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FAQs about the In-House Attorney–Client Privilege

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It's simple—the attorney–client privilege protects from discovery communications between a client and her lawyer. It's challenging—the privilege applies to communications between (some) corporate representatives and outside counsel, depending whether federal or state privilege law applies, and if state law, which state. It's convoluted—the privilege protects communications between (some) corporate representatives and in-house counsel, but only if U.S. law applies, the issue arises in an advantageous jurisdiction, and in-house counsel satisfy a heightened burden, prove the communication arose in a legal (rather than business) capacity, and the company employee did not waive the privilege by inappropriately disseminating the communication.

American law acknowledges the protections of an in-house attorney–client privilege, but "what is unclear is exactly how far this protection extends regarding the corporation's employees and agents."[1] Courts recognize that "[d]efining the scope of the privilege for in-house counsel is complicated,"[2] and in-house lawyers and their in-house clients should, too. The greatest source of confusion concerns whether the employee communicated with the in-house lawyer so that she could render legal advice to the company. Courts effectively correlate in-house lawyers with Janus, the two-faced Roman God of Transition, with one face symbolizing counsel's lawyer role and the other personifying her business role.

Other concerns exist. The privilege does not protect all employee–in-house lawyer communications. Non-lawyer employees may not simply copy an in-house lawyer on an email and expect the privilege to preclude its disclosure. Privilege notices at the end of corporate emails, without more, are likely insufficient to invoke the privilege. In-house lawyers have several questions about their privilege, and the list below answers some of the more frequent ones.

1. When are employee–in-house communications privileged?

It depends. Whether the attorney–client privilege protects from compelled discovery an employee's communication with an in-house attorney depends on: (1) whether the communication meets certain universal,

threshold privilege requirements; and (2) the jurisdiction in which the privilege challenge arises.

The threshold privilege requirements are threefold. The in-house lawyer must first establish that the document over which she seeks protection is a communication—the privilege only protects communications, not fact-related documents. For example, the privilege likely does not protect minutes from a corporate committee meeting, but likely protects an employee's communications to in-house counsel about those minutes.[3]

Second, in-house counsel must not only prove that the communication was confidential at the time of its creation, but also that the parties intended for the communication to remain confidential. The intent-to-remain-confidential prong is crucial; the in-house lawyer should implement measures to ensure that a confidential communication remains so by, for example, monitoring its filing location and instructing recipients not to disseminate communication.[4]

The third threshold privilege requirement requires evidence that the employee communicated with in-house counsel for the purpose of the lawyer rendering legal advice to the company. The dual business and legal roles concern courts, and most courts presume employee–in-house lawyer communications concern business issues and impose a "heightened scrutiny" when considering the "rendering legal advice" element.[5]

Even if the in-house lawyer meets these three threshold requirements, obtaining privilege cover for employee communications still depends on the jurisdiction deciding the privilege issue. Some states follow the so-called "control group" test, which holds that the privilege does not apply to all employees' communications with in-house lawyers, but rather, only to communications of those employees within the company's control group. The control group consists of top management persons who have the responsibility of making final decisions, and employees whose advisory role to top management in a particular area is such that management would not make a decision without their advice or opinion.[6]

In contrast to the control group test, federal common law and the majority of states follow the subject-matter test, which provides that:

> [a]n employee of a corporation, though not a member of its control group, is sufficiently identified with the corporation so that his communication to the corporation's attorney is privileged where the employee makes the communication at the direction of his superiors in the corporation and where the subject matter upon which the attorney's advice is sought by the corporation and dealt with in the communication is the performance by the employee of the duties of his employment.[7]

The privilege in these jurisdictions applies to all employees so long as they communicate with the in-house lawyer about matters within the scope of their employment.

2. Will a boilerplate contractual choice-of-law provision ensure the company receives its preferred privilege law?

This FAQ has no consensus answer. The answer to FAQ 1. reveals that whether the attorney–client privilege protects an employee–in-house lawyer communication turns on the law applied to the communication. In-house lawyers would gain some comfort if they could ensure that favorable privilege law—for example, the law of a subject-matter state rather than a control-group state—applied in contract litigation. Parties in contract negotiations often agree upon and insert a choice-of-law provision, but the question is whether this boilerplate provision is sufficient to apply the chosen state's privilege law. Not necessarily.

Although few courts have addressed this issue, one court ruled that a contract's choice-of-law provision did not require application of the chosen state's privilege law. In *Hercules, Inc. v. Martin Marietta Corp.*,[8] the *Hercules* court applied Utah's privilege law even though the contract

governing the dispute called for application of Colorado law. The court reasoned that the choice-of-law provision pertained to the contract interpretation, and that "[n]othing in the express terms of the contract applie[d] to the law of privileged communications."[9] The take-away is that courts may not construe boilerplate choice-of-law provisions broadly enough to cover privilege disputes. The in-house lawyer, therefore, should consider broadening her contractual choice-of-law provisions to expressly include the chosen state's privilege law.

3. Will the privilege cover in-house counsel's communications with employees of corporate owners, subsidiaries, or affiliates?

Yes, in certain circumstances. Answering this FAQ requires a case-by-case, fact-intensive analysis. The privilege generally covers a company's in-house counsel communications with employees of a sufficiently related company. For example, the Restatement comments that, "when a parent corporation owns a controlling interest in a corporate subsidiary, the parent corporation's agents who are responsible for legal matters of the subsidiary are considered agents of the subsidiary."[10] And courts consider the corporate client to include not only the company that employs the in-house lawyer, but also the parent, subsidiary, and affiliate corporations,[11] but only if there is sufficient controlling interest.[12]

So, what degree of relationship does the privilege require? In-house lawyers should look to the joint client doctrine and the common interest doctrine for assistance, and the court's decision in *SCR–Tech LLC v. Evonik Energy Servs., LLC*[13] provides guidance. Ebinger, a corporation, owned 37% of SCR–Tech GmbH which, in turn, owned 100% of SCR–Tech LLC. Ebinger, SCR–Tech LLC, and legal counsel engaged in several communications pertaining to negotiations that ultimately led to the sale of SCR–Tech LLC to an unrelated third entity. In subsequent litigation, the defendant moved to compel these communications, claiming that Ebinger was not SCR–Tech LLC's parent for purposes of extending the attorney–client privilege. The court disagreed and invoked concepts of "joint client" and the common interest doctrine to support its decision.

The *Evonik* court noted that many lawyers and courts improperly interchange the "joint client" doctrine and the common interest doctrine (or joint defense doctrine). These concepts are distinct and contain "analytical differences." The joint client doctrine focuses on client identity and the relationship between two entities. The common interest doctrine, however, focuses on the common legal interests between two entities, regardless of their relationship. Rather than drawing a bright-line rule that a corporation must own a certain percentage of an affiliated corporate entity before the joint client doctrine applies, the court looked at the totality of circumstances to determine whether the entities "are sufficiently united such they may properly be considered joint clients."

This guidance suggests that if the degree of common ownership is sufficient to evidence control of the subject matter of the putatively privileged communications, then the court will apply the joint client doctrine and consider both entities as one client for privilege purposes. On the other hand, if the circumstances reveal that the relationship does not rise to that level, then the court will look more at the common legal interest between the two entities to determine whether the common interest doctrine protects the sharing of privileged information.

4. Are employees' communications with a foreign-based in-house lawyer privileged?

This FAQ is of increasing importance given the number of corporations with operations and lawyers divided between the United States and multiple foreign countries. And answering this FAQ requires discussion of two concepts: whether the foreign country recognizes an evidentiary privilege for in-house lawyers; and conflicts-of-law rules governing privileges between the United States and the foreign country at issue.

A country-by-country in-house privilege review is beyond the scope of the FAQs, but several foreign countries do not recognize an evidentiary privilege governing communications between a company's non-lawyer employees and its in-house lawyers. The European Union, for example, rejected an in-house counsel privilege in *Akzo Nobel Chem. Ltd. v. European Commission*.[14]

But when does American or foreign law apply? The Second Circuit provides the most developed law on the subject and applies the "touch base" approach. This analysis requires a determination as to which country has the most compelling or predominant interest in whether the communication should remain confidential.[15] As applied, communications relating to U.S. legal proceedings or advice on American law "touch base" with the United States and, therefore, American privilege law applies. But communications regarding a foreign legal proceeding or foreign law requires application of foreign privilege law.[16]

In sum, there is no privilege for communications between a U.S. based employee and a foreign-based attorney if the communication concerns foreign law and that law rejects an in-house counsel privilege. But the privilege covers a foreign employee's communication with a U.S. based in-house counsel about American law issues.

5. Does the privilege apply if the in-house lawyer is not licensed in the state where she works?

Yes, so long as she is licensed in another jurisdiction. In the United States, the attorney–client privilege applies only

to communications with attorneys licensed to practice law.[17] Courts recognize that in-house lawyers often maintain multijurisdictional practices and move nationally and internationally with their corporate employer. Consequently, the privilege applies to in-house lawyers even if they are not licensed in the state where they work so long as they are licensed in some jurisdiction.[18] This includes licensure in a foreign jurisdiction.[19]

The privilege is inapplicable, however, if the in-house attorney is not licensed in any jurisdiction,[20] or if the in-house lawyer allows his licensure to lapse.[21] Courts recognize a "reasonable belief" exception, which holds that the privilege applies if the in-house lawyer is not licensed where the client "reasonably believes that the person to whom the communications were made was in fact an attorney."[22] The exception applies to a mistake of fact—where the client mistakenly believed in the in-house lawyer's licensed status—not a mistake of law, such as where the client believed that privilege law would protect the communication regardless of the license status.[23] Under the reasonable belief exception, courts are more likely to apply the exception where the in-house lawyer previously held a license, but allowed it to lapse or go inactive, and less likely to apply the exception where the attorney never obtained a license.

