrated “a prima facie case by showing statistically that the proposed merger would produce an entity controlling an undue percentage of the relevant market,” but nevertheless denied the FTC’s motion for preliminary injunction in favor of the hospitals’ nonprofit status and efficiency defense.<sup>86</sup> Out of the four general acute care hospitals in Grand Rapids, Michigan, the two nonprofit hospitals seeking a merger owned 857 general acute care beds out of the 1,108 total.<sup>87</sup> The hospitals agreed with the government’s calculations that with respect to the primary care inpatient hospital market, “the merged entity would control between 65 and 70% of the market” and “that the post-merger HHI would range from 2767 to 4521, reflecting an increase of between 1064 and 1889 points.” Despite these overwhelming statistics demonstrating “high market concentration,” the court held that the hospitals demonstrated that the “intended acquisition would result in significant economies and that these economies ultimately would benefit competition and, hence, consumers.”<sup>88</sup>

The court found that the primary impetus of the proposed merger was to prevent the “ongoing medical arms race” by “avoid[ing] substantial capital expenditures which both hospitals would otherwise be required to make and to achieve significant operating efficiencies by coordinating activities and eliminating duplicative services.”<sup>89</sup> The defendant hospitals contended

that “high concentration in the hospital industry should not be presumed to result in anticompetitive effects.”<sup>90</sup> In support, the hospitals asserted that higher hospital concentration actually results in lower prices possibly “attributable to greater coordination of activities among hospitals and greater avoidance of duplicative equipment and other capital expenditures.”<sup>91</sup> In response, the FTC argued that even if “market dominance may not be positively correlated with higher prices, it is correlated with smaller managed care discounts, which reflect anticompetitive effect emanating from exercise of market power.”<sup>92</sup> A potential expansion of this type of anticompetitive effect created an “appreciable danger.”<sup>93</sup>

The court was ultimately persuaded “that the proposed merger would result in significant efficiencies, in the form of capital expenditure avoidance and operating efficiencies, totaling in excess of \$100 million.”<sup>94</sup> Further, these savings, “in view of defendants’ nonprofit status and the Community Commitment,” would “invariably be passed on to consumers.”<sup>95</sup> The court relied heavily on the hospitals’ nonprofit status and that the boards of the merging hospitals were “comprised of community business leaders who have a direct stake in maintaining high quality, low cost hospital services.”<sup>96</sup> Although the FTC did not challenge “that board members . . . [had] community interests at heart,” they did point to evidence that “board members quickly develop institutional loyalty that may overcome their vigilance of community interests.”<sup>97</sup> In particular, the FTC pointed to the above-average profit margins realized in recent years by the merging hospitals to demonstrate “that both boards have exercised market power to charge higher than necessary prices and realize above-average profits, which are not in the community’s best interests.”<sup>98</sup>

Despite the FTC’s efforts, the court placed emphasis on a “community commitment” offered by the merging hospitals, which it saw as a “serious commitment by defendants” and a way to hold the merging parties accountable on their promise to refrain from exercising market power in injurious ways to the consuming public.<sup>99</sup> Moreover, the community commitment “corroborate[d] other evidence that nonprofit hospitals may be treated differently under the antitrust laws, and further undermine[d] the predictive value of the FTC’s prima facie case.”<sup>100</sup> Thus, the court rejected the government’s prima facie showing of anticompetitive effects.<sup>101</sup>

In *F.T.C. v. Freeman Hospitals*, the court rejected the government’s proposed post-merger levels of market concentration resulting in “an HHI of 3887 based on beds and 4356 based on admissions” and denied the FTC’s request for a preliminary injunction to enjoin the merger of two nonprofit hospitals.<sup>102</sup> There, Freeman Hospital and Oak Hill Hospital, located in Joplin, Missouri were seeking to merge into a new nonprofit organization.<sup>103</sup> Joplin consisted of approximately 40,000 people and was home to three general acute care hospitals.<sup>104</sup> The parties conceded that the relevant product market “consisted of ‘acute care inpatient hospital services.’”<sup>105</sup> However, despite ample evidence, the court held that the FTC failed to meet its burden of establishing the relevant geographic market.<sup>106</sup> An expert for the FTC established a service area spanning 27 miles in each direction of Joplin by using the zip codes of patients admitted into the hospitals in Joplin, estimating that 90 percent of admissions resided in the proposed service area.<sup>107</sup> The HHI, well above the FTC guidelines for a prima facie showing of anticompetitive effects, indicated a highly concentrated industry.<sup>108</sup> Despite expert testimony as well as testimony of

market participants stating that if prices increased after the merger due to collusion few patients would travel outside the FTC's geographical market, the court reasoned that the expert testimony "did not sufficiently demonstrate where consumers could practically turn for alternative sources of acute care inpatient hospital services."<sup>109</sup>

Since establishing a relevant market is a necessary predicate to a successful challenge under the Clayton Act, the court refused to address FTC allegations that the merger would result in high "levels of concentration, high barriers to entry, and probable collusion."<sup>110</sup> Moreover, the lower court believed that the HHI used by the FTC was "more useful in the traditional for-profit business setting."<sup>111</sup> Therefore, the Eight Circuit adopted the lower court's reasoning that "[w]hile such statistical machinery may raise red flags with the FTC, it is this Court's duty to look beyond the numbers and analyze the reality that will exist for hospital consumers after the consolidation."<sup>112</sup>

In failing to "look beyond the numbers," the "FTC essentially ignores the relevance of the merging hospitals' status as nonprofit entities" and that "by simply doing what is in their own economic best interest, certain nonprofit organizations ensure a competitive outcome, regardless of market structure."<sup>113</sup> The court was persuaded that "a private nonprofit hospital that is sponsored and directed by the local community is similar to a consumer cooperative. It is highly unlikely that a cooperative will arbitrarily raise prices merely to earn higher profits because the owners of such an organization are also its consumers."<sup>114</sup> Therefore, the court held that the "interest in maintaining competitive hospital prices" could not overcome the high burden of demonstrating that the balance of equities nevertheless militate in favor of granting the requested relief.<sup>115</sup>

In *U.S. v. Long Island Jewish*, the district court ignored the government's assertion that the merger would "result

in a 20 percent price increase for primary/secondary services" and found that the DOJ failed to establish the relevant product market.<sup>116</sup> The underlying reason for the denial of a permanent injunction in the court's decision seemed to be its belief in the economic efficiencies of the merger and the nonprofit status of the hospitals.<sup>117</sup> There, the two nonprofit hospitals seeking to merge were Long Island Jewish Medical Center ("LIJ") and North Shore Manhasset ("NSM").<sup>118</sup> The hospitals, located on Long Island, New York, were within two miles of each other. LIJ consisted of 820 acute care beds, and the patient population was categorized as "30 percent Medicare, 20 percent Medicaid, 20 percent classic indemnity insurance carriers, and 30 percent various types of managed care insurance carriers."<sup>119</sup> NSM consisted of 705 acute care beds, and "the patient profile at NSM is 40 percent Medicare and Medicaid and 30 percent managed care ... [and] [t]he rest of the patients have commercial insurance companies or are self-payers."<sup>120</sup> Both hospitals provided approximately 80 to 85 percent of primary or secondary services; the remaining services were for tertiary care.<sup>121</sup>

