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From the Editor in Chief

Colleagues:

I am constantly amazed by the breadth of legal issues health lawyers face every day. As one of the only types of legal practice focusing on an industry rather than a type of law, our practice is richly diverse. This issue showcases that diversity with articles ranging from federal regulations to state common law malpractice. Our authors in this issue are also very diverse, ranging from government attorneys to attorneys practicing in firms; from law professors to law students.

The role of the Office of Inspector General is again highlighted in [Examining Covert Kickbacks: The OIG Carve-out Rule](#) by Russell Caldwell Ramzel. Patient issues are addressed both in [The National Vaccine Injury Compensation Program and Maternal Immunizations](#) by Emily Marcus Levine and Andrea Sudell Davey and in [Emerging Duties Under Unsettled Disability Law: Web Access and Service Animals in Health Care](#) by Anne Ruff and Adriana Fortune. I am going to venture a guess that the latter article may be the first time that miniature horses have been mentioned in this Journal. Our readers who have an interest in risk management will benefit from Daniel J. D'Alesio Jr.'s Comment: [A Litigation Attorney's Formula for Changing the Factors that Influence a Patient's Decision to Sue](#). The [Reasonable Limits on Antitrust Liability for Reverse Payment Patent Settlements Brief Insight](#) by Peter A. Hecker addresses a very interesting twist in the law addressing bringing generic drugs to market and the Brief Insight [Cybersecurity Report Identifies Unique Challenges to Tackling Cybersecurity in Health Care](#) written by Deborah R. Farringer addresses the ever present security threat to electronic information.

I find the immense diversity in our practices endlessly interesting and we hope you find this issue insightful and useful in your practice.



A handwritten signature in black ink that reads "Susan O. Scheutzow".

Susan O. Scheutzow

Editor in Chief, Journal of Health & Life Sciences Law

Examining Covert Kickbacks: The OIG Carve-out Rule

Russell Caldwell Ramzel

What is the issue? The Office of Inspector General of the Department of Health and Human Services (OIG) has consistently interpreted the Anti-Kickback Statute to find that arrangements that pay for commercial business while attempting to carve out federal health care program business may nonetheless violate the statute if any potential nexus exists between payments for commercial business and generation of federal health care program business.

What is at stake? Recent changes have increased civil penalties under the False Claims Act, potentially making lawsuits brought by quit tam relators based on anti-kickback violations more lucrative. Health care providers must consider whether the OIG's interpretation of the Anti-Kickback Statute increases the risk of such a lawsuit arising from carve-out arrangements.

What do you need to know? The scope of OIG advisory opinions is limited to the specific facts examined and may be relied on only by the requesting party. Further, the OIG has never determined that a carve-out arrangement violates the anti-kickback statute. Nevertheless, there is a risk that courts will find the OIG's opinions persuasive regarding whether a carve-out arrangement *potentially* violates the statute. Counsel should consider factors the OIG has found suspect or protective in carve-out arrangements.

Russell Caldwell Ramzel, *Examining Covert Kickbacks: The OIG Carve-out Rule*, J. HEALTH & LIFE SCI. L., Oct. 2017, at 1, © American Health Lawyers Association, www.healthlawyers.org/journal. All rights reserved.

Ramzel: OIG Carve-out Rule

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Introduction

Imagine this not uncommon scenario: A representative of a laboratory attempts to convince Dr. Smith to order more of a certain diagnostic test now that Medicare, Medicaid, and commercial payers have started paying for the test. The laboratory will happily pay a fee to Dr. Smith each time she orders this test for her patients. Dr. Smith knows it is illegal for the laboratory to pay her commissions to reward her for ordering tests for her Medicare and Medicaid patients, so she is hesitant to accept the offer. The representative is empathetic to Dr. Smith's concerns but remains undeterred and offers instead to pay only for the tests she orders for patients who have commercial insurance. Under this arrangement, Dr. Smith would still be able to order the test for her Medicare/Medicaid patients but would not receive a fee or commission for those tests.

Under the Anti-Kickback Statute (AKS), it is a felony for a person to knowingly and willfully offer or pay (or solicit or receive) remuneration “directly or indirectly, overtly or covertly, in cash or in kind” to induce (or reward) referrals or the generation of federal health care program business.¹ Like Dr. Smith, most providers understand that the AKS prohibits direct payment or receipt of remuneration² for referrals or generation of federal health care program business. It is not uncommon, however, for providers to believe that the AKS permits arrangements that exchange remuneration for referrals or generation of *commercial* business, to the exclusion of federal health care program business.

While the AKS on its face does not prohibit the exchange of remuneration for referrals or generation of commercial business, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) has consistently interpreted the AKS in its advisory opinions to find that “carving out” federal health care program business from an arrangement that exchanges

1 42 U.S.C. § 1320a-7b(b)(1).

2 “Remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. OIG Advisory Op. No. 12-05, at 3 (Apr. 24, 2012), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/advopn12-05.pdf>.

remuneration for commercial referrals does not immunize the arrangement from prosecution under the AKS. On the contrary, under the OIG's "Carve-out Rule," the exchange of remuneration for commercial business can give rise to the inference that remuneration exchanged for commercial business is actually disguised remuneration for the referral or generation of federal health care program business.

This article will discuss the OIG's decades-long development of [the so-called Carve-out Rule](#) through its advisory opinions, as well as the [limitations of advisory opinions](#), especially whether a court or jury may rely on them to determine potential AKS liability; the [current environment of increased enforcement and larger penalties](#) as a result of amendments made to the AKS; and the concept of "swapping" and [the OIG's analysis of swapping arrangements in relation to the Carve-out Rule](#). This article will also review several [suspect carve-out arrangements](#) that were examined by the OIG, as well as [commercial business only arrangements](#) that the OIG excepted from the Carve-out Rule. Finally, the article will provide suggestions on [how a health care provider can respond to an existing or proposed carve-out arrangement](#) to minimize or eliminate her risk of violating the AKS.

Increased Enforcement and Larger Penalties Under the False Claims Act

Recent increased enforcement of the AKS warrants the renewed attention of health care lawyers and health care providers to the Carve-out Rule. On December 14, 2016, the United States Department of Justice (DOJ) reported it had recovered "more than \$4.7 billion in settlements and judgments from civil cases involving fraud and false claims against the government in fiscal year 2016 ending Sept. 30 . . ."³ This represents the third highest annual amount recovered in the history of enforcement of the False Claims Act⁴ (FCA).⁵ Of

3 Press Release, DOJ, Justice Department Recovers Over \$4.7 Billion from False Claims Act Cases in Fiscal Year 2016: Third Highest Annual Recovery in FCA History (Dec. 14, 2016) [hereinafter *Press Release, DOJ*], available at www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016.

4 31 U.S.C. §§ 3729–33.

5 *Press Release, DOJ*.

that total, health care fraud and abuse cases accounted for over \$2.5 billion.⁶ A total of 570 new referrals, investigations, and qui tam actions alleging health care fraud and abuse were brought in 2016, of which 69 were brought directly by the DOJ and 501 were brought by qui tam relators.⁷ In addition, the DOJ charged 802 and convicted 658 persons of health care fraud-related crimes in 2016.⁸ Many of these cases involved alleged violations of the AKS, which is punishable by criminal fines and up to five years in prison.

Civil enforcement of the AKS occurs mainly through the FCA. The FCA provides that any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval”⁹ to the federal government or a “contractor, grantee, or other recipient” of the federal government for federal funds,¹⁰ or conspires to do so,¹¹ is liable to the federal government for a civil penalty of “not less than \$5,000 and not more than \$10,000” as adjusted for inflation, “plus 3 times the amount of damages which the Government sustains because of the act of that person.”¹² An FCA case may be brought either by the federal government directly¹³ or by a private individual as a qui tam relator on behalf of the federal government.¹⁴ Relators who prevail may receive up to 30% of the amount recovered in the case, depending on whether the federal government decides to intervene in the action and on the source of the allegations in the action.¹⁵ These potential rewards for bringing an FCA action account, in part, for the fact that qui tam relators filed nearly 88% of the FCA cases in 2016.

6 *Id.*

7 CIVIL DIV., DOJ, FRAUD STATISTICS – OVERVIEW: OCTOBER 1, 1987 – SEPTEMBER 30, 2016 [hereinafter 2016 FRAUD STATISTICS], available at www.justice.gov/opa/press-release/file/918361/download.

8 HHS & DOJ, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM: ANNUAL REPORT FOR FISCAL YEAR 2016, at 1 [hereinafter 2016 REPORT] (Jan. 2017), available at <https://oig.hhs.gov/publications/docs/hcfac/FY2016-hcfac.pdf>.

9 31 U.S.C. § 3729(a)(1)(A).

10 *Id.* § 3729(b)(2)(A)(ii).

11 *Id.* § 3729(a)(1)(C).

12 *Id.* § 3729(a)(1)(G).

13 *Id.* § 3730(a).

14 *Id.* § 3730(b).

15 *Id.* § 3730(d).