6. Who in the company has authority to waive the privilege?

Not all employees may waive the corporation's attorney–client privilege; rather, only employees who manage or control the company's activities may waive the privilege. The court's decision in *Hedden v. Kean University* illustrates this point.[24] *Hedden* concerned whether the privilege covered a head basketball coach's email to university in-house counsel and whether the coach's distribution of that email to the NCAA constituted privilege waiver. Applying the subject-matter test, the court ruled that the privilege protected "communications made by mid or low-level employees within the scope of their employment to the corporation's attorney for purposes of aiding counsel in providing legal advice." The coach and her email fell into this privileged-employee category, but as to the waiver issue, the court held that the reverse is not true—not all employees may waive the corporation's privilege, only officers, directors, or "those who manage or control its activities." The coach did not fall into this category, and her disclosure of the email to the NCAA was not privilege waiver.

States applying the control group test, discussed in FAQ 1. above, consider privileged only those communications involving a certain level of employees. The subject-matter test, followed by federal courts and the majority of states, holds that all employees may have privileged communications with the in-house lawyer so long as the communication's subject falls within the scope of the employees' duties. Courts such as *Hedden* hold that only employees who manage or control the company's activities may waive the privilege.

7. Does the privilege protect communications to the company's lawyer–lobbyist?

Yes, if the communication concerns legal advice rather than purely lobbying efforts. Many companies employ government-relations lawyers who primarily lobby local, state, or federal governments on the corporation's behalf. The attorney–client privilege protects communications with a lawyer–lobbyist so long as she is "acting as a lawyer."[25] The privilege does not protect communications and information conveyed to the lawyer–lobbyist for the purpose of fulfilling her lobbyist role.[26]

The privilege's application in the lawyer–lobbyist context is highly fact specific. On the one hand, the privilege likely does not protect communications from lawyer–lobbyists that simply summarize legislative meetings, update legislative activity, or update the progress of certain legislation because these types of communications do not fall within the legal-advice sphere. On the other hand, the privilege likely protects communications from the lawyer–lobbyist that includes a legal analysis of certain legislation.[27]

8. Does the privilege cover conversations between two non-lawyer employees?

Yes, in certain circumstances. Although the privilege applies to communications between company's employee and its in-house lawyer, courts recognize that "[m]anagement should be able to discuss amongst themselves the legal advice given to them as agents of the corporation with an expectation of privilege."[28] The privilege, therefore, attaches to communications between non-lawyer employees where the employees discuss or transmit legal advice given by counsel or where an employee discusses her intent to seek legal advice about an issue.[29] The key issue is whether the employee–employee communications occurred for purposes of seeking a legal opinion, rendering legal services, or providing assistance in some proceeding.[30]

9. May in-house lawyers communicate with outside consultants under the privilege umbrella?

It depends. In control group states, the privilege likely will not apply to consultants because they generally do not fall within top management persons who have the responsibility of making final decisions, nor do they serve an advisory role to top management in a particular area such that management would not make a decision without their advice or opinion. In subject-matter jurisdictions, the privilege likely applies if the outside consultant qualifies as the functional equivalent of an employee.

The court in *In re High–Tech Employee Antitrust Litigation*[31] encountered an interesting privilege situation involving Bill Campbell, the Board Chairman for Intuit, Inc. who simultaneously served in several roles with Google, Apple, and other technology-based companies. Prior to 2007, Campbell served, while Intuit chairman and without a Google contract, as an advisor to Google's management team and Board of Directors. In 2007, Campbell entered an agreement with Google that made him a part-time Google employee.

The *High-Tech* court had to determine whether the attorney–client privilege protected Campbell's email communications with Google employees—most often sent through his Intuit email address. Questions regarding Campbell's role prior to 2007, when he had no formal agreement with Google, complicated the analysis. The court followed the leading functional-equivalent-employee cases of *U.S. v. Graf*[32] and *In re Bieter Co.*[33] which held that there is no legitimate reason to distinguish between a company's employee and its consultant for attorney–client privilege purposes, and that the privilege extends to consultants who are "in all relevant respects the functional equivalent of an employee." The court must examine the consultant's role and determine whether he was the primary agent who communicated with counsel, whether he acted as a corporate agent in a significant capacity, whether he managed employees, or had substantial input into the development of the litigation-related issues.

In *High–Tech*, the court found that Campbell was the functional equivalent of a Google employee even while he served as Intuit's Board Chairman. The court found that Campbell advised Google's management and Board of Directors on business strategy, organizational development, and internal business processes. The court also found significant Campbell's important advisory role, noting that he emailed with Google executives regarding "confidential and highly sensitive matters related to Google's compensation practices, policies, and strategies."

But because of Campbell's roles with Apple, Intuit, and other companies, the court stopped short of issuing a blanket privilege protection for all of Campbell's email communications. Google still had to prove that the communications otherwise fell within the corporate attorney–client privilege, meaning it had to further prove the email communications were to Google in-house or outside counsel, were intended to be, and actually were, confidential, and were, for purposes of Google's counsel, rendering legal advice.

10. Is an email discussing business *and* legal issues privileged?

Yes, the privilege covers these "dual-purpose" emails, but only if the in-house lawyer establishes that the emails were sufficiently legal-based under one of two tests, depending on the jurisdiction. Courts apply two standards to determine whether

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these dual–purpose emails receive privilege protection: the "because of" standard and the "primary purpose" standard.

The so-called "because of" standard requires in-house lawyers to prove that, under the totality of the circumstances, including the nature of the document and the factual situation, the employee prepared the document because of litigation or a legal purpose. Courts borrow this standard from the work–product doctrine, but apply it where mixed communications involve both business and legal advice.[34] Under the primary purpose standard, the privilege protects in-house lawyers' communications involving business and legal advice if the primary purpose of the communication is to obtain or give legal advice.[35]

The "because-of" standard requires a lesser burden of proof, demanding that in-house lawyers simply show that the employee prepared the putatively privileged communication because of legal issues. The primary purpose standard requires a higher burden of proof, focusing on whether each communication was for the primary purpose of rendering legal advice.

In a thorough opinion, the U.S. District Court for the District of Nevada recently evaluated both standards and applied the primary purpose standard to in-house counsel email communications. Although noting that the "because of" standard had supplanted the "primary purpose" standard in some jurisdictions, the court found that the Ninth Circuit had not done so. And noting that "merely copying or 'cc-ing' legal counsel, in and of itself, is not enough to trigger the attorney–client privilege," the court reviewed each challenged email to determine whether the primary purpose of its creation was legal-advice related.[36]

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1 *See E.I. DuPont de Nemours & Co. v. Forma-Pack, Inc.*, 718 A.2d 1129, 1141 (Md. Ct. App. 1998).
2 *See U.S. Postal Serv. v. Phelps Dodge Refining Corp.*, 852 F. Supp. 156, 160 (E.D.N.Y. 1994).
3 *See Neuder v. Battelle Pacific Nw. Nat'l Lab.*, 194 F.R.D. 289 (D.D.C. 2000).
4 *See Se. Pa. Transp. Auth. v. Caremarkpcs Health, L.P.*, 254 F.R.D. 253 (E.D. Pa. 2008).
5 *See Kincaid v. Wells Fargo Sec., LLC*, 2012 WL 712111 (N.D. Okla. Mar. 1, 2012).
6 *See Sullivan v. Alcatel-Lucent USA, Inc.*, 2013 WL 2637936 (N.D. Ill. June 12, 2013).
7 *See Harper & Row Publishers, Inc. v. Decker*, 423 F.2d 487, 491–92 (7th Cir. 1970); *S. Bell Tel. & Tel. Co. v. Deason*, 632 So. 2d 1377 (Fla. 1994).
8 *See Hercules, Inc. v. Martin Marietta Corp.*,143 F.R.D. 266 (D. Colo. 1992).
9 *Id.* at 268.
10 *See* Restatement (Third) Law Governing Lawyers, §73 cmt. d.
11 *See U.S. v. Am. Tel. & Tel. Co.*, 86 F.R.D. 603 (D.C. Cir. 1979).
12 *See Moore v. Medeva Pharm., Inc.*, 2003 WL 1856422 (D.N.H. Apr. 9, 2003).
13 *See SCR–Tech LLC v. Evonik Energy Servs., LLC*, 2013 WL 4134602 (N.C.Super. Ct. Aug. 13, 2013).
14 *See Akzo Nobel Chem. Ltd. v. European Commission*, 2010 EUR-Lex CELEX LEXIS 62007J0550, P44 (Sept. 14, 2010).
15 *See Astra Aktiebolag v. Andrx Pharm., Inc.*, 208 F.R.D. 92 (S.D.N.Y. 2002).
16 *See Gucci Am., Inc. v. Guess?, Inc.*, 271 F.R.D. 58 (S.D.N.Y. 2010); *Anwar v. Fairfield Greenwich Ltd.*, 2013 WL 6043928 (S.D.N.Y. Nov. 8, 2013).
17 *See Anwar v. Fairfield Greenwich, Ltd.*, 2013 WL 6043928 (S.D.N.Y. Nov. 8, 2013); *Wultz v. Bank of China, Ltd.*, 2013 WL 5797114 (S.D.N.Y. Oct. 25, 2013).
18 *See Florida Marlins Baseball Club, LLC v. Certain Underwriters at Lloyd's London*, 900 So. 2d 720 (Fla. Dist. Ct. App. 2005).
19 *See Renfield Corp. v. E. Remy Martin & Co., S.A.*, 98 F.R.D. 442 (D. Del. 1982).
20 *See Fin. Tech. Int'l, Inc. v. Smith*, 2000 WL 1855131 (S.D.N.Y. Dec. 19, 2000).
21 *See Gucci America, Inc. v. Guess?, Inc.*, 2010 WL 2720079 (S.D.N.Y. 2010).
22 *Anwar*, 2013 WL 6043928, at *3.
23 *Id.* at *8.
24 *See Hedden v. Kean Univ.*, 2013 WL 5745994 (N.J. Super. Ct. Oct. 24, 2013).
25 *In re Grand Jury Subpoenas Dated Mar. 9, 2001*, 179 F. Supp. 2d 270, 285 (S.D.N.Y. 2001).
26 *Id.*
27 *See A&R Body Specialty & Collision Works, Inc. v. Progressive Cas. Ins. Co.*, 2013 WL 6044342 (D. Conn. Nov. 14, 2013).
28 *See McCook Metals, LLC v. Alcoa Inc.*, 192 F.R.D. 242, 254 (N.D. Ill. 2000).
29 *See Datel Holdings Ltd. v. Microsoft Corp.*, 2011 WL 866993 (N.D. Cal. Mar. 11, 2011).
30 *See Johnson v. Sea–Land Serv., Inc.*, 2001 WL 897185 (S.D.N.Y. Aug. 9, 2001).
31 *In re High–Tech Employee Antitrust Litig.*, 2013 WL 772668 (N.D. Cal. Feb. 28, 2013).
32 *U.S. v. Graf*, 610 F.3d 1148 (9th Cir. 2011).
33 *In re Bieter Co.*, 16 F.3d 929 (8th Cir. 1994).
34 *See In re CV Therapeutics, Inc. Sec. Litig.*, 2006 WL 1699536 (N.D. Cal. June 16, 2006).
35 *See U.S. v. Chevron Corp.*, 1996 WL 444597 (N.D. Cal. May 30, 1996).
36 *See Phillips v. C.R. Bard, Inc.*, 290 F.R.D. 615 (D. Nev. 2013).