The DOJ contended that the "relevant product market consist[ed] of the bundle of acute inpatient services provided by anchor hospitals to managed care plans."<sup>122</sup> The DOJ defined anchor hospitals as those possessing "prestigious reputations, broad ranging and highly sophisticated services, and high quality medical staffs," and argued that "community hospitals are not 'reasonably interchangeable' with anchor hospitals."<sup>123</sup> Robert Wheeler, the Chief Executive Officer of Northeast Operations of United-Healthcare, the third largest health-care insurer at the time, stated that these were "must have" hospitals and that if United had to drop NSM and LIJ, it could not "build a marketable network on Long Island."<sup>124</sup> Additionally, Richard Wildzunas, the Senior Vice President of the managed care

organization MagnaCare testified that in order to operate in Long Island, "you have to have one of these facilities in [your] network."<sup>125</sup> Nevertheless, the court found the classification of "anchor hospitals" to be "unduly restricted," and that the government "failed to establish that the acute inpatient services produced at these so called 'anchor hospitals' [were] unique and would support its own relevant product market."<sup>126</sup>

Although dicta, underlying the strict scrutiny of the government's proposed product market was the court's belief in the nonprofit status of the hospitals and the economic efficiency of the merger.<sup>127</sup> Despite expert government testimony that managed care organizations would "be forced to pay on the order of \$55,000,000 per year more to these hospitals," the court held that the testimony was "totally speculative" and relied on the "efficiency defense."<sup>128</sup> Under the efficiency defense, "the defendants must clearly demonstrate that the proposed merger itself will, in fact, create a net economic benefit for the health care consumer."<sup>129</sup> Although "difficult to establish," the rationale for the efficiency defense is that "[e]fficiencies generated through a merger can enhance the merged firm's ability and incentive to compete, which may result in lower prices, improved quality, enhanced service, or new products."<sup>130</sup> The court recognized that the "proposed merger [would] result in significant efficiencies in the form of annual operating savings in expenses in the sum of approximately 25 to 30 million dollars per year."<sup>131</sup> Further, it believed that this would be passed onto consumers because as nonprofit hospitals they "provide millions of dollars worth of free medical care to individuals in need" and that "[a]ny profit is funneled back into the community in the form of new programs and facilities."<sup>132</sup> Thus, "it would appear that the same profit-maximizing incentives driving private companies are less central to the merging hospitals'

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progress.”<sup>133</sup> The government was defeated once again in its challenge of a proposed hospital merger.<sup>134</sup>

The court trend to side with the hospitals had a chilling effect on government enforcement.<sup>135</sup> There was no government challenge to a hospital merger from 2001 to 2007.<sup>136</sup> Consolidation of the healthcare market flourished.<sup>137</sup> In fact, “the median and mean Herfindahl-Hirschman Index (HHI) for U.S. hospital markets rose steadily from 1985 to 2000, with a ‘very concentrated’ mean HHI of 3995 in 2000.”<sup>138</sup> However, a majority of recent studies have shown that hospital mergers resulting in higher market power lead to higher prices, despite the potential efficiencies of the merger and charitable nature of the hospitals.<sup>139</sup> Thus, it appears that the courts placed too much emphasis on the policy concerns and not enough on the statistical evidence of potential anti-competitive effects.

## Part D: Recent Studies Illustrating that Reliance on Hospitals to Transfer Cost Savings onto Consumers is Inefficient

The courts’ belief in cost savings being passed onto consumers based on efficiency and the charitable nature of nonprofit hospitals contradicts most empirical studies of post-merger hospitals. Although some studies recognize the efficiency and price decrease of consolidation, “[f]or the most part, empirical work investigating the effect of hospital mergers on pricing finds that hospital mergers that create market power do lead to higher prices, and this is true for both for-profit and nonprofit hospitals.”<sup>140</sup> In fact, “most consolidating hospitals raise prices by more than the median price increase in their markets.”<sup>141</sup> Further, “[e]mpirical research on the cost effects of hospital mergers generally finds that

most hospital mergers lead to either no cost savings or small cost savings.”<sup>142</sup> Post-merger empirical research regarding quality is less developed, “but the handful of studies on this topic typically find either no effect on quality, mixed effects on quality, or small reductions in quality from hospital mergers.”<sup>143</sup> One study from the University of Chicago used seven years of data from 2001 to 2007 on competition and charity care provision by California hospitals.<sup>144</sup> This study found “no evidence that nonprofit hospitals are more likely than for profit hospitals to provide more charity care in response to an increase in market share.”<sup>145</sup> The study concluded that there is “no justification for applying a different antitrust standard to nonprofit hospitals than to for profit hospitals.”<sup>146</sup>

Perhaps the most convincing evidence that relying on hospitals to pass costs onto the consumer does not work is the decision of the Chief Administrative Law Judge, affirmed by the FTC, in the case *In the Matter of Evanston Northwestern Healthcare*, decided in 2007.<sup>147</sup> There, two nonprofit hospitals in Illinois merged in 2000.<sup>148</sup> Since the FTC’s challenge was brought four years after the merger had consummated, the FTC was “able to examine not only pre-merger evidence, but also evidence about what happened after the merger.”<sup>149</sup> There was no dispute that shortly after the merger the hospital “substantially raised its prices.”<sup>150</sup> The Chief Administrative Law Judge and the FTC held that “the transaction enabled the merged firm to exercise market power and that the resulting anti-competitive effects were not offset by merger-specific efficiencies.”<sup>151</sup>

The evidence demonstrated that the hospitals “anticipated that the merger would give them greater leverage to raise prices, that the merged firm did raise its prices immediately and substantially after completion of the transaction, and that the [hospitals]

attributed the price increases in part to increased bargaining leverage produced by the merger.”<sup>152</sup> In addition, the FTC held that the hospital’s “status as a nonprofit entity does not suffice to rebut complaint counsel’s evidence of anti-competitive effects.”<sup>153</sup> Relying on the Seventh Circuit, the FTC stated that “[t]he adoption of the nonprofit form does not change human nature..., as the courts have recognized in rejecting an implicit antitrust exemption for nonprofit enterprises.”<sup>154</sup> Thus, the FTC affirmed the Chief Administrative Law Judge holding that the merger violated Section 7 of the Clayton Act.<sup>155</sup> Since this decision, which has been called “a game-changer in hospital merger analysis” due to the court’s unusual strict application of antitrust enforcement to a hospital merger and long overdue government victory, “the FTC has experienced unprecedented success in challenging hospital mergers.”<sup>156</sup>

Additionally, scholars have argued that even if prices are statistically lower in nonprofit hospitals as opposed to for-profit hospitals, the focus should be on comparing “nonprofit-hospital pricing in the presence of market power to nonprofit-hospital pricing in the absence of market power.”<sup>157</sup> The real test should be whether nonprofit hospitals are exploiting market power as a result of the merger, not whether the exploitation of nonprofit hospitals is less than that of for-profit hospitals.<sup>158</sup> In regard to that issue, it seems relatively straightforward that “high hospital concentration is associated with increased prices, regardless of whether hospitals are for-profit or nonprofit.”<sup>159</sup>