False Claims Act Lawsuits Based on Anti-Kickback Statute Violations Made Easier

In 2010, the Patient Protection and Affordable Care Act (ACA)¹⁶ made it easier to bring an FCA action based on an AKS violation. First, the ACA reduced the required showing of bad intent. The ACA amended the AKS to provide that a person “need not have actual knowledge of [the AKS] or specific intent to violate” the AKS in order to violate the AKS.¹⁷ Previously, the U.S. Court of Appeals for the Ninth Circuit held that proof of specific intent to violate the AKS was necessary to prove a violation of the AKS.¹⁸ Now, an AKS violation occurs whenever the defendant willfully and knowingly offers, pays, solicits, or receives remuneration intended to induce or reward referrals or the generation of federal health care program business, regardless of whether the defendant is aware of the AKS or that he or she violated the AKS.

Second, the ACA made claims for items and services resulting from a violation of the AKS automatic false claims under the FCA.¹⁹ Previously, the theory of express false certification required the plaintiff to prove that the defendant certified compliance with the AKS *at the time of* claim submission and that compliance with the AKS was material to the federal government’s decision to pay the claim.²⁰ The theory of implied false certification required the plaintiff to prove that the defendant certified compliance with the AKS *at some time prior to* claim submission, such as through provider agreements, and that compliance with these prior false certifications was material to the government’s decision to pay the claim.²¹ The AKS amendments in the ACA eliminated the need to prove false certification in an FCA case based on claims made as a direct result of an arrangement violating the AKS.

16 Pub. L. No. 111-148, 124 Stat. 119 [hereinafter *ACA*].

17 *Id.* at 759 § 6402(f)(2) (codified at 42 U.S.C. § 1320a-7b(h)).

18 *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).

19 *ACA* § 1128J(f)(2).

20 *See, e.g., United States ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008).

21 *See, e.g., United States ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010).

While the intensity of health care fraud enforcement under the Trump Administration remains to be seen, AKS enforcement in 2017 may exceed 2016's \$2.5 billion in health care fraud settlements and may even break the 2012 record of \$3.1 billion.²² Effective February 3, 2017, the DOJ adopted a new rule²³ increasing the minimum civil penalty per violation of the FCA to \$10,957 and the maximum to \$21,916, more than doubling the previous statutory minimum and maximum.²⁴ This change will likely encourage even more cases by qui tam relators who, as noted, bring 88% of health care fraud civil actions. In its Semiannual Report to Congress, the OIG reported 468 criminal actions and 461 civil actions against individuals or entities involved in health care fraud in the first half of Fiscal Year 2017.²⁵ Thus, the federal government is on pace to bring 936 criminal actions in Fiscal Year 2017, which would represent a 16% increase over Fiscal Year 2016.

The Carve-out Rule

Under the Carve-out Rule, remuneration exchanged for commercial business may be considered an indirect covert payment to induce or reward the referrals or generation of federal health care program business prohibited under the AKS.²⁶ The Carve-out Rule is not set forth in any statute or regulation. Rather, the Rule developed through interpretations of the AKS in OIG advisory opinions.

Those advisory opinions and other OIG guidance summarize the Carve-out Rule as follows:

The “carve-out” of Federal business is not dispositive . . . on the question of whether the proposed program potentially violates the [AKS]. The OIG has a long-standing

22 2016 FRAUD STATISTICS.

23 As required by the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. No. 101-410, 104 Stat. 890.

24 Civil Monetary Penalties Inflation Adjustment for 2017, 28 C.F.R. § 85.5.

25 HHS OIG, SEMIANNUAL REPORT TO CONGRESS: OCTOBER 1, 2016 TO MARCH 31, 2017 ix, available at <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-spring-2017.pdf>.

26 42 U.S.C. § 1320a-7b(b).

concern about arrangements pursuant to which parties “carve-out” referrals of Federal health care beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. Such arrangements may violate the [AKS] by disguising remuneration for Federal referrals through the payment of amounts purportedly related to non-Federal business.²⁷

The Carve-out Rule, as developed in the advisory opinions, logically follows from the following premises:

1. The AKS prohibits all direct *and indirect*, and overt *and covert*, remuneration exchanged with the intent to induce or reward the generation of federal health care program business.
2. As such, the “source of the funding for a potential kickback payment is not determinative of the intent of the payment.”²⁸ The fact that remuneration exchanged between parties is calculated based on the generation of commercial business is not determinative of whether the exchanged remuneration is in fact intended to reward or induce the generation of federal health care program business.
3. Rather, arrangements that exchange remuneration for the generation of commercial business only “[implicate and]²⁹ may violate the [AKS] by disguising remuneration for Federal referrals through offers or payments of inflated amounts for non-Federal business or simply by offering or paying remuneration for non-Federal referrals to ‘pull through’ the Federal business.”³⁰ The OIG examines such arrangements to determine whether the remuneration exchanged

27 OIG Advisory Op. No. 06-02, at 7 (Mar. 21, 2006), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/ao0602.pdf> [hereinafter *OIG Advisory Op. No. 06-02*].

28 *Id.* at 8.

29 OIG Advisory Op. No. 11-08, at 5 (June 14, 2011), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-08.pdf>.

30 OIG Advisory Op. No. 00-08, at 5 (Dec. 5, 2000), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_8.pdf; see also OIG - HHS, Special Fraud Alert: Laboratory Payments to Referring Physicians, 79 Fed. Reg. 40115, 40117 (July 11, 2014).

for commercial business may actually be intended as an indirect and covert payment for federal health care program business.

In its advisory opinions, the OIG has relied on the above premises to determine that it *might* impose sanctions against an arrangement *if any potential nexus exists* between remuneration exchanged for commercial business and the generation of federal health care program business because such payment may be indirect covert payments for federal health care program business.

Limitations of Advisory Opinions

The OIG is limited to determining in an advisory opinion whether (i) the remuneration paid under a proposed arrangement constitutes prohibited remuneration under the AKS,³¹ (ii) the proposed arrangement meets a regulatory or statutory safe harbor to the AKS,³² or (iii) the proposed arrangement constitutes grounds for sanctions under the AKS.³³ The OIG generally may not later impose sanctions against an arrangement if it determines it will not impose sanctions against the proposed arrangement in an advisory opinion.³⁴

Importantly, in its advisory opinions, the OIG never states that arrangements running afoul of the Carve-out Rule necessarily violate the AKS, even though the OIG has repeatedly found that the AKS is implicated by carve-out arrangements and that it will not afford protection against sanctions for such arrangements. As a criminal statute, the AKS requires the parties to have the requisite *mens rea* of “knowingly and willfully” paying or receiving remuneration with the intent to induce or reward the generation of federal health care program business. Even in advisory opinions where the OIG concludes it could impose sanctions against a proposed arrangement because of the Carve-out Rule, the OIG states that any “definitive conclusion regarding the

31 42 C.F.R. § 1008.5(a)(1).

32 *Id.* § 1008.5(a)(2), (3).

33 *Id.* § 1008.5(a)(5).

34 *Id.* § 1008.59(b). An advisory opinion binds the Department unless the OIG later rescinds, terminates, or modifies the opinion, which requires the OIG to provide preliminary notice to the requestor and an opportunity to respond. *Id.* § 1008.45.

existence of an [AKS] violation *requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.*³⁵

Advisory opinions by their nature only address the specific facts presented for review in each opinion. Only “the requestor(s) may rely on an advisory opinion,”³⁶ and “an advisory opinion . . . [does] not bind or obligate any agency” other than HHS.³⁷ In addition, an advisory opinion may not be introduced into evidence by a person who is not a party to the advisory opinion as proof that the person did not violate the AKS.³⁸

Even though the regulations state that no person other than a requestor may rely on an advisory opinion, there is a risk a court or a jury might find the OIG’s advisory opinions persuasive or, in an extremely rare case, even subject to deference. For example, the court in *Zimmer v. Nu Tech Medical* found that while the advisory opinion obtained by a party to that case was not binding, the opinion “as an agency interpretation of the [AKS], is entitled to deference as an ‘informed judgment to which courts and litigants may properly resort for guidance.’”³⁹ Consequently, if a court finds that the OIG has determined that an arrangement has the potential to violate the AKS, the court may give deference

35 OIG Advisory Op. No. 12-06, at 2 (May 25, 2012), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-06.pdf> (emphasis added). In the preamble to the final rule establishing the advisory opinion process, the OIG specifically stated that intent would not be determined through the advisory opinion process: “These regulations are designed to avoid the potential pitfalls of advisory opinions on intent-based statutes, such as the anti-kickback statute. First, it is not practical for the agency to make an independent determination of the subjective intent of the parties based only upon written materials submitted by the requestor. . . . It is most unlikely that written materials prepared by the requestor could encompass all the information necessary to enable the OIG to make a reliable determination of the subjective intent of the parties.” 62 Fed. Reg. 7350, 7351-52 (Feb. 19, 1997).

36 42 C.F.R. § 1008.53.

37 *Id.* § 1008.59(b).

38 *Id.* § 1008.55(b).