The Corner

A Message from the Affinity Group Chairs

Welcome to the Affinity Group (AG) Corner! *The Corner* is a repository of articles, information, and announcements that may be of specific interest to the members of the three AGs sponsored by the Hospitals and Health Systems Practice Group (HHS PG). We hope that, with each publication of *Hospitals & Health Systems Rx,* you will look to *The Corner* to read about our AGs' activities, and learn more about what our members are talking about. For more information about anything published in *The Corner*, or to become a member of one of the AGs represented in *The Corner,* please do not hesitate to contact one of us.

Sincerely,

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AG Events and Announcements

Fair Market Value AG

Roundtable and Webinar Series: Please tune into our roundtable and webinar series: *Rules, Tools, and Fools: "Hot Button" Issues in Physician Compensation Planning*. The remaining sessions in this series will take place November 14, January 21 (joint session with the Real Estate AG), March 12, and April 10. Registration information is available at www.healthlawyers.org/Pages/Distance-Learning.aspx.

Volunteer/Member Call: Learn about opportunities to participate in the activities of the Fair Market Value (FMV) AG. This call will be held in early to mid-November. Please contact the PG staff at pgs@healthlawyers.org to join the FMV AG and/or receive an invitation to the call.

Second Annual "FMV Year in Review": If you are able to make it to the Physicians and Hospitals Law Institute in Las Vegas and you want to know more about the FMV questions that have come before counsel, clients, and courts in the last year, don't miss this session. Our panel, which includes a physician transactions expert, in-house hospital counsel, and a former government regulator, could be just what you are looking for!

In-Person Networking Events: In collaboration with the Public Health System and Children's Hospital AGs, we are planning cocktail and dinner networking events at several upcoming AHLA in-person programs. If you enjoyed last year's events at Commander's Palace (New Orleans), Ruth's Chris Steak House (Nashville), or the Central Park Boathouse (New York), or if you are sorry that you missed these events, please look for networking event sign-up information in the registration materials for upcoming in-person programs.

Collaboration with the National Association of Certified Valuators and Analysts: The FMV AG is working with the AHLA/National Association of Certified Valuators and Analysts (NACVA) workgroup, which is led by former FMV AG Chair Greg Anderson.

If you are in San Diego in December, check out the presentations of FMV AG leaders and members Joe Wolfe, Curtis Bernstein, Jim Lloyd, and Greg Anderson at the NACVA Advanced Healthcare Valuation and Consulting Symposium.

Real Estate AG

On January 21, we will be co-sponsoring a webinar (with the FMV AG), to introduce the AHLA FMV Toolkit for leasing arrangements. Registration information is available at www.healthlawyers.org/Pages/Distance-Learning.aspx.

The article below, brought to you jointly by the Public Health System and FMV AGs, addresses FMV lessons that may be learned from recent enforcement actions, with specific focus on lessons for public health systems.

Doing Good vs. Doing Right: Lessons for Public Health Systems in *United States ex rel. Baklid-Kunz v. Halifax* and Other Recent Whistleblower Suits

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This article is inspired by a recent presentation of the authors, entitled "Is it All About the Money? 10 Lessons on Fair Market Value from Halifax and Other Recent Cases."

In March 2014, on the first day of jury selection for its impending trial, Halifax Health (Halifax) agreed to pay $85 million to settle allegations that, through its affiliates, it violated the False Claims Act (FCA) by knowingly submitting claims for payment by Medicare in violation of the Physician Self-Referral Law (Stark Law). The $85 million settlement amount is the largest to date in a Stark Law case. However, the amount represents a small fraction of the $350 million to $1.14 billion[1] that the federal government and relator may have been awarded if they were victors in the trial.

Halifax is a public, nonprofit health system created by an act of the Florida Legislature to serve residents of Volusia County, FL and surrounding communities. Halifax has the power to tax local property owners to carry out its mission and fund operating shortfalls, and a board appointed by the Florida Governor oversees the system's operations. Like many public health systems in Florida and elsewhere, Halifax has three main sources of revenue: (1) payments it receives for services provided; (2) money it generates from bond sales; and (3) the ad valorem taxes levied on and paid by property owners in the relevant taxing district.[2] Ironically, the federal government's lawsuit, aimed in part at recovering public health care dollars, threatened the first two sources of revenue, and may have resulted in a greater burden and reliance on the third source, public tax funds.[3]

Proponents of the lawsuit against Halifax, including U.S. Department of Justice (DOJ), argue such cases are key in guarding against improper financial incentives in health care, including overutilization and related dangers to patient safety. In the words of DOJ, "[f]inancial arrangements that compensate physicians for referrals encourage physicians to make decisions based on financial gain rather than patient needs [and for this reason, DOJ] is committed to preventing illegal financial relationships that undermine the integrity of our public health programs."[4]

With this backdrop, consider the publicly available information about Halifax:

- Halifax is reported to be a major provider of health care services in East Central Florida.[5] During the years that were the focus of the qui tam lawsuit, Halifax operated a 678-bed tertiary care center that served local residents with the area's only Level II or higher trauma center, as well as a comprehensive stroke center, neonatal and pediatric intensive care units, child and adolescent behavioral services, and a kidney transplant program;[6]
- Like most tax-supported health care providers, Halifax is a safety net provider that fills gaps in the health care delivery system by ensuring the availability of a full range of health care services to local residents, regardless of patients' ability to pay. Like most public health systems, particularly those that operate trauma centers, Halifax has a history of providing care for Medicaid and uncompensated care patients, and has a relatively high case-mix index, meaning that it services some of the sickest patients requiring the most-complex services;[7] and
- Despite these challenges, a 2012 report commissioned under Florida House Bill 711[8] indicates that Halifax has historically performed well on both quality and efficiency measures.[9] Information reported on a website maintained by the Safety Net Hospital Alliance of Florida (of which Halifax is a member) states that Halifax has "consistently ranked in the top five percent of all hospitals in the nation in clinical outcomes in areas such as cardiology, orthopedics, neurosciences, oncology and trauma care."[10]

This information does not paint a picture of Halifax as a threat to the integrity of public health programs. Indeed, the information seems to paint the opposite picture. So, then, how did Halifax become the center of one of the most expensive Medicare fraud and abuse cases to date?

Halifax's costly lawsuit—at least the portion of the lawsuit related to alleged violations of the Stark Law—started when a long-time Halifax employee, Elin Baklid-Kunz, alleged that Halifax had improper financial relationships with some of its employee physicians, including six oncologists, two psychiatrists, and three neurosurgeons. The general theme in Kunz's allegations was that Halifax's employment agreements with the physicians provided for compensation that was excessive for the services that the physicians performed. Kunz filed a qui tam complaint on the basis of these allegations.[11]

Kunz was an employee of Halifax for approximately 15 years before filing the qui tam suit.[12] She stated that, in her role as director of physician contracting, she advised her colleagues and superiors that Halifax's compensation arrangements with employee physicians might be in violation of the Stark Law and the federal Anti-Kickback Statute. In a recent interview, Kunz stated that her colleagues and superiors told her that Halifax would not be liable for such violations due to its status as a tax-supported entity.[13]

Kunz's qui tam complaint was filed under seal in June 2009, and was amended at least twice. The federal government joined in the Stark Law portion of the lawsuit in October 2011, citing as motivation for intervening that "[i]mproper financial arrangements between hospitals and physicians threaten patient safety because personal financial considerations, instead of what's best for the patient, can influence the type of healthcare that is provided."[14]