## Part E: Recent Success of the FTC

In 2007, the FTC Congressional Budget Justification Report recognized that the “rapidly rising cost of health care [was] a matter of concern

for consumers, employers, insurers, and the nation as a whole.”<sup>160</sup> The FTC expressed its concern that “[h]ealth-related products and services now account[ed] for more than 15 percent of GDP, and that share has grown by 25 percent since 1990.”<sup>161</sup> Therefore, the FTC made “promoting competition in the health care sector . . . a major priority for the FTC.”<sup>162</sup> After “eight straight government losses between the mid-1990s and 2001 and then a long hiatus in hospital enforcement,” the government finally won a merger challenge in *Evanston Northwestern Healthcare*.<sup>163</sup> Since then, the government has had a string of successes.”<sup>164</sup> According to Melinda Hutton, Senior Vice President and General Counsel of the American Hospital Association, “[t]he F.T.C. is on a winning streak,” and its victories have had a “chilling effect” on hospital mergers.<sup>165</sup> In these victories, the courts, rightfully so, have been “skeptical about the efficiencies defense in general and about its scope in particular.”<sup>166</sup>

In *Penn State Hershey Medical Center*, the Third Circuit held that a post-merger HHI of 5,984 of two hospital systems, “more than twice that of highly concentrated market,” and a 2,582 point increase, “well beyond the 200-point increase that is presumed likely to enhance market power,” warranted a preliminary injunction.<sup>167</sup> The Third Circuit “note[d] at the outset that [it] ha[d] never formally adopted the efficiencies defense” and was “skeptical that such efficiencies defense even exists.”<sup>168</sup> Even though the court recognized that capital savings could result in “nearly \$277 million” and that Hershey could forgo building a 100-bed tower, it could “not overlook that the HHI numbers here eclipse any others we have identified in similar cases.”<sup>169</sup> So, too, in *St. Luke’s Health System*, the Ninth Circuit held that a post-merger HHI of 6,219 between a nonprofit hospital and a physician group and an increase of 1,607 points was prima facie anticompetitive and ordered divestiture of

affiliation between the providers. The Ninth Circuit rejected the efficiency argument, stating that “[i]t is difficult enough in § 7 cases to predict whether a merger will have future anticompetitive effects without also adding to the judicial balance a prediction of future efficiencies.”<sup>170</sup> The court believed the hospital should be “applauded for its efforts to improve the delivery of health care in the Treasure Valley,” but found “there are other ways to achieve the same effect that do not run afoul of the antitrust laws and do not run such a risk of increased costs.”<sup>171</sup> Although these cases involve mergers of for-profit hospitals, they illustrate the future direction of the courts in hospital merger challenges. Further, this logic has been applied to nonprofit hospital mergers.<sup>172</sup>

In *OSF Healthcare System*, a district court in Illinois held that a merger of two nonprofit healthcare systems would be anticompetitive and warranted a preliminary injunction. The post-merger market percentage of the merged entity would be 59.4 percent of the general acute care market, well above the 30 percent marker that “raise[s] an inference that the effect of the contemplated merger . . . may be substantially to lessen competition.”<sup>173</sup> Additionally, the increase in market concentration based on patient days would result in an HHI from 3,353 points pre-merger to 5,406 points post-merger, for an increase of 2,053 points.<sup>174</sup> Thus, the FTC established a prima facie case of anticompetitive effects from the merger.

Once again, the court was skeptical of the proposed efficiencies, finding that “courts only consider efficiencies that are verifiable and merger-specific, and it is incumbent upon the court to undertake a rigorous analysis of the kinds of efficiencies being urged by the parties in order to ensure that those efficiencies represent more than mere speculation and promises about post-merger behavior.”<sup>175</sup> Further, the court expressly rejected the argument put forth in *Butterworth*, finding that nonprofit

hospitals “exercise . . . bargaining leverage to obtain the most favorable reimbursement rates possible from commercial health plans.”<sup>176</sup> In rejecting the nonprofit hospital defense, the court held “that nonprofit hospitals do seek to maximize the reimbursement rates they receive.”<sup>177</sup> Thus, the court correctly placed more weight on the FTC’s “overwhelming” market share and market concentration evidence rather than vague promises by the hospitals to pass costs onto consumers.”<sup>178</sup>

This trend of recent success shows that courts have correctly started to place more emphasis on the statistics of anticompetitive effects rather than placing blind reliance on hospitals to not exercise their market share. This reasoning correctly rejects the efficiency and nonprofit arguments put forth by hospitals in the face of overwhelming evidence of market concentration. This promising trend correctly applies the bedrock principles of antitrust law, and allows antitrust law to promote efficiency rather than rely, perhaps mistakenly, on the charitable nature of hospitals.

## Conclusion

Although in the 1990s “[a]ntitrust agencies . . . appropriately identified growing market power as an enforcement priority,” they “found little success, losing each of the [eight] suits initiated since 1994 [through 2001] to challenge proposed hospital mergers.”<sup>179</sup> Courts were heading down a dark and dangerous road by placing blind reliance in hospitals to not act on their highly concentrated post-merger market share. While the hospitals may have intended to be more efficient and provide better quality care, the intentions of the parties should not be the focus of an antitrust claim. As Deborah Feinstein, the Director of the Bureau of Competition at the FTC, notes, “[e]ven if the price increase is motivated by a desire to invest more in the business, that’s problematic.”<sup>180</sup> The focus should be on

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whether the resulting merger will have anticompetitive effects, because often “their goal is not just to control costs or improve care, but to ‘get increased leverage’ in negotiations with health insurance companies and employers.”<sup>181</sup> Therefore, courts should rely on the principles of antitrust law as opposed to the “[v]ague promises and aspirations that an acquisition will reduce costs.”<sup>182</sup>

Although the harsh judicial treatment resulted in a lack of enforcement from 2001 until 2007, the rising cost and growing percentage of the United States’ GDP attributed to healthcare encouraged the government to put aside its losses and refocus on hospital mergers.<sup>183</sup> The FTC has experienced a wave of success since *Evanston* in 2007.<sup>184</sup> Courts have correctly placed emphasis on the statistical evidence of anticompetitive effects presented by the FTC while rejecting the promises of the hospitals that the merger will result in efficiencies that will be passed onto the consumer.<sup>185</sup> Further, courts have now expressly rejected the premise that nonprofit hospitals do not exercise their highly concentrated post-merger market share. This recent trend of court decisions correctly returns to the basic foundations of antitrust law which, without specific legislation exempting nonprofit hospitals from antitrust scrutiny, is the best approach.



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The writing competition is open to all current law students. Contact [rachel.blakley@americanbar.org](mailto:rachel.blakley@americanbar.org) for information on the 2018 – 2019 competition.

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- 185 See *Fed. Trade Comm’n v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 346-347 (3d Cir. 2016); *Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke’s Health Sys., Ltd.*, 778 F.3d 775, 790 (9th Cir. 2015); *F.T.C. v. OSF Healthcare Sys.*, 852 F. Supp. 2d 1069, 1078 (N.D. Ill. 2012).