39 *Zimmer, Inc. v. Nu Tech Med., Inc.*, 54 F. Supp.2d 850, 856 (N.D. Ind. 1999) (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 139–40 (1944)) [hereinafter *Zimmer*]; *but see United States ex rel. Perales v. St. Margaret’s Hosp.*, 243 F.Supp.2d 843, 849 (C.D. Ill. 2003) (finding OIG opinion letter not entitled to *Chevron* deference, although “may be considered as persuasive precedent”); *United States ex rel. McDonough v. Symphony Diagnostic Servs.*, 36 F.Supp.3d 773, 780 (S.D. Ohio 2014) [hereinafter *Mobilex*] (refusing to find OIG’s definition of swapping in advisory opinion binding on court).

to an advisory opinion⁴⁰ with regard to the determination of that potential, but intent must still be proven to establish a violation of the AKS.⁴¹ However, *Zimmer* gave deference to the advisory opinion at issue in this case *because* a party to the case requested that the advisory opinion be introduced into evidence “so its introduction of and reliance on that opinion is not improper.”⁴² Deference should arguably not be afforded to an advisory opinion in cases where the party seeking to introduce an advisory opinion in a lawsuit is not the party who requested the opinion.

Swapping and Its Relationship to Carve-outs

In the late-1990s, the OIG introduced the concept of “swapping,” where a supplier bills a provider heavily discounted rates for items or services provided by the supplier for which the *provider* bills third-party payers, but the supplier does not offer the discounts if the *supplier* bills third-party payers. In Advisory Opinion 99-13, the OIG examined an arrangement where a laboratory billed federal health care programs and their beneficiaries directly for laboratory services provided to federal health care program patients of hospitals and physician groups.⁴³ For the groups’ and hospitals’ commercial patients, however, the laboratory billed the groups/hospitals for commercial laboratory services, and the group/hospital would then bill commercial payers and patients for those services. Under this arrangement, the laboratory requested approval from the OIG to bill heavily discounted rates to the groups and

40 See, e.g., *Zimmer*, at 856 (While Advisory Opinion 98-1 is not binding authority, “considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer”) (*quoting* *Hanson v. Espy*, 8 F.3d 469, 473 (7th Cir. 1993) (*quoting* *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 844 (1984))).

41 While giving deference to the OIG’s determination that the arrangement could potentially violate the AKS, the court in *Zimmer* acknowledged that the OIG did not find that the arrangement in question necessarily violated the AKS because a violation of the AKS requires the requisite intent, a determination of which is beyond the scope of the advisory opinion process. *Zimmer*, at 859.

42 *Zimmer*, at 856.

43 OIG Advisory Op. No. 99-13 (Nov. 30, 1999), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_13.htm [hereinafter *OIG Advisory Op. No. 99-13*].

hospitals for commercial patient laboratory services. These discounts would not be available for federal health care program patients.

The OIG concluded that, under the arrangement, a nexus “may exist between the discount to the physicians for non-Federal health care program business and referrals of Federal health care program business,” and that, as such, the arrangement “gives rise to an inference that the laboratory and physician may be ‘swapping’ discounts on [commercial business] in exchange for profitable non-discounted” federal program business.⁴⁴

While a swapping analysis has been applied where a discount is provided for services billed to commercial payers to the exclusion of services billed to federal health care programs, it is typically applied where suppliers propose providing discounts to a nursing facility for Medicare Part A business to secure referrals of the nursing facility’s Medicare Part B or Part D business.⁴⁵ Nursing facilities must pay for all required medical services for a patient in a covered Part A stay within the first 100 days of discharge from a hospital in exchange for Medicare’s per diem rate paid to the nursing facility.⁴⁶ Except for certain excluded services,⁴⁷ a person or entity that provides medical services to a patient in a Part A stay must look solely to the nursing facility for payment and may not bill Medicare or the patient for those services.⁴⁸ In the typical scenario, a supplier of services offers deep discounts to the nursing facility for services for which the nursing facility must pay under Part A consolidated

44 *Id.* (emphasis added).

45 While the OIG has most often analyzed “swapping” arrangements in the context of nursing homes, the OIG still applies the “swapping” analysis where deep discounts in commercial business could affect referrals of non-discounted federal program business in non-nursing home contexts. *See, e.g.*, OIG Advisory Op. No. 13-02 (June 4, 2013) (applying a swapping analysis to a proposed orthotics sales arrangement), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2013/AdvOpn13-02.pdf>; OIG Advisory Op. No. 12-09 (July 23, 2012) (applying a swapping analysis to proposed discounts to veterans’ homes), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/advopn12-09.pdf>.

46 42 U.S.C. § 1395yy(e)(2)(a)(i).

47 *See* 42 C.F.R. § 411.15(p).

48 42 U.S.C. § 1395y(a)(18).

billing, but the supplier bills Medicare its normal higher rates for services provided to those nursing facility residents not in a covered Part A stay.⁴⁹

While discount swapping is not precisely analogous to the situation in which a supplier directly pays remuneration to a provider for commercial business and carves out federal health care program business from the arrangement, the similarities warrant consideration of the OIG's analysis of swapping arrangements when analyzing the Carve-out Rule. The only significant difference between the OIG's swapping analysis and its carve-out analysis are that in a swapping arrangement, the remuneration exchanged between the parties is the money saved by the provider based on the discount offered by the supplier, whereas in a carve-out situation the provider is paid directly for commercial business.

Consequently, the following factors that the OIG considers suspect in swapping arrangements may be viewed as equally suspect when analyzing carve-out arrangements:

1. an exclusive supplier agreement coupled with a discount on services billed by the provider, where the discount is not offered on services billed by the supplier, or, in the case of a carve-out arrangement, coupled with payment for commercial business where payment is not made for federal health care program business; and
2. a discount on services billed by the provider, or, in the case of a carve-out arrangement, payment for commercial business “made in conjunction with explicit or implicit agreements to refer other facility business to the supplier, including Part B or other [federal] health care program business.”⁵⁰

49 See e.g. OIG Advisory Op. No. 99-2 (Feb. 26, 1999), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_2.htm [hereinafter *OIG Advisory Op. No. 99-2*]; OIG Advisory Op. No. 10-26 (Dec. 20, 2010), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2010/AdvOpn10-26.pdf>; OIG Advisory Op. No. 11-11 (July 28, 2011), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-11.pdf>; see also HHS, Health Res. & Servs. Admin., Notice of Meeting of the Advisory Committee on Organ Transplantation, 73 Fed. Reg. 56832, 56844 (Sept. 30, 2008).

50 *OIG Advisory Op. No. 99-2*.

The ultimate question in a swapping analysis is whether the discount “is tied or linked directly or indirectly to referrals of other Federal health care program business.”⁵¹ Similarly, the ultimate issue in a carve-out analysis is whether any nexus exists between the payments made for commercial business and the federal health care program business generated by the parties.⁵² Like in suspect swapping arrangements, exclusive supply arrangements and implicit or explicit agreements that the provider will send federal health care program business to the supplier in exchange for payments for commercial business can give rise to an inference that such a nexus exists in carve-out arrangements.

The recent decision in *United States ex rel. McDonough v. Symphony Diagnostic Services (Mobilex)* refused to give deference to the OIG’s swapping analysis. The qui tam relator argued that an x-ray provider, Mobilex, violated the AKS by charging nursing homes lower prices for Part A business than it charged for patients not in a covered Part A stay.⁵³ The relator urged the court to find that Mobilex engaged in swapping as defined by the OIG because Mobilex charged less than its total cost, including Mobilex’s overhead, for Part A services.⁵⁴ While the court acknowledged that pricing Part A services too low might implicate the AKS, the court held that even though Mobilex priced its Part A services below its fully loaded costs, there was no evidence that Mobilex priced its Part A services at the lower rates to induce the purchase of other federal health care program business.⁵⁵ Instead, Mobilex presented evidence that it attempted to price its Part A contracts above costs.⁵⁶ Likewise, although a court might agree that an inference may be made in a carve-out case that remuneration exchanged for commercial business is concealed remuneration for federal health care program business, a defendant might be able to overcome this inference by introducing evidence of a different intent for exchange of remuneration for commercial business other than the generation of federal health care program business.

51 *OIG Advisory Op. No. 99-13.*

52 *OIG Advisory Op. No. 13-03*, at 5 (June 7, 2013), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2013/AdvOpn13-03.pdf> [hereinafter *OIG Advisory Op. No. 13-03*].

53 *Mobilex*, at 775.

54 *Id.* at 780.

55 *Id.* at 781.

56 *Id.*

Suspect Carve-out Arrangements Examined by the OIG

The various advisory opinions in which the OIG has utilized the Carve-out Rule to find that a proposed arrangement posed more than a minimal risk to federal health care programs are summarized below. The biggest obstacle to these proposed carve-out arrangements was that the OIG could not rule out the existence of a nexus between payments for commercial business and the generation of federal health care program business because the parties engaged or could engage in federal health care program business apart from the proposed commercial arrangement.

Significance of the One Purpose Test—Advisory Opinion 06-02

In Advisory Opinion 06-02, a durable medical equipment (DME) supplier proposed to sell and rent DME to physicians and be paid by the physicians pursuant to a fixed fee schedule or at a daily rate.⁵⁷ The physicians would then sell or rent the DME to commercial patients only and bill commercial plans or patients directly for the DME.⁵⁸ For commercial patients only, the DME supplier would provide all billing and collections services for the physicians and would provide the physicians a trained technician to fit and train patients on the DME.⁵⁹ While the physicians would still prescribe the supplier's DME to federal health care program patients, federal health care program business would be carved out of the arrangement, such that the physicians would instruct federal health care program patients to fill their prescriptions from local DME suppliers rather than through the physicians.⁶⁰ Consequently, neither the DME supplier nor the physicians would bill federal health care programs for DME prescribed to the physician's federal health care program patients.⁶¹

⁵⁷ *OIG Advisory Op. No. 06-02*, at 2–3.