In November 2013, the U.S. District Court for the Middle District of Florida issued partial summary judgment for the federal government and Kunz, holding that Halifax's arrangements with the oncologists violated the Stark Law.[15] The court noted that incentive bonuses paid to the oncologists varied based on referrals for designated health services (DHS) by the physicians, and as such, the arrangements failed to meet the Stark Law's requirement that compensation *not* be determined in a manner that takes into account, directly or indirectly, the volume or value of DHS referrals by the referring physician to the employer.[16] The court explained that, even though the bonuses may have been paid based on the volume of *personally performed* services (as would be permitted under the Stark Law employment exception) the pool from which the bonuses were paid was equal to 15% of the operating margin of Halifax's medical oncology program, and the program's revenue (and thus operating margin) varied with the volume and value of certain DHS, including outpatient prescription drugs and outpatient hospital services that the physicians did not personally perform.[17]

A few days after issuing summary judgment for the federal government and Kunz on the issues related to the oncologists' compensation, the court issued another blow to Halifax by denying Halifax's motion for summary judgment on the claims related to excessive compensation for the neurosurgeons' services.[18] In denying Halifax's motion, the court cited a report prepared by the plaintiffs' valuation expert, which indicated that the compensation paid to the neurosurgeons exceeded fair market value (FMV) for the services they performed, and was not commercially reasonable.[19] The court said that the existence of this report raised genuine issues of material fact that a jury would need to decide. As such, a trial date was set to address both: (1) whether Halifax *knowingly* submitted false claims to the government with respect to the illegal arrangements with the oncologists, which would create the grounds for penalties under the Stark Law and FCA; and (2) whether, in addition to violating the Stark Law through its arrangements with the oncologists, Halifax also violated the Stark Law through above-FMV and non-commercially reasonable arrangements with the neurosurgeons and, if so, whether Halifax had *knowingly* submitted false claims for neurosurgery services to the government in violation of the FCA.

As of the date of its historic settlement, it was reported that Halifax already had incurred more than $21 million in legal fees.[20] The trial may have taken Halifax down a long legal road that may have required substantially greater legal fees, and at the end of that road, Halifax may have faced repayments, penalties, and damages of more than $1.1 billion. For all but a few insiders, any discussion of the factors weighing in Halifax's decision to accept the record-setting settlement amount and accompanying corporate integrity agreement requires some speculation. However, factors that Halifax might reasonably have considered include: (1) the existence of written communications and documents that the court already ruled were not protected as attorney-client privileged or attorney work product, and that the plaintiffs may seek to construe as evidence of knowing violation of the Stark Law and FCA;[21] (2) the recent specter of *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, in which eight years of legal wrangling, including a trial, verdict, appeal, and retrial resulted in Tuomey Regional Medical Center, a community hospital in South Carolina, having to pay more than $237 million for violations of the Stark Law and FCA (in addition to associated legal fees and expenses); and (3) other recent instances in which DOJ monitored and/or pursued cases of suspected "excessive" physician compensation, including DOJ's intervention in the case against Infirmary Health System[22] (a safety net provider in Alabama), and DOJ's filing of a Statement of Interest in the case against All Children's Health System[23] (a not-for-profit provider of pediatric care in Florida).

In the Statement of Interest filed in the *All Children's* case, DOJ asserted that liability under the Stark Law and FCA will arise from the billing of services rendered to Medicaid

patients (in that case, pediatric Medicaid patients) when the billing provider has a financial relationship that fails to meet the requirements for a Stark Law exception. By filing the Statement of Interest, DOJ underscored that any suspect physician compensation, even if it is ostensibly to do what would widely be regarded as "good" work that serves vulnerable populations, should and will be subject to penalties if not compliant with both the letter and spirit of the law.

Together with the physician compensation cases that came before and after it, the *Halifax* case is the basis for a number of "lessons" for public health systems. Recognizing that the formulating and ranking of these lessons are both subjective and debatable, the authors set forth their "top five" below:

1. Trouble Follows Money

- High compensation amounts draw scrutiny. This may be particularly true in public health systems, where limited public funds may be used to help pay the compensation; and
- Whether compensation is "not FMV" is a question of fact (a *jury* question) that may be determinative of a Stark Law violation. As such, a claim that compensation is "above FMV" or otherwise "not FMV" makes a strong basis for initial qui tam pleadings, and may well survive initial motions for dismissal and summary judgment, driving up legal defense fees. Perhaps for this reason, compensation "above FMV" (or in some cases, "below FMV") is an initial claim in many recent Stark Law qui tam suits, even when issues include or are ultimately decided on the basis of questions other than FMV, such as commercial reasonableness and/or compensation based on volume or value of referrals or other business.

2. Safety-Net Providers Won't Escape Notice

- Do not assume that there will be an exception or leniency in federal Stark Law enforcement on account of being a safety-net provider or publicly owned and operated entity;
- Do not assume that the Stark Law does not apply if a provider's patients include many or mostly Medicaid patients rather than Medicare patients; and
- Do not assume that common perceptions of the "worth" of physicians' services—whether it be their worth for advancing the public good or their worth to achieving a noble mission, such as filling gaps in the health care system—negate expert analysis of FMV and commercial reasonableness. Perceptions are not always consistent with data, and, in the event of a qui tam lawsuit or government investigation, data will probably trump perception.

3. Good Intentions Probably Don't Matter, but Bad Ones Might

Even though neither good work nor good intent may matter to the question of whether a defendant has violated a strict liability statute such as the Stark Law, the progression of recent cases, including the *Halifax* case, suggests evidence that may be interpreted as showing *bad* intent may affect the outcome of an enforcement action.

First, evidence of bad intent may raise credible claims under, and/or result in liability for violations of, the Anti-Kickback Statute. A colorable argument of Anti-Kickback violations, in addition to Stark Law and FCA violations, gives a qui tam relator more substance for a complaint, and raises the stakes for the defendant by increasing potential penalties, infusing the possibility of criminal liability, and adding additional complexity (and probably cost) to the defense. Second, evidence of bad intent may increase the probability of a negative outcome for the defendant in a Stark Law case, at least to the extent that the evidence may: (1) be manifested through evidence of "knowing" violation or disregard for the law; and (2) increase the likelihood of DOJ intervention in the case.

In short, the facts matter in a qui tam or other government case. The trier of fact will seek to establish the parties' intentions through the evidence, and even an appearance of improper intent—for example, an evidenced desire to pay excessive compensation regardless of any FMV finding—may play a central role in the outcome.

For public health systems that transact business through public documents and public meetings, and that may be subject to a high level of public and media scrutiny because of their taxpayer support, any evidence of bad intent, if it exists, may be ferreted out more quickly and easily than it would be in the case of a private actor.

4. Memories Fade, but Documents Can Last Forever[24]

In a qui tam case or government investigation, "bad facts" may make for a bad outcome. Bad facts might be evidenced by "smoking gun" documents that indicate knowing violation of the law, and/or no documents, as might suggest a failure to obtain appropriate legal or FMV analysis. This being the case, it is worth noting that many public health systems are subject to public records and/or public meetings laws, and, as a result:

- The protections of attorney-client privilege and the attorney work-product doctrine may be limited;
- Certain documents and records may have to be retained and available for public access for an extended period of time, making them readily available for discovery, and/or to fill gaps in memories, years after they were created; and
- Would-be relators and members of the press may have easy access to documents through a public records request made before and, in some case, during a qui tam lawsuit or investigation.

For these reasons, good management of the transaction planning process, with careful oversight of the documents created in that process, may be of particular importance for public health systems.

5. A Few Dollars of Prevention Early Can Save Millions Later

Public health systems must responsibly manage resources to ensure that they can effectively serve their public mission over the long term. The expense of independent legal and valuation analysis for every physician transaction may not seem like an optimal use of the limited public resources available to support their mission. However, in some cases, the benefits of independent analysis by appropriately qualified, credible experts could be substantial, particularly for complicated or contentious transactions. If appropriately documented and heeded, expert analysis could undermine relator claims of "knowing" violation of the Stark Law and Anti-Kickback Statute. Moreover, when managed well, the process of obtaining objective, prospective transaction analysis can both focus and document the mission-critical purposes and benefits of the transaction, creating a helpful record of facts and circumstances for when controversies arise (and memories have faded) years later.

Conclusion

The *Halifax* case and other recent qui tam lawsuits contain numerous lessons for hospitals and health systems. Some are particularly significant for public hospitals and health systems, which face unique challenges due to their important role in providing for community health care needs even when it is financially challenging do so. As the title of this article suggests, the authors believe that the key lesson for public health systems is that the current regulatory climate warrants careful consideration of the distinction between "doing good" and doing things right. Even the most vital safety-net providers should pay careful attention to the process by which they carry out their mission, including whether that process complies with federal laws designed to protect against Medicare fraud and abuse.

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1 These figures are from an information sheet released by the defendant, Halifax Health. The information sheet, entitled, *The Government's $1 Billion Case Against Halifax Hospital: Who Would Ultimately Pay and Who Would Benefit?* contains a section labeled, "The government's math: at a glance." The content of this section indicates that the government sought $350 to $600 million for claims related to the oncologists' compensation and $375 to $540 million for claims related to the neurosurgeons' compensation, for a total of $725 million to $1.14 billion.

2 *See The Government's $1 Billion Case Against Halifax Hospital: Who Would Ultimately Pay and Who Would Benefit* (a publication of Halifax Health).

3 *Id. See also Fitch Downgrades Halifax Health's (Florida) Revs to 'BBB'*, Reuters, Mar. 17, 2014.

4 *Florida Hospital System Agrees to Pay the Government $85 Million to Settle Allegations of Improper Financial Relationships with Referring Physicians*, U.S. DOJ, Office of Public Affairs (Mar. 11, 2014).

5 *Available at* www.Halifaxhealth.org/history-facts.

6 *Id.*

7 *Id.*

8 Florida House Bill 711, codified at Fla. Stat. § 155.40(5)(d), requires the governing body of a public hospital to formally study "whether it is more beneficial to taxpayers and the affected community for the hospital to be operated by a government entity, or whether the hospital can be operated by a not-for-profit or for-profit entity with similar or better cost-efficiencies or measurable outcomes." To comply with the requirements of House Bill 711, the governing board of Halifax commissioned a report of the cost structure and quality of Halifax compared to those of similarly situated health systems.