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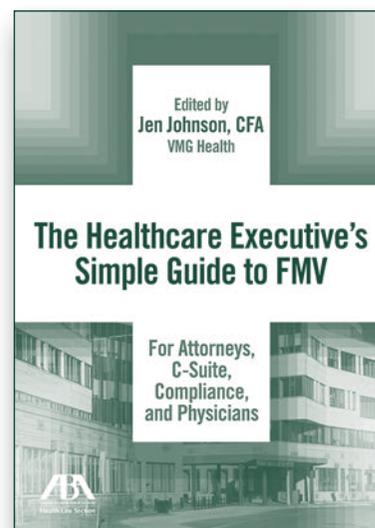
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# UPDATES ON THE MEDICARE APPEALS BACKLOG AND NEW OPPORTUNITIES IN MEDICARE'S APPEALS PROCESS

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Providers and suppliers that bill Medicare may challenge a denial or reduction of a claim for Medicare reimbursement through a five-step administrative appeals process.<sup>1</sup> Congress designed this five-level appeals process to afford providers and suppliers (“appellants”) an opportunity for expedited review; however, due to an extreme backlog of appeals at the third level of appeal, appellants are now waiting well in excess of the statutorily established timeframe for a determination on appeal at this level of the appeals process.<sup>2</sup> Specifically, federal regulations impose a 90-day time limit for Administrative Law Judges (“ALJs”) to hear and decide appeals at the third level of the administrative appeals process.<sup>3</sup> However, the Department of Health and Human Services (“HHS”) Office of Medicare Hearings and Appeals (“OMHA”), which administers the ALJ hearing program, recently released statistics reflecting that the average processing time frame for appeals at the third level of appeal has increased year after year since 2008 and most recently topped 1,216 days.<sup>4</sup> Therefore, although appellants are entitled to a hearing and decision on their appeal within 90 days, they are waiting well over three years.

The delay in adjudication capacity is expected to continue for the foreseeable future. OMHA has advised that as of January 26, 2018, OMHA had 502,000 appeals pending, noting that this is down from over 880,000 appeals pending at the end of fiscal year (“FY”) 2015 due to prior initiatives to expedite appeal

resolution (discussed below) and increased resources (such as additional ALJs) at the third level of appeal.<sup>5</sup> However, the disposition capacity for OMHA in FY 2018 is estimated at 93,500 appeals. Therefore, OMHA has approximately 5.36 times as many appeals pending as can be decided in FY 2018. With these statistics in mind, appellants should be prepared for the adjudication delays to continue.

In response to these projections and pressure from the appellant community, the Centers for Medicare & Medicaid Services (“CMS”) and OMHA have released a number of newer initiatives in recent months as well as expanded previous initiatives to combat the backlog of appeals and improve efficiencies in the Medicare appeals process.<sup>6</sup> These initiatives are welcome opportunities for Medicare providers and suppliers to achieve an alternative and expedited resolution to pending appeals as compared to the traditional Medicare appeals process.

On November 3, 2017 CMS announced two alternative resolution programs for eligible Medicare appellants: the expanded Settlement Conference Facilitation Program (“SCF”) and the Low Volume Appeals (“LVA”) Initiative. SCF and the LVA Initiative have complementary eligibility criteria that collectively have the opportunity to resolve nearly every Medicare Part A or Part B claim under \$100,000 in billed charges that is pending at the ALJ or Medicare Appeals Council (“Council”) levels of the Medicare appeals process as of November 3, 2017. The Statistical Sampling Initiative (“SSI”) is a third alternative dispute resolution process available to Medicare Part A and Part B appellants with at least 250 eligible claims pending at the ALJ level of the

appeals process. These are not mandatory programs, so their success in reducing the backlog and curtailing its growth depends entirely upon appellants’ voluntary participation. Because each of these programs provides an opportunity for an expedited resolution to large volumes of pending, eligible appeals, Medicare appellants that satisfy the eligibility criteria should consider participation in these programs, each of which is discussed in greater detail below.

## Settlement Conference Facilitation

SCF is an alternative dispute resolution process which applies mediation principles to allow Medicare Part A and Part B appellants to negotiate a lump sum settlement of eligible claims with CMS. If a settlement is reached, a settlement agreement is signed the day of the settlement conference and the settled claims are withdrawn and dismissed from the Medicare appeals process.

SCF was initially released in June 2014 and made available to Medicare Part B providers and suppliers.<sup>7</sup> OMHA then expanded SCF in a “Phase II” program in the fall of 2015.<sup>8</sup> In February 2016, OMHA expanded SCF to all Medicare Part A providers in a “Phase III” program.<sup>9</sup> As of December 31, 2017, OMHA resolved 70,785 appeals through the various phases of the SCF program. Notably, this is the equivalent of almost an entire year’s disposition capacity for all of OMHA.<sup>10</sup> Resolving nearly an entire year’s worth of appeals from the ALJ level of the appeals process frees up considerable resources for OMHA to adjudicate claims that are either not eligible for SCF or other resolution processes, or

that appellants preferred to try at hearing.

CMS has published eligibility criteria for the expanded SCF, which include:

1. The appellant must be a Medicare provider or supplier that has been assigned a National Provider Identifier (“NPI”) (a unique identification number for healthcare providers who participate in Medicare);
2. The appeals involve request(s) for ALJ hearing or Council review filed on or before November 3, 2017 with at least 25 eligible appeals pending at OMHA and the Council combined; or with less than 25 eligible appeals pending at OMHA and the Council combined if at least one appeal has more than \$9,000 in billed charges;
3. The request(s) for ALJ hearing and/or Council review must arise from a Medicare Part A or Part B Qualified Independent Contractor (“QIC”) reconsideration decision;<sup>11</sup>
4. All jurisdictional requirements for OMHA or Council review were met for the eligible appeals;
5. The billed amount of each individual claim in an appeal must be \$1,000,000 or less (for the purposes of an extrapolated statistical sample, the overpayment amount extrapolated from the universe of claims must be \$1,000,000 or less);
6. The appellant cannot have filed for bankruptcy and/or expect to file for bankruptcy in the future;
7. Certain appellants that have or have had False Claims Act litigation or investigations pending against them, or other program integrity concerns, including pending civil, criminal, or administrative investigations will be ineligible;
8. The beneficiary must not have been found liable for the amount in controversy after the initial determination or participated in the reconsideration; and
9. The appeals must not involve payment disputes (i.e. the appellant

was paid as billed but the appellant disputes that the paid amount is sufficient payment).<sup>12</sup>

The expanded SCF program is designed to resolve large volumes of claims at the ALJ or Council levels, or lower volumes of claims at the ALJ or Council levels with high billed charges. With such broad eligibility criteria, it is anticipated that many appellants will be eligible to participate in the SCF process. Additionally, appellants should note that under the newly expanded SCF, appeals that were eligible but not settled under the CMS Hospital Appeals Settlements (discussed below) will still be eligible for resolution.<sup>13</sup> This is a significant departure from the prior SCF programs, in which appeals that were eligible for resolution under the CMS Hospital Appeals Settlements were ineligible for SCF regardless of whether the provider participated in the settlements.