⁵⁸ *Id.* at 3.

⁵⁹ *Id.*

⁶⁰ *Id.* at 3–4.

⁶¹ Because the OIG concluded that the proposed arrangement resembled suspect joint ventures, it did not examine whether the proposed arrangement would potentially meet a safe harbor. *OIG Advisory Op. No. 06-02*, at 3.

While the DME supplier certified that all of the various contracts constituting the arrangement would meet applicable safe harbors, except for the rental of DME at a daily rate,⁶² the OIG looked at the multiple contracts as a singular arrangement that had the characteristics of suspect joint ventures previously identified by the OIG in its Special Advisory Bulletin on Contractual Joint Ventures, in which a service provider expands into another line of services at little or no risk,⁶³ except that in this case, federal health care program business was carved out of the arrangement.⁶⁴ Despite this carve-out, the OIG concluded that, because the physicians could still prescribe the supplier's DME to federal health care program patients, the OIG:

... cannot conclude that there would be no nexus between the potential profits physicians may generate from the private pay DME . . . and prescriptions of the [supplier's] products for Federally insured patients. For example, . . . the possibility [exists] that participating physicians *may have an extra incentive to steer [federal program] beneficiaries* to the [supplier's] products . . . [to] potentially secure more favorable pricing on private pay products.⁶⁵

In a marked departure from the swapping analysis discussed [above](#)—which inferred that actual discounts provided for commercial business could be remuneration for federal health care program business—the OIG denied a favorable opinion due solely to the potential that the physicians *might steer* federal health care program patients to the DME supplier to secure more favorable pricing for commercial patients.

The fact that the OIG denied a favorable opinion in this instance does not mean that the proposed commercial business only arrangement would violate the AKS. If the DME supplier and physicians did not have the intent to induce

62 This aspect of the arrangement would not meet the equipment rental safe harbor because the aggregate rental would not be set in advance. *OIG Advisory Op. No. 06-02*, at 3.

63 HHS, OIG, Publication of OIG Special Advisory Bulletin on Contractual Joint Ventures, 68 Fed. Reg. 23148 (Apr. 30, 2003).

64 *OIG Advisory Op. No. 06-02*, at 7.

65 *Id.* (emphasis added).

or reward the generation of federal health care program business through the commercial patient program, then the program would not violate the AKS. The OIG and most federal circuits have, however, adopted the position that if even one purpose of an arrangement is to induce or reward the generation of federal health care program business, then the arrangement violates the AKS, even if the arrangement has other legitimate purposes.⁶⁶

While a criminal conviction under the AKS requires the government to prove beyond a reasonable doubt that at least one purpose of payments made under an arrangement was to induce or reward the generation of federal health care program business,⁶⁷ a civil prosecution under the FCA, based on an alleged violation of the AKS, requires the government⁶⁸ or a qui tam relator⁶⁹ to prove the same only by a preponderance of the evidence.

Even with the lower civil burden of proof, however, the government or qui tam relator must prove by a preponderance of the evidence that at least one purpose of the parties' arrangement was to induce or reward the generation of federal health care program business through payments made for commercial business. Where the parties generate a relatively small volume or value of federal health care program business compared to commercial business, a defendant might successfully argue that the fact that some federal health care program business was generated between the parties is not enough to prove that one purpose of the arrangement was to induce or reward the generation of federal health care program business, but rather proves that the parties did not intend the payments to induce or reward the generation of that business. In

66 See *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20 (1st Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011) [hereinafter *Borrasi*]; *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000).

67 *Borrasi*, at 782.

68 31 U.S.C. § 3731(d).

69 While Section 3731(d) on its face appears to require a court to apply a preponderance of the evidence standard only where the government brings or intervenes in an FCA action, readers should keep in mind that a relator is bringing an action *on behalf of* the government, and courts have applied the same burden of proof to qui tam relators. See *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 714 (7th Cir. 2014).

support of this argument, the defendant could cite the OIG opinions, discussed in detail [below](#), issued for carve-out arrangements that generated little or no federal health care program business.

The outer limits of an advisory opinion’s persuasiveness—Advisory Opinions 11-08 and 12-06

Two OIG advisory opinions in particular—Advisory Opinion 11-08 and Advisory Opinion 12-06—demonstrate how the premises on which the OIG has declined to issue favorable opinions for carve-out arrangements vary greatly, and why those differences will likely affect the potential persuasiveness of each opinion. Advisory Opinion 11-08 involved payments made by a DME supplier to a testing facility, and Advisory Opinion 12-06 involved an arrangement between an anesthesia group and ambulatory surgical centers.

Advisory Opinion 11-08

In Advisory Opinion 11-08, the OIG examined an arrangement under which a DME supplier utilized the staff of independent diagnostic testing facilities (IDTFs) performing sleep studies to educate the IDTFs’ commercial patients who selected the supplier’s DME on the set up and use of the DME. The DME supplier paid the IDTFs a per-commercial patient fee for these services.⁷⁰ Some of the IDTFs were owned by physicians who could prescribe the supplier’s DME. Federal health care program patients were carved out of this arrangement.

The OIG found that “IDTFs participating in the [arrangement] *may still influence referrals of Federal health care program beneficiaries* to the [supplier] for DME” and, consequently, a nexus may exist between the supplier’s payment to the IDTFs for commercial business and the generation between the supplier and the IDTF of federal health care program business.⁷¹ Further, the OIG found that the arrangement did not meet potentially applicable safe harbors

70 OIG Advisory Op. No. 11-08 (June 14, 2011), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-08.pdf>.

71 *Id.* at 5 (emphasis added).

because it did not specify the exact schedule of services for which payment would be made.⁷²

Advisory Opinion 12-06

In Advisory Opinion 12-06, an anesthesia group contracted to be the exclusive anesthesia services provider for certain ambulatory surgical centers (ASCs). The group proposed to pay the ASCs an anesthesia management fee on a per-commercial patient basis.⁷³ Federal health care program patients were carved out of the arrangement. The OIG concluded that because the anesthesia group was the ASCs' exclusive provider for both federal and commercial patients, "carving out Federally insured patients . . . does not reduce the risk that the [anesthesia group's] payment to the [ASCs] would be paid to induce referrals to the [group] of Federally insured patients."⁷⁴

A comparative analysis of the persuasiveness of Advisory Opinions 11-08 and 12-06

In both opinions, the OIG refused to issue a favorable finding for a proposed arrangement because the Carve-out Rule gave rise to an inference that a per-patient fee for the generation of commercial business was potentially a disguised fee for federal health care program business, but the premise on which the OIG declined to issue a favorable opinion in each case varies greatly and will likely affect the relative persuasiveness of each advisory opinion to a court.

In [Advisory Opinion 06-02](#), recall that the OIG found that a nexus might exist between commercial payments and the generation of federal health care program business when a provider generates federal health care program business where a suspect commercial arrangement exists. In [Advisory Opinion 11-08](#), the fact that the IDTF *might influence* the generation of federal health care program business was, according to the OIG, sufficient to find that

⁷² See 42 C.F.R. § 1001.952(d)(3).

⁷³ OIG Advisory Op. No. 12-06 at 4, available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/advopn12-06.pdf> [hereinafter *OIG Advisory Op. No. 12-06*].

⁷⁴ *Id.* at 6.

the commercial arrangement had the potential for generating remuneration prohibited under the AKS.

In Advisory Opinion 11-08, the mere possibility of influencing the generation of federal health care program business prevented a favorable finding.⁷⁵ Mere possibility, however, will likely not be sufficient for a judge or jury to find by a preponderance of the evidence that a commercial-only arrangement is intended to unlawfully induce or reward the generation of federal health care program business. At a minimum, a judge likely will require proof that federal health care program business was actually generated between the parties to find intent to induce or reward the generation of federal health care program business through a carve-out arrangement such that a party might be civilly or criminally liable for a violation of the AKS, and, as discussed in relation to [Advisory Opinion 06-02](#), the generation of only a small volume or value of federal health care program business will likely be insufficient.

In Advisory Opinion 12-06, by contrast, the OIG had proof that the ASC generated substantial federal health care program business for the anesthesia group due to the exclusive nature of the arrangement. A jury could easily find a violation of the AKS where the party providing exclusive services for both commercial and federal health care program patients pays the party generating business any type of per-commercial patient fee. Advisory Opinion 12-06 reiterates that the same types of considerations, such as exclusive arrangements being suspect, apply to both carve-out cases and swapping cases.

Incentives to refer federal health care program business—Advisory Opinion 13-03

A clinical laboratory proposed creating a management company to help physician groups set up their own laboratories that would provide services only to commercial patients.⁷⁶ The laboratory would provide the groups with space and management and would lease all personnel and equipment to the groups for the operation of the groups' laboratories. The groups would bill

⁷⁵ See 42 C.F.R. § 1008.5(a)(1).