9 *Available at* www.halifaxhealth.org/121105_Halifax_HB711_Board%20Presentation_FINAL.pdf.

10 *Available at* http://safetynetsflorida.org/public (last visited Oct. 9, 2014).

11 Case 6:09-cv-01002-GAP-TBS.

12 *United States ex rel. Baklid-Kunz v. Halifax Med. Ctr. d/b/a Halifax Health a/k/a Halifax Med. Ctr. and Halifax Staffing, Inc.*, (Second Am. Compl. Feb. 8, 2011).

13 Joe Carlson, *Caught Between Competing Pressures*, Modern Healthcare (Mar. 8, 2014) ("I was always told that Halifax was not liable under (the False Claims Act) because we were a tax-supported hospital").

14 *U.S. Joined False Claims Act Lawsuit Against Florida's Halifax Med. Ctr. and Halifax Staffing, Inc.*, U.S. DOJ, Department of Public Affairs (Sept. 9, 2011).

15 *United States and Baklid-Kunz v. Halifax Hosp. Med. Ctr. & Halifax Staffing, Inc.*, No: 6:09-cv-1002-Orl-31TBS, Order (Document 396, Nov. 13, 2013).

16 *Id.*

17 *Id.*

18 *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr. & Halifax Staffing, Inc.*, Case No: 6:09-cv-1002-Orl-31TBS, Order (Document 399, Nov. 18, 2013).

19 *Id.* at 10.

20 Skyler Swisher *Halifax Health's legal fees for massive whistle-blower lawsuit now total $21 million*, The Daytona Beach News-Journal, Feb. 3, 2014.

21 *United States ex rel. Baklid-Dunz v. Halifax Hosp. Med. Ctr. & Halifax Staffing, Inc.*, No: 6:09-cv-1002-Orl-31TBS, Order (Document 188, Nov. 6, 2013).

22 *U.S. Joins False Claims Act Lawsuit Alleging Illegal Physician Compensation By Mobile, AL., Health Firm*, U.S. DOJ, Office of Public Affairs (July 8, 2013). The government's complaint in intervention focused on alleged failure to meet billing and other requirements of the Stark Law's exception for in-office ancillary services; however, it also included claims highlighting the comparatively high compensation amounts of the relevant physicians in relation to the compensation supported by FMV opinions. (*See United States ex rel. Heesch v Diagnostic Physicians Group, P.C.*, Complaint in Intervention (Aug. 7, 2013). The relator's initial and first through third amended complaints focused on "excessive compensation and productivity bonuses directly related to each physician's referrals."

23 *United States ex rel. Schubert v. All Children's Health Sys., Inc.* No. 8:11-cv-01687-T-27EAJ, 2013 U.S. Dist. Lexis 163075 (M.D. Fla. Nov. 15, 2013).

24 The authors did not coin this phrase. It has appeared in AHLA presentations and publications by colleagues in recent years.

Recent Developments in 340B Orphan Drug Exclusion

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This article reports on recent developments concerning orphan drug exclusion under the 340B Federal Drug Pricing Program (340B Program), which affects critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and free-standing cancer centers. A brief background on relevant aspects of the 340B Program (including the impact of the Affordable Care Act) and the Orphan Drug Act also is provided.

To summarize recent developments, U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) recently issued an interpretive rule[1] (effective July 21, 2014) regarding 340B discount pricing for orphan drugs under Section 340B(e) of the Public Health Service Act (PHSA).[2] Under this interpretive rule, CAHs, SCHs, RRCs, and free-standing cancer hospitals, which recently became eligible to participate in the 340B Program, may purchase orphan drugs at discounted 340B prices if used to treat non-orphan conditions, but not if used to treat the rare conditions for which they were originally designated as orphan drugs. According to HHS, the interpretive rule intends to provide clarity in the marketplace, maintain savings under the 340B Program for these newly eligible providers, and protect financial incentives for manufacturing orphan drugs designated for rare diseases or conditions.

This interpretive rule comes on the heels of a recent (May 23) federal court decision, which vacated an HHS final rule implementing this orphan drug exclusion policy.[3] As further discussed below, the U.S. District Court for the District of Columbia, in *Pharmaceutical Research & Manufacturers of America (PhRMA) v. HHS*,[4] held that, due to limitations imposed by the U.S. Congress, HHS lacked authority to implement the final rule. However, in its decision, the court neither invalidated HHS' statutory interpretation nor precluded HHS' issuance of interpretive guidance.

340B Program

The 340B Program was established in 1992 and is administered by HRSA's Office of Pharmacy Affairs (OPA). The 340B Program mandates that those pharmaceutical manufacturers who wish to participate in the Medicaid program must discount outpatient drugs to certain qualifying health care providers, known under the 340B Program as covered entities. Among such covered entities, several types of hospitals may currently participate in the program, provided they meet all applicable requirements. These are disproportionate share hospitals, children's hospitals and free-standing cancer hospitals, CAHs, RRCs and SCHs, and hospital outpatient facilities.[5]

Under the 340B Program, the highest price that a manufacturer is permitted to charge a covered entity (ceiling price) is based on a statutory formula set forth at 42 U.S.C. § 256b(a)(1). If the manufacturer makes a covered drug available to any other purchaser at any price, it must make the drug available to covered entities at or below the ceiling price. Participation in the 340B Program is voluntary, but strong incentives exist for both health care providers and drug manufacturers to participate. Covered entities, for example, may receive drug discounts under the 340B Program estimated between 20-50%.[6] For pharmaceutical manufacturers, the incentive is for their drugs to be covered under the Medicaid program, since 340B participation is required for this coverage designation.

The 340B Program has not, however, been without criticism. On September 23, 2011 the U.S. Government Accountability Office (GAO) published a report from a study that it conducted concerning the 340B Program.[7] The GAO report was critical of HRSA's oversight of the 340B Program, noting that this oversight has mainly been left to self-policing on the part of Program participants. The various problems that GAO noted include a lack of HRSA guidance on key requirements under the 340B Program, which has left room for various inconsistent interpretations. In recent years, this has led to increased congressional scrutiny of the 340B Program, as well as increased HRSA Program oversight, including the auditing of covered entities for 340B Program compliance—developments that Program participants can hardly have failed notice.

Orphan Drug Act

Evidence of a drug's safety and efficacy is required for the U.S. Food and Drug Agency (FDA) to approve the drug for marketing in the United States.[8] Typically, this requires data obtained from clinical trials. Because of the costs that must be incurred in conducting such trials and obtaining FDA approval, pharmaceutical companies reportedly have tended to focus on developing treatments for common diseases, which provide a greater opportunity for recouping research and development costs, and realizing profits, than by focusing on relatively rare diseases. The Orphan Drug Act of 1983[9] was enacted as a countering measure. The Orphan Drug Act provides certain incentives for developing and commercializing drugs for treating rare diseases, defined as a condition or disease affecting fewer than 200,000 patients in the United States.[10]

These incentives include seven-year market exclusivity, a tax credit of 50% of the cost of conducting qualified clinical trials, and an exemption from drug-application user fees charged by FDA, as well as faster regulatory reviews and assistance from FDA reviewers during the developmental and review process.[11] And, unlike traditional patent law, the seven-year market exclusivity under the Orphan Drug Act does not begin until the drug is granted FDA approval and is independent of the drug's current patent status. The incentives are so strong that some pharmaceutical companies, like Pfizer, have created separate research divisions for orphan drugs.[12]

FDA reports that the Orphan Drug Program has been a success, citing data showing that more than 400 drugs and biologic products for rare diseases have come to market since 1983. In contrast, FDA cites data showing that fewer than ten such industry-supported products came to market between 1973 and 1983.[13] However, like the 340B Program, the Orphan Drug Program also has had its critics. Much of the criticism centers on the monopolization that the Orphan Drug Program allows, because of the extended market exclusivity, as well as companies marketing orphan drugs for non-orphan use.[14] There is little doubt among its proponents, however, that the Orphan Drug Program has benefitted those with rare diseases.[15]

340B Orphan Drug Exclusion

The Patient Protection and Affordable Care Act of 2010,[16] as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA),[17] revised the 340B statute for the first time since its 1992 enactment. Among these changes, children's hospitals, free-standing cancer hospitals, CAHs, RRCs, and SCHs were added to the list of 340B covered entities.[18] However, free-standing cancer hospitals, CAHs, RRCs, and SCHs are excluded from access to 340B drug pricing for an orphan drug used for a rare disease or condition. As amended by HCERA and Section 204 of the Medicare and Medicaid Extenders Act of 2010,[19] Section 340B(e) of the PHSA sets forth the following:

> EXCLUSION OF ORPHAN DRUGS FOR CERTAIN COVERED ENTITIES—For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M), (N), or (O) of subsection (a)(4)), the term 'covered outpatient drug' shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition.[20]

Covered entities and pharmaceutical manufacturers have each interpreted this exclusion language differently: covered entities have argued that the exclusion only applies when using the orphan drug for the orphan indication; and pharmaceutical manufacturers have argued that, under the text of the exclusion, it applies to the drug regardless of the indication for which it is used.[21] In May 2011, HHS issued a proposed rule setting forth that the orphan drug exception would apply only when the orphan drug is used for the orphan indication. Despite arguments from the pharmaceutical industry, on July 23, 2013 HHS issued a final rule (Orphan Drug Exclusion Rule) that basically followed the earlier proposed rule. Under the Orphan Drug Exclusion Rule, CAHs, SCHs, RRCs, and free-standing cancer hospitals could purchase orphan drugs at discounted 340B prices only if used to treat non-orphan conditions. For example, as discussed in *PhRMA v. HHS*,[22] the drug Prozac has orphan drug designation from FDA for the treatment of autism and body dysmorphia in children, as well as a non-orphan indication for treating depression. Under the Orphan Drug Exclusion Rule, CAHs, SCHs, RRCs, and free-standing cancer hospitals could obtain Prozac, when used for the treatment of depression (a non-orphan use), at 340B prices.