CMS has identified on its website categories of appeals that are not eligible for the expanded SCF. For example, appeals of claims that involve unlisted, unspecified or miscellaneous healthcare codes are not eligible. Claims that are eligible for resolution under the LVA Initiative or other CMS settlement options made available on or after November 3, 2017, or appeals that are in OMHA’s SSI (discussed below) are also not eligible for the expanded SCF.<sup>14</sup>

Unlike prior versions of the SCF program, under the expanded SCF appellants with appealed claims that have billed amounts of \$100,000 or less or an extrapolated overpayment that is \$100,000 or less is eligible for a “fast track” resolution through an “SCF Express” settlement offer. Through the SCF Express process, CMS will offer appellants a non-negotiable settlement value on the appellant’s eligible claims. The SCF Express settlement offer will not be based off a medical review of the appellant’s eligible claims; however, appellants should expect that the SCF Express settlement offer will be based on preliminary data available to CMS

regarding the appellant and its claims, such as the appellant’s track record of favorable findings before ALJ hearing and the Council, or the number or scope of prior audits initiated by CMS regarding the appellant. If an appellant rejects the SCF Express settlement offer, the appellant has the opportunity to continue to the SCF facilitation conference, discussed below, during which the appellant will have an opportunity to negotiate a settlement value with CMS.<sup>15</sup>

There are recommended best practices and strategies for participation in SCF. Prior to the facilitation, an OMHA facilitator will schedule a pre-facilitation conference to discuss the SCF process and set the date for the facilitation and schedule deadlines for the submission and exchange of any facilitation documents. Prior to the facilitation and likely after the pre-facilitation conference CMS will select a sample of claims. CMS will then review these claims and form an opinion on the strength of these claims prior to the facilitation. Appellants, therefore, should prepare a thorough evaluation of the sample claims through a comprehensive position paper with supporting documentary evidence and testimonial support. Appellants should also consider showcasing their major strengths, accolades and any unique considerations for CMS’ review. Appellants should then submit their position paper and comprehensive work-ups to CMS for its consideration. A thorough and strong posturing of the case prior to the facilitation can have a substantial impact on its success. Although at the facilitation there are no findings of fact or rulings of law, participants should be prepared to make an opening statement which highlights major issues and concepts for CMS’ consideration. Following opening statements, the facilitation then proceeds through private sessions with the OMHA facilitator, who acts as a neutral intermediary in facilitating a resolution between the appellant and CMS.

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# Updates on the Medicare Appeals Backlog and New Opportunities

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The voluntary and expedited nature of the SCF process should be attractive to Medicare appellants. If settlement is not reached, an appellant's claims return to the ALJ appeals process in the order in which they were originally received. Although OMHA did not establish a firm time table for initiation and completion of the SCF process, a conservative estimate based on prior versions of this process is that the expanded process will take a minimum of 10 weeks from the date an appellant receives OMHA's spreadsheet identifying eligible claims until the date of the facilitation. That is considerably faster than the Medicare traditional five-step appeals process that at recent estimates takes nearly 173 weeks at the ALJ level of appeal alone.

## The LVA Initiative

The LVA Initiative is offered as an alternative resolution to the SCF process. It is a settlement offer that is open to Medicare Part A and Part B appellants with eligible fee-for-service appeals pending in the administrative appeals process. CMS defined "low volume" as appellants with less than 500 appeals pending before the ALJ or Council levels of review combined.<sup>16</sup> Eligible and participating appellants are permitted to withdraw pending, eligible appeals from the backlogged Medicare appeals process in exchange for a non-negotiable settlement sum as final resolution of the disputed appeals. Through the LVA Initiative, appellants are offered 62 percent of the net Medicare approved amount of their eligible claims.

The LVA Initiative is not the first settlement opportunity offered by CMS. Through two separate settlement opportunities, CMS previously offered to pay eligible hospitals 68 percent and then 66 percent of the net payable amount of their patient status claim denials in exchange for the

hospitals' acceptance of an administrative agreement as the full and final administrative and legal resolution of their claims.<sup>17</sup> The prior settlements, known as the Hospital Appeals Settlements, were fairly restrictive on participant and claim eligibility. Specifically, they were limited to critical access hospitals and acute care hospitals, including those paid via the Prospective Payment System ("PPS"), Periodic Interim Payments ("PIP"), and Maryland waiver. Other hospitals and provider types were not eligible for participation, which left large volumes of backlogged claims in the Medicare appeals process. Additionally, the Hospital Appeals Settlements were limited to patient status claims with dates of admission prior to October 1, 2013. Despite these restrictions, the Hospital Appeals Settlements resolved approximately 346,000 claims from the backlogged Medicare appeals process through settlements with 2,022 hospitals, amounting to nearly \$1.47 billion dollars paid to participating hospitals.<sup>18</sup>

Unlike the Hospital Appeals Settlements, the LVA Initiative has broader appellant eligibility criteria. All Medicare Part A and Part B providers and suppliers are eligible, so long as they have less than 500 eligible appeals pending at the ALJ and Council levels of appeal, combined, as noted above. Also, unlike the prior Hospital Appeals Settlements, which required that eligible claims have dates of service prior to October 1, 2013, the LVA Initiative contains no date of service restriction on eligible claims. CMS provided the following appeal eligibility criteria for the LVA Initiative:

1. The appeal was pending before the OMHA and/or Council level of appeal as of November 3, 2017;
2. The appeal has a total billed amount of \$9,000 or less;
3. The appeal was properly and timely filed at the OMHA or Council level as of November 3, 2017;

4. The claims included in the appeal were denied by a Medicare contractor and remain in a fully denied status in the Medicare system;
5. The claims included in the appeal were submitted for payment under Medicare Part A or Part B;
6. The claims included in the appeal were not part of a statistical extrapolation;<sup>19</sup> and
7. As of the date the LVA Settlement Agreement is fully executed, the appeal was still pending at the OMHA or Council level of review.<sup>20</sup>

Although there are not significant strategic considerations for providers regarding how to participate in the LVA Initiative, given that it is a non-negotiable settlement opportunity, there are practical considerations for appellants to consider while participating in the process. First, an appellant cannot choose to settle some eligible claims and not others. Rather, by participating in the LVA Initiative, an appellant agrees to settle all pending and eligible claims.<sup>21</sup> Therefore, appellants that practiced an aggressive appeal philosophy in appealing all or nearly all of their denied claims stand to benefit from participation in the LVA Initiative as it offers a guaranteed payout sum on claims that otherwise may not have achieved favorable resolution before the ALJ or Council.

Secondly, as with the prior settlements, neither the appellant nor CMS make any admissions of fault or liability, and the claims settled will remain denied in CMS' Common Working File.<sup>22</sup> Therefore, by settling claims through the LVA Initiative, appellants may incur refund obligations to other payors due to coordination of benefit rules.<sup>23</sup> Further, in settling appeals through the LVA Initiative, appellants are entitled to a refund of any interest payments made to CMS during the pendency of the appeals process, and any interest that accrued on claims but was

not paid as of the date of the settlement agreement will be adjusted to zero.<sup>24</sup>

Lastly, appellants are instructed to consider the 62 percent settlement as payment in full on the resolved claims.<sup>25</sup> Therefore, participating appellants are not entitled to any 935 interest payment on claims resolved through the LVA Initiative. This type of interest derives its name from Section 935 of the 2003 Medicare Prescription Drug, Improvement and Modernization Act and requires CMS to pay interest to providers and suppliers in post-payment overpayment matters. According to CMS, as there was no finding of law or fact on appeals resolved through the Hospital Appeals Settlements, the LVA Initiative or SCF, appellants are not entitled to 935 interest under law. Therefore, under these alternative resolution programs no 935 interest payment can be made.

The LVA Initiative initially was released with two eligibility periods, depending on an appellant's NPI number. For appellants with NPIs ending in an even number, the initial participation period ran from February 5, 2018 through March 9, 2018. For appellants with NPIs ending in an odd number, the LVA Initiative was open from March 12, 2018 through April 11, 2018. CMS created two separate participation timeframes, as it expected strong participation from the appellant community. On March 30, 2018, CMS announced that it was extending the deadline for appellants to participate to June 8, 2018. Appellants with either an odd or an even NPI that meet the eligibility criteria had between April 12, 2018 and June 8, 2018 to initiate participation in the program.<sup>26</sup>

It is currently too soon to gauge the success of the LVA Initiative. However, given the program's broad eligibility criteria for both appellants and appeals, it is expected that the LVA Initiative will make some impact on clearing the backlog and freeing adjudication resources for OMHA and the Council.