⁷⁶ *OIG Advisory Op. No. 13-03*, at 2.

commercial patients and payers directly for commercial laboratory services. The groups were free to refer federal health care program business to either the clinical laboratory providing them management services or to any unrelated clinical laboratory. The clinical laboratory would be paid a fixed fair market value fee for managing the groups' laboratories, space, personnel, and equipment with respect to commercial business.⁷⁷

Despite the fact that all remuneration paid by the groups to the clinical laboratory under the arrangement was certified to be fair market value and that each component of the arrangement taken separately would likely meet a safe harbor,⁷⁸ the OIG concluded that the proposed arrangement included suspect remuneration to the physician groups in the form of a "potentially lucrative opportunity to expand into the clinical laboratory business with little or no business risk."⁷⁹ This remuneration offered by the clinical laboratory was not protected by the carve-out of federal health care program business.⁸⁰

The OIG found that under this arrangement, the groups might refer or generate additional federal health care program business for the clinical laboratory to secure better rates for the management, space, equipment, and personnel charged to the groups' laboratories for commercial laboratory services, or simply because the groups may prefer to send all clinical laboratory business to the same laboratory.⁸¹ As such, the OIG could not "conclude that there would be no nexus between the potential profits the Physician Groups may generate from the private pay clinical laboratory business, on the one hand, and orders of the Parent Laboratory's services for Federally insured patients, on the other."⁸²

Advisory Opinion 13-03 raises additional questions about the use of advisory opinions in court. Here, the clinical laboratory did not give discounts

⁷⁷ *Id.* at 3.

⁷⁸ Although the OIG did not reference its prior Special Advisory Bulletin on Contractual Joint Ventures, this arrangement had many of the characteristics of suspect joint ventures discussed in the DME/physician practice joint venture examined in Advisory Opinion 12-06.

⁷⁹ *OIG Advisory Op. No. 13-03*, at 5.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

and made no payments to the groups to secure the generation of either commercial or federal health care program business. Rather, the clinical laboratory merely provided the means for the groups to profit on commercial laboratory business. If no federal health care program business was ever generated between the parties under the arrangement, it would be very difficult to make a case that the AKS was violated. In addition, it remains an open question whether a court would accept the premise that merely providing the means for a provider to pursue commercial business constitutes the exchange of remuneration under the AKS. Given that the physician groups were paying what was certified to be fair market value for the services provided by the clinical laboratory for commercial business, a counterargument could be made that the physician groups were in fact accepting at least the risk of paying the fair market value fees under the contracts with the clinical laboratory regardless of whether the venture succeeded.

Commercial Business Only Arrangements Excepted from the Carve-out Rule

In four advisory opinions, the OIG decided it would not impose sanctions against carve-out arrangements. In each case, one of the following factors aided the OIG's favorable opinion: (i) the carve-out of certain federal health care program business was required by other applicable federal law,⁸³ or (ii) despite the carve-out of federal health care program business, no—or a limited—nexus existed between payment for commercial business and federal health care program business because the entity receiving payment for commercial business would generate little or no federal health care program business under the commercial business arrangement.⁸⁴

83 OIG Advisory Op. No. 98-15 (Nov. 2, 1998), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_15.htm [hereinafter *OIG Advisory Op. No. 98-15*].

84 OIG Advisory Op. No. 00-01 (Mar. 9, 2000), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_1.htm [hereinafter *OIG Advisory Op. No. 00-01*]; OIG Advisory Op. No. 00-08 (Dec. 5, 2000), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_8.pdf [hereinafter *OIG Advisory Op. No. 00-08*]; OIG Advisory Op. No. 05-12 (Oct. 31, 2005), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0512.pdf> [hereinafter *OIG Advisory Op. No. 05-12*].

Pharmacies and Section 340B of the Public Health Services Act—Advisory Opinion 98-15

A university's hemophilia treatment center (HTC) qualified as a covered entity under Section 340B of the Public Health Services Act.⁸⁵ The university proposed an agreement under which a pharmacy would dispense anti-hemophilia factor to the HTC's patients and be paid a fixed amount by the HTC per unit dispensed.⁸⁶ The parties certified that the payment from the HTC to the pharmacy would be fair market value. The arrangement carved out Medicaid fee-for-service patients because Section 340B and Medicaid prohibit dual discounts.⁸⁷

The OIG determined the arrangement would not meet the personal services and management contracts safe harbor because neither the exact schedule of the services to be provided by the pharmacy nor the aggregate compensation under the arrangement would be set in advance. Nevertheless, the OIG would not seek sanctions against the proposed arrangement even though it carved out Medicaid fee-for-service patients because (i) the pharmacy would not set the price for Section 340B drugs or bill federal health care programs for such drugs, (ii) the pharmacy would not be paying the HTC remuneration in the form of below-market value services to secure federal health care program business, and (iii) the exclusion of Medicaid fee-for-service patients was consistent with Section 340B's prohibition against duplicate discounts.⁸⁸

Carve-outs involving little or no federal health care program business

In some cases, the OIG has issued a favorable advisory opinion when a carve-out arrangement involves little or no federal health care program business, as examined in the following advisory opinions involving an auditing company

85 42 U.S.C. § 256b(a)(4)(G).

86 *OIG Advisory Op. No. 98-15*.

87 42 U.S.C. § 256b(a)(5)(A).

88 *OIG Advisory Op. No. 98-15*.

that serviced commercial payers, a non-profit housing referral service, and a group of psychiatrists that wished to establish a pediatric day treatment facility.

An arrangement to audit commercial payers only—Advisory Opinion 00-01

An auditing company worked with commercial payers to reconcile incorrect bills that had been submitted by providers.⁸⁹ The providers paid a percentage of the amount they collected as a result of this reconciliation to the auditing company. The auditing company did not audit bills reimbursed by federal health care programs.

The OIG reaffirmed that arrangements that carve out federal health care program business may “have a ‘spillover’ effect on billing or coding for Federal health care program items or services” and if such effect “is intended by one or both parties, the [AKS] may be implicated.” The OIG nonetheless issued a favorable advisory opinion because the auditing company certified that the arrangement involved absolutely no federal health care program business.

Percentage fee for commercial patient only facilities and fixed fee for facilities with federal health care program business—Advisory Opinion 00-08

A non-profit housing referral service charged any facility that accepted only commercial patients a fee for the referral of each patient based on a percentage of the patient’s first month rent.⁹⁰ The referral service would charge a fixed annual fee for the referral service if the facility accepted any federal health care program business.

The OIG found that the Carve-out Rule in this case would not create an inference that payments for commercial business were potentially payments for federal health care program business. The commercial facilities that paid the referral service a percentage fee served absolutely no federal health care program beneficiaries. There was no nexus between the payments for commercial business to the referral service and the generation of federal health care program business by these commercial-only facilities. The fixed payment made

⁸⁹ OIG Advisory Op. No. 00-01.

⁹⁰ OIG Advisory Op. No. 00-08, at 2.

for the referral services made by all facilities accepting federal health care program business met the requirements for the referral service safe harbor.⁹¹

Joint venture with limited Medicaid reimbursement structure—Advisory Opinion 05-12

A group of psychiatrists with their own patient bases proposed a partnership to establish a pediatric day treatment facility.⁹² The facility would not treat any federal health care program beneficiaries except for patients enrolled in Medicaid health maintenance organizations. Each psychiatrist owner could refer patients to the facility, so the OIG determined that the safe harbor for small entity investments would not apply.⁹³

Even though the arrangement would implicate the AKS, the OIG determined that it would not pursue sanctions. The OIG acknowledged the Carve-out Rule but found that it was unlikely the arrangement was designed (or intended) to channel the generation of federal health care program business because (i) the “facility’s line of business—pediatric psychiatric day treatment—inherently limits the universe of potential Federal health care program patients to children, a group primarily represented in the Medicaid population” and (ii) “the only Federal health care program beneficiaries who will be treated at the facility will be clinically-eligible children enrolled in a Medicaid HMO.” The psychiatrists also had certified that the facility’s Medicaid HMO business would result in no more than two percent of the facility’s revenue.

Much of the above discussion has focused on how the advisory opinions developing the Carve-out Rule have found carve-out arrangements potentially problematic and the potential persuasiveness of these opinions in litigation. The last four opinions discussed might likewise have a persuasive effect if used by a defendant, subject to the limitations of advisory opinions discussed above.

91 42 C.F.R. § 1001.952(f).

92 *OIG Advisory Op. No. 05-12*.

93 42 C.F.R. § 1001.952(a)(2).

Dealing with Carve-out Arrangements⁹⁴

Given the increased enforcement activity by the federal government and qui tam relators for AKS violations, health care attorneys and providers should carefully examine any arrangement that seeks to avoid the AKS by paying only for commercial business and carving out federal health care program business. Regardless of whether an advisory opinion is entitled to deference, there is a possibility that a court or jury reviewing a carve-out arrangement may find the OIG's analysis of the Carve-out Rule, or its opinions protecting certain carve-out arrangements, persuasive in a criminal AKS or a civil FCA case. In any case, if an arrangement does not meet an applicable AKS safe harbor, health care counsel must always keep in mind that the key issue in a case based on an alleged AKS violation is whether one of the parties to the arrangement had the intent to induce or reward the referral or generation of federal health care program business.

Absent contrary evidence, the Carve-out Rule advisory opinions may be persuasive to support an inference that payments made for the generation of commercial business to the exclusion of federal health care program business have the potential to violate the AKS if the requisite intent is present. However, as discussed [above](#), in cases involving the similar theory of swapping, courts have not given deference to the advisory opinions but relied on the evidence introduced by one of the parties showing that the intent of the remuneration exchanged between the parties was not to induce the referral or generation of federal health care program business.