According to HHS, the Orphan Drug Exclusion Rule reflects a balancing of congressional intent to lower drug costs for these providers while preserving incentives for drug manufacturers to develop orphan drugs. However, several stakeholders, including the trade group PhRMA, questioned HHS' authority to promulgate the Orphan Drug Exclusion Rule.

In September 2013, PhRMA sued HHS challenging the validity of the Orphan Drug Exclusion Rule, claiming that the Rule contradicted the underlying statutory language for the 340B Program. As mentioned above, on May 23, the court in *PhRMA v. HHS* sided with PhRMA in issuing a Memorandum Opinion that vacated the Orphan Drug Exclusion Rule.[23] In holding that HHS had exceeded the scope of its statutory authority, the court noted that Congress only specifically authorized HHS to implement rules under PHSA Section 340B in three areas: (1) establishing an administrative dispute resolution process; (2) issuing regulations on the methodology used for calculating ceiling prices; and (3) imposing monetary civil sanc-

tions. In contrast, the court noted that the congressional intent to provide financial incentives to manufacturers for the development of orphan drugs was unambiguous.[24]

The court's criticism focused on what it viewed as HHS' improper exercise of its legislative rulemaking authority. Whether the Orphan Drug Exclusion Rule would survive as an interpretive rule was beyond the scope of this particular ruling, though the court did offer some skepticism in this regard. Note that prior to this ruling, comprehensive 340B proposed rules had been anticipated for a June 2014 release. Such rules, however, have yet to be released, and it is likely that this process has been put on hold as a result of *PhRMA v. HHS*.

As mentioned above, HRSA has responded to the court ruling by implementing the orphan drug exclusion policy as an interpretive rule rather than as a final regulation that has been subject to the notice-and-comment rulemaking process. PhRMA, in turn, argued before the same DC district court that this interpretive rule is materially the same as the final rule that the court vacated and thus should likewise be vacated. The court, however, declined to do so, holding that PhRMA's complaint originally only challenged the final rule promulgated by HRSA.[25] Accordingly, the court found PhRMA's challenge to the new interpretive rule to be beyond the scope of the present lawsuit.

On October 9, PhRMA responded by filing with the same DC court a legal challenge specifically directed against HRSA's July 2014 interpretive rule, this time focusing on the substantive nature of the rule rather than HHS' rule-making authority. In its complaint,[26] PhRMA argues that the statutory text of the 340B Orphan Drug Exclusion is self-executing and that the exclusion is based on the designation of the orphan drug, rather than on how it is used. PhRMA is asking the court to invalidate and permanently enjoin enforcement of the interpretive rule and block any future HRSA actions to adopt HHS' orphan drug exclusion policy.

Current Status

For the time being and pending the outcome of PhRMA's most recent challenge, at least, HRSA's current interpretive rule remains in effect. To help enable covered entities to identify drugs with orphan designations, HRSA will publish listings of such designations, which will identify the drugs by name and designated indication. Such lists are to be

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updated on the first day of the month prior to the end of each calendar quarter. HRSA also maintains a listing of covered entities that have indicated inability to track drug use by indication or otherwise do not wish to purchase orphan drugs through the 340B Program. Such listings will be updated quarterly. Here, according to HRSA, the purpose is to:

> allow drug manufacturers and wholesalers to identify affected hospitals that will purchase orphan drugs under the 340B Program and will maintain auditable records to demonstrate compliance with the orphan drug exclusion (Orphan Drug Participation = Yes), or that cannot or do not wish to maintain auditable records regarding compliance with the orphan drug exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used (Orphan Drug Participation = No).[27]

Clearly, the burden falls on those free-standing cancer hospitals, CAHS, RRCs, and SCHs (and their contract pharmacies) that wish to take advantage of 340B pricing to ensure that orphan drugs purchased under the 340B Program are used only for the non-orphan indications. According to HRSA:

> 340B hospitals subject to the orphan drug exclusion (critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers) are responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act.[28]

And clearly the burden falls on such hospitals to maintain auditable records demonstrating compliance. Such hospital providers purchasing drugs under the 340B Program should anticipate the possibility of future audits by HRSA to determine compliance under the 340B Program, as well as by pharmaceutical manufacturers seeking repayment for any inappropriate purchases of orphan drugs under the 340B Program.

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1 *Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities under the 340B Program, available at* www.hrsa.gov/opa/programrequirements/interpretiverule/interpretiverule.pdf (last visited on Sept. 28, 2014). *See also Availability of Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program*. 79 Fed. Reg. 42801 (July 23, 2014).
2 Codified at 42 U.S.C. § 256b.
3 78 Fed. Reg. 44016 (July 23, 2013).
4 No. 13-1501 (D.D.C. May 23, 2014).
5 42 U.S.C. § 256b(a).
6 U.S. Government Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* GAO-11-836 (Sept. 23, 2011).
7 *Id.*
8 21 U.S.C. § 355(b)(1).
9 21 U.S.C. § 360bb(a)(1).
10 Anna B. Laakman, *Collapsing the Distinction Between Experimentation and Treatment in the Regulation of New Drugs*, 62 Ala. L. Rev. 305, 315 (2011); *see also* Li-Hsien Rin-Laures & Diane Janofsky, *Recent Developments Concerning the Orphan Drug Act*, 4 Harv. J. Law. & Tec 269, 274 (1992).
11 21 U.S.C. § 360cc; 26 U.S.C. § 45C; 21 U.S.C. § 379h(a)(1)(F). *See also* Kara Cheever, *FDA Clarifies the Orphan Drug Act*, regblog.org, *available at* www.regblog.org/2013/08/13/fda-clarifies-the-orphan-drug-act/ (last visited Sept. 26, 2014).
12 Kevin Grogan, *Pfizer Creates Orphan Disease Research Division*, PharmaTimes, *available at* www.pharmatimes.com/Article/10-06-15/Pfizer_creates_orphan_disease_research_division.aspx (last visited Sept. 26, 2014); *see also* Benjamin Conway, *Big Pharma Reassesses Orphan Drug Sector*, GEN, *available at* www.genengnews.com/gen-articles/big-pharma-reassesses-orphan-drug-sector/3202/?page=1 (last visited Sept. 26, 2014).
13 *See Developing Products for Rare Diseases & Conditions*, fda.gov, *available at* www.fda.gov/forindustry/DevelopingProductsforrareDiseasesConditions/default.htm (last visited Sept. 26, 2014).
14 *Funding Orphan Drugs: Pitfalls of the Orphan Drug Act*, Harvard College Global Health Review, *available at* www.hcs.harvard.edu/hghr/print/student/orphan-drug-act/ (last visited Sept. 26, 2014); *see also* Andrew Pollack, *Orphan Drug Law Spurs Debate*, N.Y. Times, Apr. 30, 1998.
15 *See For Orphan Drug Act and NORD: A Day to Remember and Celebrate*, Rarediseases.org, *available at* www.rarediseases.org/news-events/news/30-years-oda (last visited Sept. 26, 2014).
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19 Pub. L. No. 111-309.
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23 *See id.*
24 *Id.*
25 No. 13-1501 (D.D.C. Aug. 27, 2014).
26 *PhRMA v. HHS*, Complaint, Civil Action No. 14-1685 (D.D.C. Oct. 9, 2014).
27 *Available at* http://opanet.hrsa.gov/opa/CEOrphanDrugSearcher.aspx (last visited on Sept. 28, 2014).
28 *Id.*

The Important Role of CRNAs in a Complex Staffing, Regulatory, and Reimbursement Environment

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Introduction

The demand for anesthesiologists (MDAs) and certified registered nurse anesthetists (CRNAs)[1] continues to rise across the United States. According to the Merritt Hawkins' *2013 Review for Physician and Advanced Practitioner Recruiting Incentives*, MDAs are still in high demand, despite not ranking among the top 20 recruited specialties reviewed during the study.[2] Merritt Hawkins attributes this largely in part to the increasing use of CRNAs, who now administer 65% of all anesthesia services nationwide.[3]

This article discusses the role of CRNAs in the context of the evolving state and regulatory framework surrounding CRNA supervision. To begin, CRNAs are much less costly to employ than MDAs. Moreover, empirical data suggest that there is no increase in risk to a patient when CRNAs perform anesthesia services independently of a physician. Given the ability of states to opt out of the Centers for Medicare & Medicaid Services (CMS) requirement that a physician supervise CRNAs, it is important to reconsider the role of CRNAs in the health care setting from a strategic, financial, and regulatory perspective. While the reimbursement model is somewhat complex, CRNAs can and have proven to be a valuable asset to the hospital staffing model.