## Statistical Sampling Initiative

A third alternative to the traditional Medicare appeals process for Medicare appellants is OMHA's SSI, which was announced in June 2017. The purpose of the SSI, like the SCF process, is to efficiently resolve large volumes of pending ALJ appeals. Unlike SCF, however, the SSI offers a consolidated ALJ hearing process with the use of statistical sampling and extrapolation. More specifically, an ALJ hearing is conducted on a random sample of an appellant's pending and eligible ALJ appeals, and the ALJ's determination on those sampled claims is then statistically extrapolated to all of the appellant's pending and eligible claims.

The SSI was previously released as a pilot project in late 2014.<sup>27</sup> Due to the structure of the pilot, however, many appellants were hesitant to participate because only one ALJ was assigned to adjudicate the sampled claims, and that ALJ's determination would then be extrapolated to all of the appellant's pending and eligible claims. It has been estimated, however, that favorable rulings on appeal range among ALJs from 18 to 85 percent.<sup>28</sup> Therefore, for many appellants participation in the pilot was simply too risky.

OMHA addressed the risks of the pilot project when designing the new SSI by utilizing a panel of ALJs rather than a single ALJ. If a provider has 250 to 749 claims at issue, three ALJs are assigned to a panel and each ALJ will hear and decide one third of the sampled claims. If a provider has 750 claims or more, four to five ALJs are assigned to a panel and each ALJ will hear and decide one fourth to one fifth of the sampled claims. Although each ALJ on the panel will conduct his/her own hearing on his/her portion of the statistically sampled claims, the lead ALJ will combine the decisions from each hearing on the sampled claims and issue one decision, which OMHA's statistical expert will extrapolate to the universe of claims.

The SSI has broad claim eligibility requirements: all jurisdictional requirements for an ALJ hearing have been met; the beneficiary was not found financially responsible for the overpayment after the initial determination nor participated in the QIC reconsideration;<sup>29</sup> the request for ALJ hearing appeals a QIC reconsideration decision; there is no outstanding request for SCF regarding the claim; and at least 250 claims are at issue per eligible claim category.

There are three eligible claim categories for the SSI: prepayment claim denials (in which a Medicare contractor reviews a claim for coverage prior to issuing payment on a claim); post-payment non-Recovery Audit Contractor ("RAC") claim denials;<sup>30</sup> and post-payment RAC claim denials from one RAC. An appellant can meet the 250 claim minimum threshold for multiple claim categories, but each claim category must have at least 250 claims at issue. In the event that an appellant has multiple categories of at least 250 claims, a separate statistical sampling will be conducted on each category. With broader eligibility criteria and the use of an adjudication panel, OMHA indicated on its website that "[OMHA] hopes these changes make this program more attractive and that appellants actively consider participation in the program."<sup>31</sup>

To participate in the SSI, an appellant can request participation through submission of an expression of interest form to CMS, or respond to an invitation to participate.<sup>32</sup> Once the SSI is initiated, OMHA will assign a lead ALJ and schedule a prehearing conference, during which the SSI process and the use of statistics will be discussed. The ALJ will then issue a post conference order, which becomes binding 10 days after receipt should no objections be filed. Once the post conference order becomes binding, participation in the SSI is no longer voluntary.

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Also, appellants should understand that by participating in the SSI they consent to the use of statistical extrapolation to resolve their pending, eligible appeals. However, appellants remain free to challenge the methodology by which the statistical sample is selected.<sup>33</sup> Therefore, appellants that are interested in participating in the SSI should consider retention of a statistical expert to evaluate the validity of the sample selection. Participating appellants should also consider retaining coding experts and/or medical necessity experts to challenge the denials of the sampled claims. Participants should additionally prepare a comprehensive position paper that discusses the merits and strengths of the sampled claims and challenges the sample selection if appropriate.

There are multiple benefits to participation in the SSI. First, it is a cost-effective option for appellants to achieve factual findings on their pending appeals. Second, the SSI makes it administratively feasible for appellants to try large volumes of cases. Also, by participating in the SSI, an appellant “jumps to the front of the line” for hearing, and will therefore achieve a faster resolution than remaining in the traditional appeals process.

## Additional Opportunities to Reduce the Backlog and Improve the Medicare Appeals Process

The settlement programs and alternative dispute resolution opportunities discussed above accompany a variety of other reforms and initiatives announced by CMS and OMHA to meaningfully reduce the backlog and improve the efficiencies of the Medicare appeals process.

One such initiative is OMHA’s “QIC Formal Discussion Period,” launched as a pilot project on January

1, 2016 for durable medical equipment (“DME”) suppliers.<sup>34</sup> The purpose of this initiative is to open and encourage dialogue between appellants and the QIC at the reconsideration level of the Medicare appeals process, which traditionally is limited to a paper review only. In this process the QIC participates in voluntary telephone discussions with DME suppliers. The suppliers are given the opportunity to present the facts of their case and provide additional documentation to support the resolution of their appeal at this level of appeal. The concept behind this process is that an open dialogue promotes a more thorough review of the record than what traditionally occurs during a paper review process only. During this discussion period the QIC may also review reconsideration decisions pending with OMHA and identify cases that may be favorably resolved through reopening and discussions with the supplier. Through this initiative, OMHA announced that as of January 1, 2018, 26,567 appeals have been favorably resolved prior to reaching OMHA and 25,025 appeals have been remanded from OMHA for the QIC to reopen or favorably resolve the appeal.<sup>35</sup>

A further step towards reduction of the appeals backlog and improvement of the Medicare appeals process is CMS’ final rule “Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures,” (“Final Rule”) published January 17, 2017 and effective March 20, 2017.<sup>36</sup>

The Final Rule promotes a three-pronged approach to addressing the appeals backlog: (1) request new resources (additional ALJs, new OMHA field offices and utilization of attorney adjudicators) to invest at all levels of appeal to increase adjudication capacity and implement new strategies to

alleviate the current backlog; (2) take administrative actions to reduce the number of pending appeals and implement new strategies (such as settlement programs and alternative dispute resolution processes) to alleviate the current backlog; and (3) propose legislative reforms that provide additional funding and new authorities to address the volume of appeals.<sup>37</sup> Certain major changes in the Final Rule include assigning precedential authority to selected Council decisions; approving the use of “attorney adjudicators” to effectuate withdrawals and dismissals at the ALJ level of appeal; restricting the opportunities for submission of new evidence at the ALJ level of appeal; and limiting the participation of CMS contractors in ALJ hearings to either CMS or a single CMS contractor unless the ALJ determines that broader participation is necessary for full examination of the issues. The Final Rule has the potential to both streamline the Medicare appeals process and help curtail the backlog of Medicare appeals.

## Conclusion

In today’s appeals climate, Medicare providers and suppliers have a variety of alternative dispute resolution options at their disposal. SCF, the LVA Initiative, the SSI and the DME QIC Formal Discussion Period all promote the efficient use of judicial and appellant resources and encourage expedited resolution opportunities. Additionally, in the coming months and years appellants may begin to enjoy the new efficiencies and improvements to the appeals process through the recently published Final Rule. For example, assigning precedential authority to selected Council decisions should improve predictability and consistency in decision making for the benefit of both adjudicators and appellants. The initiatives and the Final Rule exhibit strong potential to make a meaningful impact in

reducing the volume of appeals caught in the backlog, while curbing the growth of new appeals.