The safe(st) harbor route

If possible, a provider's counsel should ensure that a carve-out arrangement meets all elements of an applicable AKS safe harbor. If a carve-out arrange-

94 State laws, other federal laws, and commercial provider agreements are outside the scope of this article. Providers' counsel should examine any state-specific health care fraud and abuse laws and other federal laws that may potentially impact the analysis of a carve-out arrangement. Likewise, a provider should ensure that none of its agreements with commercial payers forbid the payment of remuneration for the generation of business payable by the commercial payer. A violation of any such clause in a provider agreement may be cause for termination of the provider agreement, which would ultimately frustrate the purpose of a carve-out arrangement.

ment meets the elements, the remuneration exchanged between the parties under that particular arrangement cannot be deemed a criminal offense under the AKS and the remuneration exchanged between the parties cannot be considered remuneration for the purposes of the AKS.⁹⁵ Consequently, meeting the elements of a safe harbor in a carve-out arrangement will prevent the inference that remuneration paid for commercial business under the arrangement is disguised payment for federal health care program business.

Nevertheless, the arrangement between two entities needs to be reviewed *as a whole*, especially where multiple contracts are involved. The OIG has found—and a court could find—that the whole of the arrangement confers some benefit on one of the parties that is greater than the benefits conferred in any individual contract. Even if the component contracts meet a safe harbor, the OIG or a court could find that some benefit conferred by the arrangement as a whole but not by any single contract does not meet a safe harbor and may infer that payments for commercial business under individual contracts are intended to induce or reward the referral or generation of federal health care program business.⁹⁶ Consequently, when reviewing a carve-out arrangement, a provider's counsel should be careful to analyze whether the *overall* contractual arrangement confers a benefit apart from the individual contracts.

The spectrum of risk and volume

If a carve-out arrangement cannot be structured to meet an AKS safe harbor, provider's counsel should use the OIG's Carve-out Rule analysis as a basis for examining the facts and circumstances of the arrangement to determine whether an inference could be made that payments for commercial business are disguised payments for federal health care program business. In other words, based on the Carve-out Rule analysis, a provider's counsel should carefully examine whether and to what extent federal health care program business will be generated between the parties to a carve-out arrangement.

95 42 C.F.R. § 1001.952.

96 See OIG Advisory Op. No. 06-02; OIG Advisory Op. No. 13-03.

The OIG's analysis discussed above indicates a spectrum of risk in relation to carve-out arrangements. At the riskiest end of the spectrum, the inference that payments for commercial business are disguised payments for federal health care program business is most likely to be made when carve-out arrangements require a provider to exclusively use a supplier for certain items or services payable by federal health care programs, regardless of whether the patient is covered by commercial insurance or federal health care programs.⁹⁷

On the other end of the spectrum are carve-out arrangements under which the parties (i) are required by law to carve out federal health care program business,⁹⁸ or (ii) cannot, do not,⁹⁹ or have contractually agreed not to generate federal health care program business within the arrangement. Where other federal law requires a carve-out arrangement, that requirement provides evidence that the carve-out was not made with the intent of circumventing the AKS by covertly paying for federal health care program business through payments for commercial business. Where the parties cannot, do not, or have agreed not to refer or generate federal health care program business between each other, no inference can arise that the parties intended payments to induce or reward federal health care program business. A health care attorney should have little concern about AKS risk if a carve-out arrangement meets one of these elements.

In the middle of the spectrum are carve-out arrangements that have a low volume of federal health care program business generated between the parties either by design¹⁰⁰ or in fact. If a high volume of federal health care program business is generated between the parties, it will be difficult to argue against an inference that payments ostensibly intended for the generation of commercial business were actually intended to generate federal health care program business. The converse is also true. Although the OIG has refused to endorse arrangements where there is a mere chance that payment for the generation of

97 See *OIG Advisory Op. No. 12-06*.

98 See *OIG Advisory Op. No. 98-15* (carve-out of Medicaid patients required for 340B program).

99 See *OIG Advisory Op. No. 00-08* (percentage based contract for referral service limited to commercial-only facilities that would not serve federal health care program beneficiaries).

100 See *OIG Advisory Op. No. 00-01* (carve-out limited to federal health care program beneficiaries covered by Medicaid HMOs and inherently limited to child beneficiaries).

commercial business *might* generate federal health care program business, the fact that the parties generate a relatively small volume of federal health care program business in relation to commercial business could be found by a court or jury to be persuasive evidence that a carve-out arrangement was not intended by the parties to induce or reward the referral or generation federal health care program business. In at least one instance, the OIG has issued a favorable advisory opinion where the parties generated a relatively small volume of federal health care program business in relation to commercial business.¹⁰¹

Analyze the carve-out arrangement based on swapping arrangement factors

As discussed [above](#), the similarities between the OIG's swapping arrangement analysis and its carve-out analysis are notable. Consequently, a health care attorney should determine whether a carve-out arrangement includes any of the factors the OIG has found suspect in a swapping arrangement. Particularly, a health care attorney should advise against a provider entering into a carve-out arrangement that pays for commercial business where the provider agrees to use the other party exclusively, including for federal health care program beneficiaries. The inference that commercial payments constitute disguised payment for federal health care program business is strongest where the provider agrees to send all federal health care program business to the other party.

Likewise, the health care attorney should identify and avoid any overall arrangement that could incentivize the generation of additional federal health care program business between the parties. The OIG has found such incentives, particularly in cases where the supplier of services who will ultimately bill federal health care programs for the items and services generated by the provider also provides non-federal items and/or services to the provider at a discounted rate.

¹⁰¹ See OIG Advisory Op. No. 00-08.

Conclusion

While the OIG, for the past two decades, has consistently interpreted the Anti-Kickback Statute to determine that arrangements that pay for referrals of commercial business while carving out federal health care program business could potentially violate the statute because a nexus may exist between the commercial payments and the generation of federal health care program business, the ultimate issue in any AKS case is whether at least one purpose of the parties in making the commercial payments was to induce or reward the referrals or generation of federal health care program business. Intent is beyond the scope of the OIG's advisory opinion process. Because the scope of advisory opinions is so limited, their potential persuasiveness in an FCA case or a criminal AKS lawsuit is equally limited. Nevertheless, the OIG's development of the Carve-out Rule indicates that there is a spectrum of risk in carve-out arrangements based on volume of federal health care program business generated between the parties, and there is a risk that a court or a jury could find the OIG's opinions to be persuasive. While the safest course is to structure a carve-out arrangement to meet a safe harbor, if the arrangement cannot be so structured, health care counsel should consider the OIG's opinions developing the Carve-out Rule, the OIG's swapping analysis, and the factors that the OIG has determined favorable and unfavorable along this spectrum. **■**



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The National Vaccine Injury Compensation Program and Maternal Immunizations

Emily Marcus Levine and Andrea Sudell Davey

What is the issue? Until the 21st Century Cures Act, the ability to file claims with the National Vaccine Injury Compensation Program (VICP) was limited with respect to claims alleging injuries sustained as a result of certain vaccines administered to pregnant women, and uncertain with respect to claims for injuries allegedly sustained *in utero*.

What is at stake? The lack of clear liability protections and questions concerning the ability to pursue compensation within the VICP for vaccine-related injuries resulting from maternal immunizations have hindered vaccine innovation and production. Such uncertainties have created barriers to acceptance of maternal immunizations, which are an important public health priority given the potential health benefits for both mother and child.

What do you need to know? The 21st Century Cures Act amended certain provisions in the National Childhood Vaccine Injury Act of 1986, as amended, thereby encouraging innovation related to maternal immunization; adding a new covered category of vaccines; providing broad liability protections to vaccine manufacturers; providing liability protections for health care providers administering such vaccines to their pregnant patients; and providing a more reliable and simple remedy for those pursuing injury claims.

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Levine and Davey: Maternal Immunizations

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Introduction

This article addresses important changes made by recent law that have received little attention but have the potential to significantly impact public health. Maternal immunization (i.e., vaccinations administered to pregnant women) has become an important public health priority given the potential benefits of such immunizations to the health of women and children. The 21st Century Cures Act (Cures Act), enacted on December 13, 2016, included provisions encouraging innovation related to maternal immunization through amendments to the National Childhood Vaccine Injury Act of 1986 (Vaccine Act).¹ These amendments will affect the ability of individuals to file claims alleging injuries sustained as a result of maternal immunizations, including injuries allegedly sustained *in utero*, both in the National Vaccine Injury Compensation Program (VICP) and in civil actions outside the VICP. The amendments enacted in the Cures Act with respect to maternal immunization appear to be a step forward in protecting the public health, minimizing litigation, and assuring a remedy for those with vaccine-related injuries.

This article aims to provide a brief overview of: (i) the [history of vaccine injury compensation in the United States](#); (ii) the [Vaccine Act and the structure and process of the VICP](#); (iii) the [legal uncertainty surrounding the scope of VICP coverage with respect to maternal immunizations and *in utero* injuries prior to the Cures Act's amendments](#); (iv) the [role of stakeholders in seeking resolution to such issues](#); (v) the [Cures Act's amendments to the Vaccine Act with respect to VICP claims alleging injuries sustained as a result of maternal immunizations, including injuries allegedly sustained *in utero*](#); and (vi) the [implications of the amendments going forward, including on the public health](#).