Understanding How CRNAs Fit into the State and Federal Regulatory Framework

To highlight the principal role CRNAs play in a health care organization, it is worth noting that CRNAs administer more than 34 million anesthesia services to patients each year in the United States, in a variety of health care settings and rural areas.[4] CRNAs also outnumber their MDA counterparts. According to the Bureau of Labor Statistics, approximately 35,430 CRNAs and 30,200 MDAs were employed in the United States as of May 2013.[5]

Incorporating CRNAs into a staffing model with MDAs can be complex, particularly in light of the supervision opt-out caveat contained in the federal regulations. CMS published a Final Rule in the November 13, 2001 *Federal Register* stating that the operating physician or an MDA must supervise CRNAs.[6] *However, the Final Rule also allows states to "opt out" or be "exempted" from this same federal requirement.* To opt out, the state's governor must send a letter to CMS attesting to the following:

- The state's governor has consulted with the state's boards of medicine and nursing about issues related to access and the quality of anesthesia services in the state;
- It is in the best interests of the state's citizens to opt out of the current federal physician supervision requirement; and
- The opt-out is consistent with state law.[7]

As CMS further states in its Final Rule, once the governor submits the letter to the CMS Administrator, the letter will be accepted at "face value" without further scrutiny by CMS of the governor's underlying rationale for selecting the opt-out.[8]

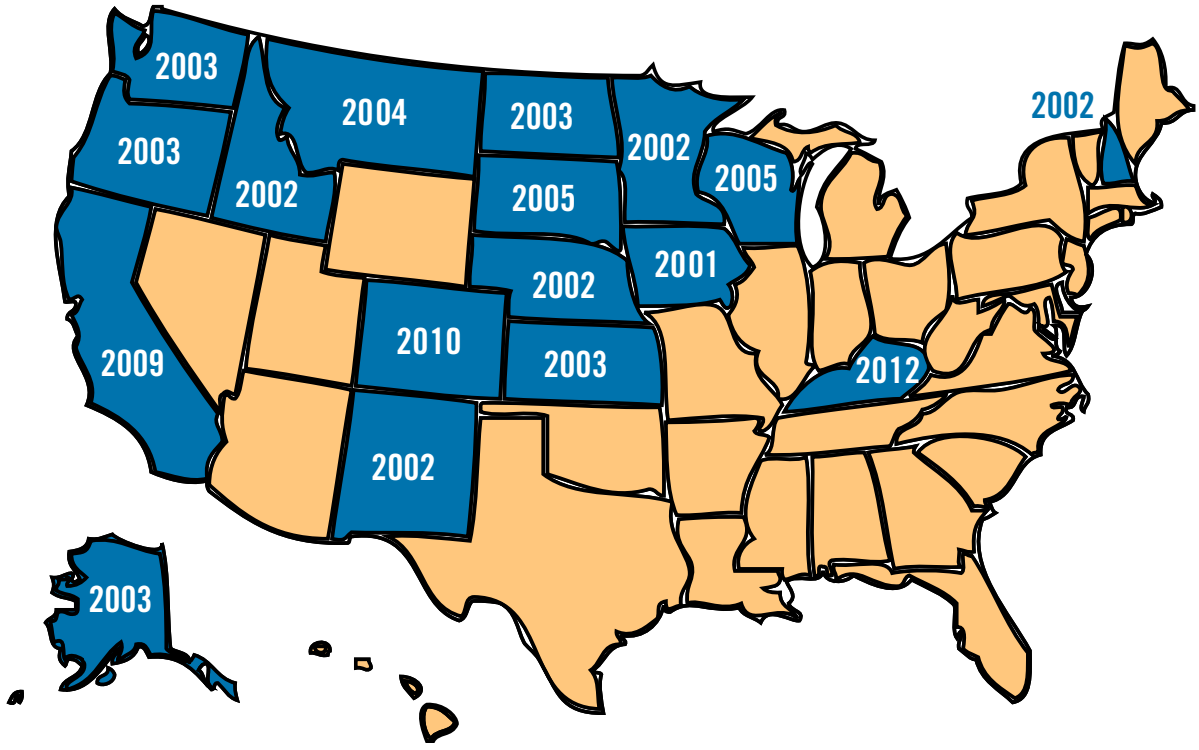
The lack of uniformity among states with respect to the decision to opt out may be concerning to some. However, the opt-out has spurred positive developments in the health care practice setting. At a minimum, from a quality and patient-safety perspective, a recent study found no evidence suggesting any increase in patient risk associated with anesthesia services provided by unsupervised CRNAs.[9] Moreover, many organizations have already developed a team care model for delivering anesthesia services. Integrating CRNA anesthesia services typically supports the organization's model, which takes into account the organization's finances, state regulations, hospital bylaws, and culture.[10] Approximately 80% of hospitals pay a subsidy to anesthesia groups to help ensure that continuous, high-quality coverage is provided.[11] As the demand for MDAs has grown, so has the frequency and dollar amount of the subsidies paid. Because CRNAs cost less to employ than MDAs and deliver quality care, arguably, integrating CRNAs into an organization's staff model provides a financial benefit to any health care organization.

"Supervised States" and "Unsupervised States"

States that have *not* opted out of the federal supervision requirements are commonly referred to as medically directed states or "supervised states." Proponents of supervision requirements believe that allowing CRNAs to practice without supervision increases the likelihood of harm to patients, as CRNA training differs from the training MDAs receive. However, as previously noted, no conclusive data exist linking independently performed CRNA services to poor health outcomes. Moreover, having the option to opt out of the supervision requirement does not mean that all organizations in that state are exercising this option.[12] Individual health care organizations are at liberty to impose stricter supervision requirements.

As of April 2012, however, 17 states had opted out of the federal supervision requirement. Below, Figure 1 depicts these "unsupervised states" along with the year each state opted out.[13] The majority of the states (14 of the 17) that chose to opt out did so within the first four years of the Final Rule's publication, and at this point, no additional states appear to be considering the opt-out. Alternatively, supporters of states without physician supervision, or non-medically directed states, argue that the lack of any supervision requirement increases patients' access to care, particularly in rural and medically underserved areas, while simultaneously reducing expenses.

Figure 1



Reimbursement

Medicare reimbursement for CRNA services is tied largely to a physician's degree of involvement. The following subsections identify the three major Medicare Part B reimbursement models for CRNA services: (A) non-medically directed CRNA services; (B) medically directed CRNA services; and (C) medically supervised CRNA services. Subsection (D) identifies an additional payment model available in certain circumstances under Medicare Part A.

A. Non-Medically Directed CRNA Services

For non-medically directed CRNA services, Medicare Part B[14] reimburses at 100% of a Medicare fee through the Medicare anesthesia fee schedule.[15] This payment is the same amount an MDA would receive performing the same service alone.

B. Medically Directed CRNA Services

For Medicare reimbursement, it is important to distinguish between medically *directed* CRNA services and medically *supervised* CRNA services. In general, medically directed services require more involvement from physicians. Medical direction occurs when physicians attest that they did the following: (1) performed a pre-anesthetic examination and evaluation; (2) prescribed the anesthesia plan; (3) personally participated in the most-demanding procedures in the anesthesia plan, including induction and emergence; (4) ensured that a qualified anesthetist performed any procedures in the anesthesia plan that the physician did not perform; (5) monitored the course of anesthesia administration at frequent intervals; (6) remained physically present and available for immediate diagnosis and treatment of emergencies; and (7) provided indicated post-anesthesia care.[16] These seven requirements reflect conditions imposed on physicians by the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982.

When the physician satisfies the seven TEFRA requirements for medical direction, Medicare Part B reimburses at 100% of a Medicare fee through the Medicare anesthesia fee schedule.[17] The CRNA is paid 50% of the fee and the medically directing physician is paid the remaining 50%.[18] As TEFRA prescribes, a physician may medically direct up to four CRNAs concurrently and seek reimbursement under the medically directed rate of 50% of the anesthesia fee schedule. However, once a physician supervises five or more CRNAs concurrently, the physician may only seek reimbursement at the medically supervised rate, as discussed in the next section.[19]

C. Medically Supervised CRNA Services

Medically *supervised* services occur when both the physician and CRNA are involved in the anesthesia services, but the physician's level of involvement cannot be classified as medically *directed* services. A physician would be considered to be supervising (and not directing) if the physician cannot attest to all seven TEFRA elements, if the physician furnishes supervision for more than four CRNA procedures concurrently, or if the physician performs services that are not permitted when medically directing.[20]

Overall, Medicare Part B reimburses medically supervised CRNA services at a lower rate than medically directed services. For medically supervised services, a CRNA is reimbursed at 50% of the Medicare fee through the anesthesia fee schedule—the same amount the CRNA would receive for services provided that are medically directed.[21] The physician involved in the medically supervised services is not reimbursed according to the anesthesia fee schedule. Instead, the physician is paid three base units per procedure (and potentially one time unit if an MDA is present at induction of service) regardless of the service and such service's Medicare fee.[22] Therefore, the medical supervision model enables Medicare to pay less than the full 100% of the Medicare fee by reimbursing supervising physicians at a lower rate than their CRNA counterparts. CRNAs are reimbursed at 50% regardless of whether they are medically directed or medically supervised.

The three reimbursement models above highlight the benefit of incorporating CRNAs into a health care organization's staffing model in terms of maximizing Medicare reimbursements. Table 1 below, which provides a summary of Medicare Part B's reimbursement for CRNA services, highlights this point more clearly.

Table 1

	Medicare Part B Reimbursement Compared to Anesthesia Fee Schedule		
Type of CRNA Service	CRNA	Physician	Total Reimbursement
Non-Medically Directed	100%	n/a	100%
Medically Directed	50%	50%*	100%
Medically Supervised	50%	Three base units per procedure and one time unit if present at induction of service**	> 50%

* Physician must attest to the seven TEFRA requirements and only receives 50% reimbursement rate for supervising no more than four CRNAs concurrently.