However, appellants should expect that just as there are multiple contributing factors for the formation of the backlog (such as more Medicare beneficiaries, more aggressive audit activity by Medicare contractors, increased claim denials and low rates of overturned appeals at the lower-levels of the Medicare appeals process), there is a need for multiple resolutions to address and eliminate the backlog. Therefore, until OMHA or CMS announce that the growth of the appeals backlog has slowed or plateaued, appellants should continue to expect the release of additional and expanded alternative dispute resolution processes in the future and continually evaluate and assess their pending appeals for eligibility in these programs.



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## Endnotes

- <sup>1</sup> There are five levels of appeal within the Medicare appeals process: (1) at level one an appellant files a request for redetermination with the Medicare Administrative Contractor ("MAC") (Part A & B appellants), Medicare Advantage Plan (Part C appellants) or Medicare Prescription Drug Plan (Part D appellants); (2) at level two an appellant files a request for reconsideration with the Qualified Independent Contractor ("QIC") (Part A & B appellants) or Independent Review Entity (Part C or D appellants); (3) at level three an appellant files a request for ALJ hearing with OMHA (Part A, B, C or D appellants); (4) at level four an appellant files a request for Medicare Appeals Council review (Part A, B, C or D appellants) (the Medicare Appeals Council is within the Departmental Appeals Board and for purposes of this article, the fourth level of appeal is referred to as the Council level of appeal); and (5) at level five an appellant files a civil action in Federal District Court (Part A, B, C or D appellants). See OMHA's website at: <http://hhs.gov/omha/process/index.html> (last accessed April 30, 2018).
- <sup>2</sup> It is not until the third level of appeal that an independent fact finder reviews the claims and makes an independent determination of coverage. Therefore, to obtain relief, most appellants appealed unfavorable determinations to the third level of the appeals process, which led to a backlog of appeals at the third level of appeal.
- <sup>3</sup> 42 C.F.R. § 405.1016(a).
- <sup>4</sup> At a recent speech regarding the appeals process and new initiatives to combat the backlog and improve the appeals process, Chief Administrative Law Judge Nancy Griswold of OMHA provided the following average

processing times: FY 2008: 88.5 days, FY 2009: 94.9 days, FY 2010: 109.6 days, FY 2011: 121.3 days, FY 2012: 134.5 days, FY 2013: 220.6 days, FY 2014: 414.9 days, FY 2015: 661.8 days, FY 2016: 877.2 days and FY 2017: 1,108.7 days. "Latest Policy & Regulatory Changes to the Medicare Appeals Process," American Health Lawyer's Association Conference, March 21-23, 2018, presentation by Nancy J. Griswold, Chief Administrative Law Judge, OMHA and Erin Diesel Roumayah, Esq.

- <sup>5</sup> *Id.*
- <sup>6</sup> *American Hospital Association, et. al. v. Burwell*, 209 F. Supp. 3d 221, (D.D.C. Sept. 19, 2016) has served as a significant catalyst for the recent efforts to combat the backlog of appeals and improve efficiencies in the Medicare appeals process. In this case, the American Hospital Association ("AHA") sought a mandamus order against the United States Secretary of Health and Human Services ("Secretary") to clear the backlog of appeals at the ALJ level and comply with the 90-day statutory timeframe for ALJ hearing. Previously, the AHA proposed an aggressive four-year timetable to eliminate the backlog of appeals by 2021. The Secretary argued that lawful compliance with the AHA's four-year timetable would be impossible and on appeal, the Court of Appeals for the District of Columbia Circuit vacated and remanded the case to the District Court to evaluate the Secretary's claim that lawful compliance was impossible. The case is currently stayed on remand before the District Court for the AHA to submit new proposals for a mandamus order for the Secretary's and District Court's consideration.
- <sup>7</sup> For a Part B claim to be eligible, an ALJ hearing request had to have been filed in 2013 and the appeal could not already be assigned to an ALJ for hearing. See OMHA's website regarding SCF of Part B claims, located at: <https://hhs.gov/about/agencies/omha/about/special-initiatives/settlement-conference-facilitation/medicare-part-b-alj-appeals/index.html> (last accessed April 30, 2018).
- <sup>8</sup> Phase II expanded claim eligibility criteria to ALJ hearing requests filed on or before September 30, 2015 and not yet scheduled for ALJ hearing. Under Phase II, at least 20 claims had to be at issue or at least \$10,000 in controversy if fewer than 20 claims were involved. See OMHA's website regarding SCF Phase II for a full list of Phase II eligibility criteria, located at: [http://www.hhs.gov/omha/OMHA%20Settlement%20Conference%20Facilitation/SCF%20Part%20B%20Docs/settlement\\_conference\\_facilitation\\_b.html](http://www.hhs.gov/omha/OMHA%20Settlement%20Conference%20Facilitation/SCF%20Part%20B%20Docs/settlement_conference_facilitation_b.html) (last accessed April 30, 2018).
- <sup>9</sup> For a Part A claim to be eligible the ALJ hearing request must have been filed on or before December 31, 2015 and not yet scheduled for ALJ hearing. Additionally, each individual claim must be \$100,000 or less and there must be at least 50 claims and \$20,000 collectively in controversy. Additional eligibility criteria for the Phase III SCF process are located on CMS' website, located at: <https://www.hhs.gov/about/agencies/omha/about/special-initiatives/settlement-conference-facilitation/medicare-part-a-alj-appeals/index.html> (last accessed April 30, 2018).
- <sup>10</sup> OMHA estimated that in FY 2017 OMHA decided 84,729 appeals. See note 1, *supra*.