History of Vaccine Injury Compensation in the United States

In the 1980s, civil courts saw a significant increase in vaccine injury claims following reports of children's deaths associated with the whole-cell diphthe-

1 See Pub. L. No. 114-255 § 3093(c) (amending provisions of the National Childhood Vaccine Injury Act of 1986, as amended, codified at 42 U.S.C. §§ 300aa-1 to -34).

ria-tetanus-pertussis vaccine.² The costs for manufacturers to defend these lawsuits and maintain liability insurance were burdensome. One manufacturer stopped producing vaccines temporarily in 1984 and others threatened to follow suit.³ Manufacturer withdrawal from the vaccine market posed a threat to the stability of the vaccine supply, which led to fears that a decline in vaccination would result in the loss of herd immunity and ultimately disease outbreaks.⁴

The Vaccine Act and the VICP Structure and Process

In 1986, Congress enacted the Vaccine Act.⁵ The Act served two primary purposes. First, it established an extensive federal role in vaccine safety and development.⁶ For example, it created the National Vaccine Program Office in the United States Department of Health and Human Services (HHS), which is charged with providing strategic direction for the coordination of vaccine research, licensing, and distribution by stakeholders across and outside of the federal government as well as encouraging public acceptance of immunization.⁷ Second, it created the VICP as a no-fault alternative to traditional vaccine-injury civil litigation. Creation of the VICP, and the attendant liability protections afforded to vaccine manufacturers, were intended to ensure an adequate supply of vaccines, stabilize vaccine costs, serve as a no-fault alternative to the traditional tort system for resolving vaccine injury claims, and provide compensation to “vaccine-injured persons quickly, easily, and with certainty and generosity.”⁸ The Supreme Court has recognized that the Vaccine Act “establishes a no-fault compensation program ‘designed to work faster and with greater ease than the civil tort system.’”⁹ The Supreme Court also has

2 H.R. REP. NO. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345.

3 H.R. REP. NO. 99-908, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347.

4 H.R. REP. NO. 99-908, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347.

5 National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, tit. III, 100 Stat. 3743, 3755 (codified at 42 U.S.C. § 300aa-1 to -34).

6 H.R. REP. NO. 99-908, at 1-2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344-45.

7 42 U.S.C. § 300aa-5.

8 H.R. REP. NO. 99-908, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344.

9 *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011) (quoting *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995)).

noted advantages to persons pursuing injury claims within the VICP. For example, no showing of causation is required for injuries satisfying the Vaccine Injury Table (Table),¹⁰ negligence or defects need not be shown, and attorney's fees and costs are provided even for unsuccessful claims so long as threshold requirements are met.¹¹

The Vaccine Act included an original statutory Vaccine Injury Table with a list of vaccines covered under the VICP.¹² Per subsequent amendments, the Secretary of HHS (the Secretary) is directed to add vaccines through a revised regulatory Table when the Centers for Disease Control and Prevention (CDC) recommends vaccines for routine administration to children.¹³ Further, coverage under the VICP only applies to such new categories of vaccines once they are subject to an excise tax under the Internal Revenue Code.¹⁴ This excise tax funds the Vaccine Injury Compensation Trust Fund, which is the source of funds for VICP awards; imposition of the excise tax serves as a requirement for coverage under the Vaccine Act.¹⁵ Once a category of vaccines is recommended by the CDC for routine administration to children and subject to an excise tax, the Secretary is required to publish a notice of coverage and amend the regulatory Table to include the new category of vaccines.¹⁶ This initiates coverage under the Vaccine Act.

In the VICP, petitioners, through an attorney or on their own, file a petition with the U.S. Court of Federal Claims (the CFC), which begins the review and adjudication process. Petitions (claims) alleging vaccine-related injuries or

10 42 C.F.R. § 100.3, available at www.gpo.gov/fdsys/pkg/CFR-2000-title42-vol1/pdf/CFR-2000-title42-vol1-sec100-3.pdf.

11 *Id.*

12 National Childhood Vaccine Injury Act of 1986 § 2114(a).

13 42 U.S.C. § 300aa-14(a), (e)(1).

14 *Id.* § 300aa-14(e); Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13632(a)(3), 107 Stat 312, 646.

15 The Internal Revenue Code defines a "taxable vaccine" as "any of the following vaccines which are manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing" and provides a list of "taxable vaccines" (e.g., "[a]ny trivalent vaccine against influenza or any other vaccine against seasonal influenza"). 26 U.S.C. § 4132(a)(1). Vaccines periodically have been added to this list through statutory amendment. All currently listed vaccine categories are recommended by the CDC for routine administration to children.

16 42 U.S.C. § 300aa-14(e).

deaths are filed against the Secretary as respondent on behalf of the government, with the U.S. Department of Justice representing HHS.¹⁷ The CFC assigns the petition to one of eight special masters, lawyers who adjudicate cases in the VICP exclusively.¹⁸ Supporting documents required by the Vaccine Act include medical records and affidavits of the parents (or other family members) regarding the vaccination and resulting injury or death.¹⁹ Expert witness reports may also accompany the initial filing.²⁰ Proceedings are expedited by eliminating formal civil discovery and rules of evidence in favor of a more informal process.²¹

To gain entitlement to compensation under the VICP, a petitioner must establish by a preponderance of the evidence that the injured person received a vaccine listed on the Table and suffered an injury or death that was caused or significantly aggravated by the vaccine.²² Causation is presumed if the alleged injury is listed on the Table, occurred within the specified time frame, and meets the Table's Qualifications and Aids to Interpretation (QAI).²³ If the petitioner sustained an injury that is not listed on the Table, occurred outside the specified time frame, or does not meet the Table's QAI (an off-Table injury), the petitioner must prove that the vaccine in fact caused or significantly aggravated the injury or death.²⁴ In either case, the Secretary may rebut the claim by proving a factor unrelated to the vaccine caused the injury or death.²⁵ Because the VICP is a no-fault program, petitioners in VICP proceedings are relieved of the burden of demonstrating negligence on the part of vaccine manufacturers or administrators.²⁶

A decision on a petition for compensation, initially heard by a special master in the CFC, is reviewable by a judge in the CFC and then by the United

17 Emily Marcus Levine et al., *Legal Issues*, in *VACCINES 1601, 1609* (Stanley Plotkin et al. eds., 7th ed. 2018).

18 *Id.*

19 *Id.*

20 *Id.*

21 *Id.*

22 42 U.S.C. §§ 300aa-11(c), 300aa-13; 42 C.F.R. § 100.3.

23 42 C.F.R. § 100.3.

24 42 U.S.C. §§ 300aa-11(c), 300aa-13(a).

25 *Id.* § 300aa-13(a).

26 *Id.* § 300aa-13.

States Court of Appeals for the Federal Circuit (the Federal Circuit), and ultimately the United States Supreme Court.²⁷ Decisions by special masters and judges in the CFC are non-precedential, which means that the decisions are not controlling over other cases.²⁸ Only decisions of the Federal Circuit and the United States Supreme Court establish precedents for later VICP cases. Thus, if the Federal Circuit decides that a provision in the Vaccine Act carries a certain meaning, the interpretation applies in all VICP cases thereafter until the interpretation is overturned by either the Federal Circuit itself or the Supreme Court, or until Congress amends the statute.

A significant number of VICP claims currently are resolved by negotiated settlement between the parties.²⁹ A settlement is not an admission by the Secretary or the United States government that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the CFC does not determine whether a vaccine caused an injury.³⁰ A settlement therefore cannot be characterized as a decision by HHS or by the CFC that the vaccine caused an injury.³¹ Claims may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss at the CFC; a desire by both parties to minimize the time and expense associated with litigating; and a desire by both parties to resolve a case quickly and efficiently.³²

The Vaccine Act offers liability protections to vaccine manufacturers and administrators.³³ Persons injured through the administration of a vaccine generally are required to file claims and exhaust their remedies within the VICP before they are allowed to bring a civil suit against vaccine manufacturers or administrators.³⁴ To exhaust VICP remedies, a petitioner must await

27 *Id.* § 300aa-12(e)–(f).

28 *See Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998) (“Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand.”).

29 *See Vaccine Injury Compensation Data*, HEALTH RES. & SERVS. ADMIN., www.hrsa.gov/vaccine-compensation/data/ (last visited July 4, 2017).

30 *Id.*

31 *Id.*

32 *Id.*

33 42 U.S.C. § 300aa-11(a)(2)(A).

34 *Id.*

expiration of specific time-frames set forth in the Vaccine Act and, if the CFC fails to issue a decision or enter judgment, withdraw his or her VICP petition or, following a CFC determination, elect to reject the CFC's judgment (regardless of whether or not compensation was awarded).³⁵ If either requirement is satisfied, the VICP petitioner may pursue a civil suit against a vaccine manufacturer or administrator. The Vaccine Act limits what post-VICP claims may be filed against vaccine manufacturers, however.³⁶ For example, the Vaccine Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for vaccine-related injuries or deaths.³⁷ Very few cases have been filed and pursued against vaccine manufacturers or administrators in post-VICP civil litigation.³⁸

Maternal Immunization Claims Prior to the Cures Act

Vaccines have greatly reduced the burden of infectious disease and save lives by preventing disease in the people who receive them.³⁹ Vaccines not only protect those who are immunized, but also can reduce disease in unvaccinated individuals thorough “herd protection.”⁴⁰ In addition, vaccines may protect against diseases related to the targeted disease, as well as cancers caused by infective agents.⁴¹ In turn, the mortality and morbidity prevented by vaccinations translates into long-term cost savings and potential economic growth.⁴² Vaccines, however, can very rarely cause serious problems, such as severe allergic reactions, in certain individuals.⁴³

35 *Id.* § 300aa-21.