** Physician's reimbursement for medically supervised CRNA services is not based on Medicare's anesthesia fee schedule.

Conclusion

CRNAs, who now administer more anesthesia services in the United States than MDAs, are in high demand. Until 2001, a federal requirement prevented CRNAs from practicing independently. However, the Final Rule CMS published on November 13, 2001 allows states to choose whether to "opt out" or be "exempted" from this requirement.[23] As previously described, 17 states have opted out of the requirement thus far, doing so arguably because they believe that opting out of the supervision requirement increases patient's access to care and reduces costs.[24] From a provider perspective, employing CRNAs to perform services independently greatly reduces anesthesia expenses for the provider. For non-medically directed services in particular, CRNAs are reimbursed at the same rate as their MDA counterparts, while costing the provider less to employ than the MDA. In addition to expense savings for providers, there appears to be no conclusive evidence linking independently performed CRNA services to increased patient risk. In sum, CRNAs are capable of performing high-quality services at a lower expense to providers, while the cost to Medicare remains the same or slightly less than when MDAs provide the services.

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1 A CRNA is a registered nurse who satisfies state licensure requirements for non-physician anesthetists, has graduated from a nurse anesthesia program accredited by the Council on Certification of Nurse Anesthetists (COA) or its predecessor, and has passed the certification exam administered by COA. 42 C.F.R. § 410.69(b).

2 Review of Physician and Advanced Practitioner Recruiting Incentives: An Overview of Salaries, Bonuses, and Other Incentives Customarily Used to Recruit, Physicians, Physician Assistants and Nurse Practitioners 13 (2013), *available at* https://programs.gha.org/Portals/5/documents/GHHS/IncentiveSurvey2013.pdf.

3 *Id*.

4 Am. Ass'n of Nurse Anesthetists, *Certified Registered Nurse Anesthetists at a Glance*, *available at* www.aana.com/ceandeducation/becomeacrna/Pages/Nurse-Anesthetists-at-a-Glance.aspx (last visited Sept. 11, 2014).

5 Bureau of Labor Statistics, *Occupational Employment Statistics, Occupational Employment and Wages, May 2013, 29-1151 Nurse Anesthetists*, *available at* www.bls.gov/oes/current/oes291151.htm (last visited Sept. 11, 2014).

6 Hospital Conditions of Participation: Anesthesia Services, 66 Fed. Reg. 56762, 56765 (Nov. 13, 2001) (codified at 42 C.F.R. § 482.52).

7 *Id*. at 56763–69 (codified at 42 C.F.R. § 482.52(c)).

8 *Id*. at 56766.

9 Brian Dulisse & Jerry Cromwell, *No Harm Found When Nurse Anesthetists Work Without Supervision By Physicians*, 29 Health Aff. 1469, 1469–75 (2010). This study examined 500,000 individual cases involving the provision of anesthesia services by unsupervised CRNAs.

10 *See generally* Somnia Anesthesia, Anesthesia Staffing Models That Drive Value and Improve Quality: How the Right Model Delivers Efficiencies, Revenue and Clinical Quality Excellence 1-11 (2010).

11 Howard Greenfield, M.D., *Anesthesia 101: Anesthesia Subsidy Drivers*, Enhance Perioperative & Anesthesia Consulting (2013), *available at* http://enhancehc.com/anesthesia-101-anesthesia-subsidy-drivers/ (last visited Sept. 11, 2014).

12 As CMS stated in its Final Rule, while states may individually exercise the option to opt out, this does not preclude hospitals from enforcing stricter supervision standards. Hospital Conditions of Participation: Anesthesia Services, 66 Fed. Reg. 56762, 56,765 (Nov. 13, 2001).

13 Am. Ass'n of Nurse Anesthetists, *Fact Sheet Concerning State Opt-Outs and November 13, 2001 CMS Rule*, available at www.aana.com/advocacy/stategovernmentaffairs/Pages/Fact-Sheet-Concerning-State-Opt-Outs.aspx (last visited Sept. 11, 2014) (hereinafter, Am. Ass'n of Nurse Anesthetists, *Fact Sheet*).

14 Medicare Part B consists of two types of services: medically necessary services and preventive services. Medically necessary services are considered to be services or supplies that are both needed to diagnose or treat a medical condition and meet accepted standards of medical practice. Preventive services include health care that aims to prevent illness or encourage early detection, when treatment is more likely to be effective. For example, Medicare Part B covers clinical research, ambulance services, mental health services, durable medical equipment, and limited outpatient prescription drugs.

15 Am. Ass'n of Nurse Anesthetists, *Reimbursement of CRNA Services* (May 2010), *available at* www.aana.com/aboutus/documents/reimbursement_crnaservices.pdf (hereinafter, Am. Ass'n of Nurse Anesthetists, *Reimbursement*). *See generally* Ctrs. for Medicare & Medicaid Servs., Pub. 100-04, Medicare Claims Processing Manual, Trans. No. 140.4.3, *Payment for Medical or Surgical Services Furnished by CRNAs*, *available at* www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf. (hereinafter, CMS MD/CRNA Transmittals).

16 42 C.F.R. § 415.110(a)(1)(i)-(vii). *See also* CMS MD/CRNA Transmittals, Trans No. 50C, *Payment at the Medically Directed Rate*, *supra* note 15.

17 CMS MD/CRNA Transmittals, Trans. No. 140.4.2, *Qualified Nonphysician Anesthetist and an Anesthesiologist in a Single Anesthesia Procedure*, *supra* note 15.

18 CMS has clarified that, where a single anesthesia procedure involves both a physician and a medically directed CRNA, payment for the service of each is 50% of that which would have been allowed had the anesthesiologist performed the services alone. *Id*.

19 CMS MD/CRNA Transmittals, Trans. No. 50C, *Payment at the Medically Directed Rate*, *supra* note 16.

20 MDA/CRNA Transmittals, *supra* note 15, 123.

21 *See generally* CMS MD/CRNA Transmittals, Trans. No. 50(C)-(K), *supra* note 16.

22 Am. Ass'n of Nurse Anesthetists, *Reimbursement*, *supra* note 15. *See generally* CMS MD/CRNA Transmittals, Trans. No. 140, *supra* note 15.

23 CMS MD/CRNA Transmittals, Trans. No. 50D, *Payment at Medically Supervised Rate*, *supra* note 15.

24 Am. Ass'n of Nurse Anesthetists, *Fact Sheet*, *supra* note 13.

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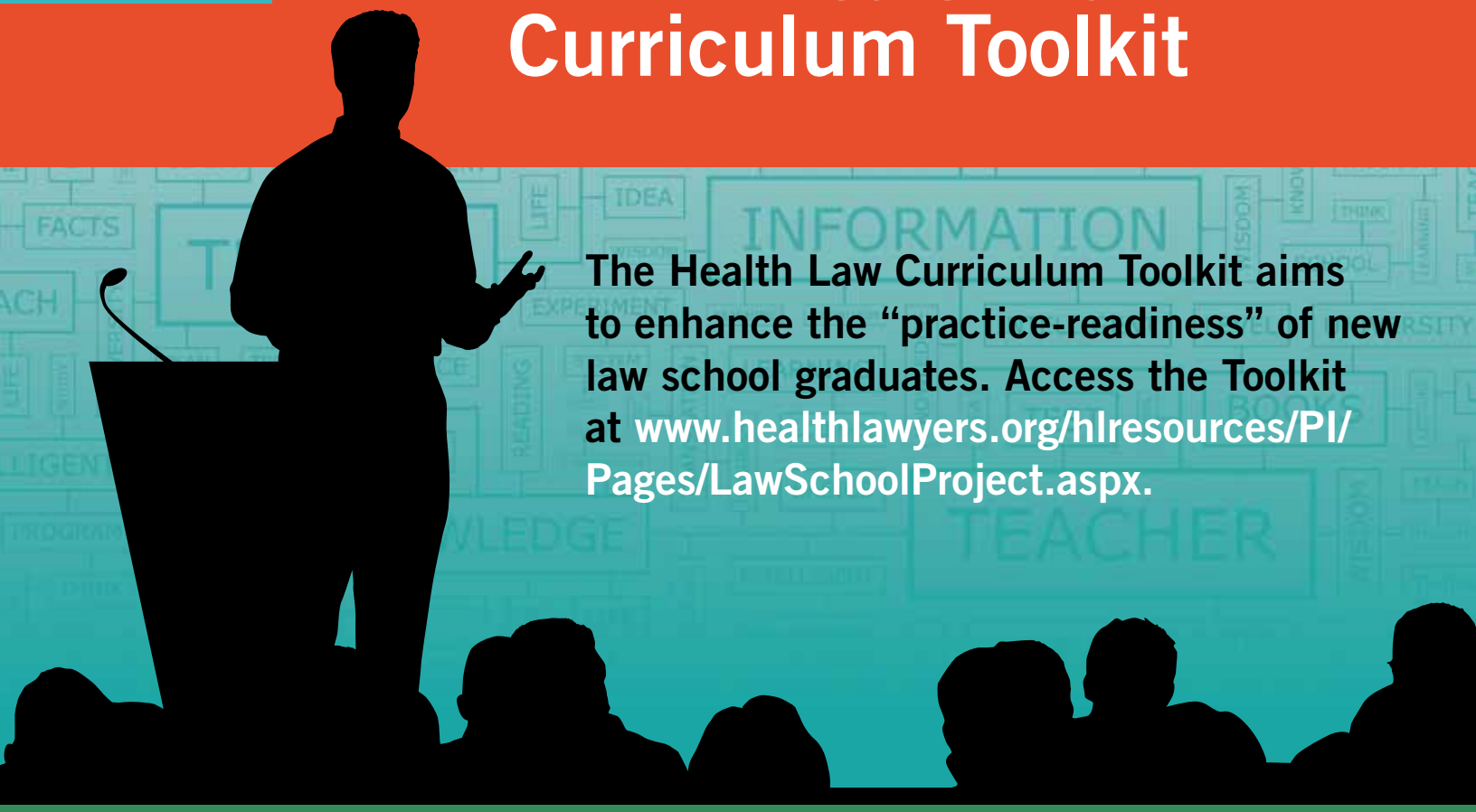

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