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- 11 A QIC is a review entity that contracts with Medicare to review and process appeals at the second level of the Medicare appeals process, known as reconsideration, for Medicare Part A or Part B appeals. However, if an appeal involves a Medicare Part C or a Part D claim for services, the second level appeal is not processed by a QIC, but rather is processed by an Independent Review Entity. Although decisions by an Independent Review Entity can be appealed to an ALJ for hearing at the third level of the Medicare appeals process, a decision by an Independent Review Entity on a Part C and Part D claim for Medicare benefits is not eligible for resolution through the expanded SCF program. To be eligible for the expanded SCF program the appeal must arise from a Medicare Part A or Part B claim for benefits.
- 12 See CMS' website regarding the expanded Settlement Conference Facilitation program for a full list of eligibility criteria at: <https://www.hhs.gov/about/agencies/omha/about/special-initiatives/settlement-conference-facilitation/index.html> (last accessed June 15, 2018).
- 13 *Id.* See also CMS' Frequently Asked Questions regarding the SCF Program at page 2 of 6, located on CMS' website regarding the expanded SCF program.
- 14 Additional eligibility limitations are explained on CMS' website at: <https://www.hhs.gov/about/agencies/omha/about/special-initiatives/settlement-conference-facilitation/index.html> (last accessed June 15, 2018).
- 15 For additional details regarding the SCF Express process, see CMS' website regarding the Settlement Conference Facilitation program.
- 16 See CMS' website regarding the LVA Initiative, located at: <https://cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Appeals-Settlement-Initiatives/Low-Volume-Appeals-Initiative.html> (last accessed April 30, 2018).
- 17 CMS defined patient status claims as claims denied on grounds that inpatient reimbursement for hospital services was not medically reasonable and necessary, but outpatient reimbursement would be appropriate. Further information regarding the Hospital Appeals Settlements is located on CMS' website at: <https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Hospital-Appeals-Settlement-Process-2016.html> (last accessed April 30, 2018).
- 18 The first Hospital Appeals Settlement (colloquially named the "68% Settlement") contained seven eligibility criteria: (1) the claim was denied by an entity which conducted review on behalf of CMS; (2) the claim was not for services or items furnished to a Medicare Part C enrollee; (3) the claim was denied based upon an inappropriate setting determination (i.e. a "patient status" denial); (4) the first day of admission was before October 1, 2013; (5) the hospital timely appealed the denial; (6) as of the date the administrative agreement is executed by the hospital and submitted to CMS the claim was either still pending at the Medicare Administrative Contractor ("MAC"), QIC, ALJ or DAB level or the hospital hadn't yet exhausted its appeal rights; and (7) the hospital did not receive payment and/or bill for the service as a Part B claim. See CMS Hospital Appeals Settlement for Fee-For-Service Denials Based on Patient Status Reviews for Admissions Prior to October 1, 2013 Frequently Asked Questions, located at: [https://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/Hospital\\_Appeals\\_Settlement\\_FAQs\\_10312014\\_508.pdf](https://cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/Hospital_Appeals_Settlement_FAQs_10312014_508.pdf) (last accessed April 30, 2018). See also CMS' Hospital Appeals Settlement website, located at: <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/medical-review/inpatienthospitalreviews.html> (last accessed April 30, 2018).
- 19 As an alternative to individual claim review and adjudication, CMS may utilize statistical sampling and extrapolation to estimate overpayments in instances involving large numbers of beneficiaries and claims. See *Chaves County Home Health Service, Inc. v. Sullivan*, 931 F.2d 914 (D.C. Cir. April 26, 1991) discussing HHS' longstanding practice of statistical sampling and extrapolation for estimating and adjudicating Medicare overpayments. See also CMS' statistical sampling guidelines found in the Medicare Program Integrity Manual at Chapter 8, located at: <https://cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c08.pdf> (last accessed April 30, 2018).
- 20 See CMS' Appeals Settlement Initiatives website regarding the LVA Initiative, located at: <https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Appeals-Settlement-Initiatives/Low-Volume-Appeals-Initiative.html> (last accessed April 30, 2018).
- 21 See CMS' Frequently Asked Questions regarding the LVA Initiative, located on CMS' website at: <https://cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Appeals-Settlement-Initiatives/LVA-FAQs.pdf> (last accessed April 30, 2018).
- 22 *Id.* CMS' Common Working File is a benefits coordination and pre-payment claims validation system for Medicare Part A and Part B claims. CMS and its contractors utilize this database to determine patient eligibility and monitor appropriate use of Medicare benefits. For further information see CMS' Medicare Claims Processing Manual at Chapter 27, Section 10, located at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c27.pdf> (last accessed April 30, 2018).
- 23 For example, if a patient has both Medicare and private insurer health coverage, coordination of benefit rules will determine which payor is obligated to pay first. If Medicare is obligated to pay first and the secondary payor pays only after Medicare has made a determination of coverage and payment, and if a claim is denied by Medicare on post payment audit and subsequently remains denied through the LVA Initiative, the private payor may demand that the appellant refund any moneys that the private payor initially paid on the claim. Whether and to what extent an appellant may incur refund obligations to other payors will depend on the appellant's contractual agreements with the payors and applicable law. See also note 20, *supra*.
- 24 See note 20, *supra*.
- 25 *Id.*
- 26 Details about the process are available at CMS' website, identified in note 19, *supra*.
- 27 The pilot was fairly limited in scope, applying to claims that were assigned to one or more ALJs or filed between April 1, 2013, and June 30, 2013.
- 28 See *Improvements are Needed at the Administrative Law Judge Level of Medicare Appeals*, HHS-OIG, OEI-02-10-00340 (November 2012); see also Nudelman, Jodi, Statement to the House Committee on Ways and Means, Subcommittee on Health, Current Hospital Issues in the Medicare Program, Hearing May 20, 2014.
- 29 The SSI was designed to resolve large volumes of claims pending in the Medicare appeals process that were filed by Medicare Part A and Part B providers and suppliers. If a beneficiary is found to be financially responsible for a Medicare overpayment, then the appeal would not be eligible for the SSI. Beneficiaries rarely participate in the Medicare hearing process. If a Medicare beneficiary does participate in the appeals process, CMS has an obligation to protect the beneficiary's exercise of his/her appeal rights and the appeal would therefore not be eligible for resolution in the SSI.
- 30 RACs are entities contracted by CMS to identify and return improper Medicare payments. RACs are compensated on a contingency-fee basis and thus tend to audit Medicare providers zealously.
- 31 See CMS' website regarding the SSI, located at: <https://www.hhs.gov/about/agencies/omha/about/special-initiatives/statistical-sampling/index.html> (last accessed April 30, 2018).
- 32 *Id.*
- 33 For example, one potential challenge could be that the sampling process employed by the statistician resulted in a non-random or non-representative sample, such that the sample itself is invalid. If the sample itself is not statistically valid, the statistical extrapolation cannot be considered statistically valid. For more information see CMS' Medicare Program Integrity Manual at Chapter 8, note 18 *supra*.
- 34 See CMS' Fact Sheet regarding the QIC DME Formal Telephone Discussion Demonstration, located at: <https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Downloads/QIC-Formal-Telephone-Demonstration-Revised-Fact-Sheet-%E2%80%93-November-18-2016v508.pdf> (last accessed April 30, 2018). See also C2C Innovative Solutions, Inc.'s website regarding the QIC DME Formal Telephone Discussion Demonstration, located at: <https://www.c2cinc.com/Telephone-Demonstration> (last accessed April 30, 2018). C2C Innovative Solutions, Inc. is the Qualified Independent Contractor for DME suppliers that submit Medicare claims.
- 35 See note 1, *supra*.
- 36 82 Fed. Reg. 4974 (January 17, 2017).
- 37 *Id.*

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## SECTION CALENDAR

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or visit the Section website at [www.americanbar.org/health](http://www.americanbar.org/health)

**June 7-9, 2018**  
Physicians Legal Issues Conference  
Chicago, IL  
*In-Person*

**June 14, 2018**  
The National Practitioner  
Data Bank Master Class  
*CLE Webinar*

**June 20, 2018**  
Can't We All Just Get Along?  
Mediating Clinical, Payer, Peer  
Review, and Corporate  
Healthcare Disputes  
*CLE Webinar*

**June 28, 2018**  
Challenges of Hospital-Based Pathology  
Compensation Arrangements  
*CLE Webinar*

**July 26, 2018**  
Drug Approval Master Class  
*CLE Webinar*

**August 23, 2018**  
HIPAA Breach  
*CLE Webinar*

**December 10-11, 2018**  
16th Annual Washington  
Health Law Summit  
Washington, DC  
*In-Person*

**March 13-16, 2019**  
20th Annual Emerging Issues in  
Healthcare Law Conference  
Orlando, FL  
*In-Person*

**June 13-15, 2019**  
Physicians Legal Issues Conference  
Chicago, IL  
*In-Person*