36 *Id.* §§ 300aa-22, 300aa-23.

37 *See* *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011); 42 U.S.C. § 300aa-22(b)(1).

38 Emily Marcus Levine et al., *Legal Issues*, in *VACCINES 1601, 1624* (Stanley Plotkin et al. eds., 7th ed. 2018).

39 Francis. E. Andre et al., *Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide*, 86 BULL. WORLD HEALTH ORG. 140 (FEB. 2008), available at www.who.int/bulletin/volumes/86/2/07-040089.pdf.

40 *Id.* at 142.

41 *Id.*

42 *Id.* at 143.

43 *See Vaccines & Immunizations: Possible Side-effects from Vaccines*, CTNS. FOR DISEASE CONTROL & PREVENTION, www.cdc.gov/vaccines/vac-gen/side-effects.htm (last visited July 4, 2017).

Concerns regarding the safety of vaccines during pregnancy are the greatest barriers to acceptance of maternal immunizations for most pregnant women.⁴⁴ Because women are encouraged to avoid certain unnecessary medicines during pregnancy, they may mistakenly believe that all vaccines should be avoided during pregnancy and may not understand the benefits of vaccinations recommended during pregnancy.⁴⁵ Some pregnant women fear that immunizations can harm the developing fetus and may not view vaccine-preventable diseases, such as influenza and pertussis, as a risk to themselves or their infants.⁴⁶

Pregnancy and early infancy are periods of relative immunosuppression, making pregnant women and infants particularly susceptible to infectious diseases.⁴⁷ In addition, a newborn's immature immune system limits its ability to generate protective antibody responses to infections and immunizations.⁴⁸ Thus, maternal immunizations have the potential to protect the pregnant woman as well as the fetus and infant through the placental passage of maternal antibodies produced during pregnancy.⁴⁹

Scientific and medical experts have long recognized the substantial health benefits to women offered by the administration of certain vaccines during pregnancy.⁵⁰ More recently, a scientific consensus has emerged concerning the significant health benefits of certain maternal immunizations to *children*.⁵¹ That is, scientific research has demonstrated that maternal immunizations are effective in reducing the morbidity of both pregnant women and their liveborn

44 Nat'l Vaccine Advisory Comm., *Reducing Patient and Provider Barriers to Maternal Immunization*, 130 PUB. HEALTH REP. 10. 18 (2015), available at www.hhs.gov/sites/default/files/nvpo/nvac/reports/nvac_reducing_patient_barriers_maternal_immunizations.pdf?language=en [hereinafter *Reducing Patient and Provider Barriers to Maternal Immunization*].

45 *Id.*

46 *Id.*

47 Catherine Mary Healy, *Vaccines in Pregnant Women and Research Initiatives*, 55 CLINICAL OBSTETRICS & GYNECOLOGY, 474 (2012), available at <http://blog.utp.edu.co/doctorgaviria/files/2015/09/Vacunas-embarazo.pdf> [hereinafter *Vaccines in Pregnant Women and Research Initiatives*].

48 *Id.*

49 *Id.*

50 *Reducing Patient and Provider Barriers to Maternal Immunization*.

51 *Id.*

infants.⁵² The CDC and the Advisory Committee on Immunization Practices (ACIP), which reports to the Director of the CDC and the Secretary of HHS, currently recommend that pregnant women receive two categories of vaccines. First, noting that pregnant women and infants are at increased risk for influenza-related complications and hospitalization, and that influenza vaccination of pregnant women can reduce the risk for influenza-related illness among pregnant women and their later-born infants under six months of age, the CDC and the ACIP recommend that all women who are pregnant or may be pregnant in an upcoming influenza season receive inactivated influenza vaccines.⁵³ Second, aiming to optimize strategies for preventing pertussis morbidity and mortality in infants, the CDC and the ACIP recommend that all pregnant women be vaccinated with tetanus, diphtheria, and acellular pertussis vaccines (Tdap) during each pregnancy.⁵⁴ Both maternal immunizations are recommended, in part, based on health benefits to children born from such pregnancies, as the vaccines have been shown to prevent influenza and pertussis morbidity and mortality in infants, which is significant given that no influenza or pertussis vaccines are licensed or recommended for newborns.⁵⁵

The safety record with respect to vaccines administered to pregnant women is robust. To date, there is no evidence that inactivated vaccines are associated with adverse effects in infants whose mothers received immunizations during

52 *Id.*

53 See Helen Ding et al., CDC, *Influenza Vaccination Coverage Among Pregnant Women—United States, 2014–15 Influenza Season*, 64 MORBIDITY & MORTALITY WEEKLY REP. 1000 (2015), available at www.cdc.gov/mmwr/preview/mmwrhtml/mm6436a2.htm [hereinafter *Influenza Vaccination Coverage Among Pregnant Women*]; Lisa A. Grohskopf, CDC, *Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2013–14*, 62 MORBIDITY & MORTALITY WEEKLY REP. 1 (2013), available at www.cdc.gov/mmwr/preview/mmwrhtml/rr6207a1.htm [hereinafter *Prevention and Control of Influenza with Vaccines*] (although these recommendations were updated for the 2016–17 influenza season, the recommendations on vaccination of pregnant women from 2013–14 remain in effect).

54 See Mark Sawyer et al., *Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) in Pregnant Women—Advisory Committee on Immunization Practices (ACIP)*, 2012, 62 MMWR 131 (2013); available at www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm [hereinafter *Updated Recommendations for Use of Tetanus Toxoid*].

55 See *Influenza Vaccination Coverage Among Pregnant Women*, at 1005; *Prevention and Control of Influenza with Vaccines*; *Updated Recommendations for Use of Tetanus Toxoid*.

pregnancy.⁵⁶ In addition, although the provision of live viral vaccines (e.g., measles, mumps, and rubella (MMR) vaccines) during a period prior to the onset of and during pregnancy is generally contraindicated due to a theoretical risk of vaccine virus transmittal to the fetus, pregnant women sometimes receive live viral vaccines (e.g., before they are aware they are pregnant).⁵⁷ In such instances, surveillance studies have shown no increased risks to the fetus.⁵⁸ Nonetheless, claims alleging injuries sustained *in utero* following maternal immunizations are on rare occasions filed in the VICP. Prior to enactment of the Cures Act, however, coverage of vaccine-related injury claims arising from maternal immunizations was not certain.

Scope of coverage of maternal immunizations

Under the Vaccine Act, only injuries resulting from covered vaccines may be eligible for compensation under the VICP.⁵⁹ Likewise, vaccine manufacturers and administrators are only afforded the liability protections of the Vaccine Act with respect to lawsuits concerning covered vaccines because such coverage triggers the requirement that remedies within the VICP be exhausted.⁶⁰ Thus, a threshold issue in the context of maternal immunizations was whether a particular category of vaccines would be covered. Prior to the Cures Act, it seemed unlikely that vaccines recommended for administration only to pregnant women, and not also to children, would be covered under the Vaccine Act, given the requirement that vaccines be recommended by the CDC for routine administration to children. As a general matter, vaccines currently administered to pregnant women (including vaccines recommended for administration during pregnancy, e.g., seasonal influenza vaccines, as well as vaccines contraindicated during pregnancy, such as MMR vaccines given to women who do not know they are pregnant) are already listed on the Table as

56 *Vaccines in Pregnant Women and Research Initiatives*, at 476 ; see also *Vaccine Safety Before, During, and After Pregnancy*, CDC, www.cdc.gov/vaccines/pregnancy/pregnant-women/index.html (last visited July 6, 2017).

57 *Id.*

58 *Id.*

59 42 U.S.C. § 300aa-11(c)(1)(A)-(C).

60 *Id.*

covered vaccines because the CDC recommends them for routine administration to children.⁶¹ Questions arose, however, as to whether future categories of vaccines intended for administration to pregnant women, but not to children after birth, for the exclusive benefit of children born from such pregnancies, would satisfy the Vaccine Act's requirement for a CDC recommendation for routine administration to children.

Scope of coverage of *in utero* injuries

The second area of uncertainty that preceded the Cures Act concerned the ability of petitioners to pursue claims in the VICP for injuries allegedly incurred *in utero*—even with respect to covered vaccines—as a result of maternal immunizations, and whether the Vaccine Act's liability protections would extend to such claims. Issues concerning *in utero* claims primarily arose from the question whether the Vaccine Act's requirement that an injured party “received” a covered vaccine did, as a general legal matter, extend to injuries allegedly sustained *in utero*, and, if so, whether, given the particular facts of a case, a vaccine was in fact received *in utero*.⁶² In addition, questions sometimes arose as to whether the Vaccine Act's “one petition rule” barred certain *in utero* claims in the event the mother alleged injuries to herself as well as to her child.⁶³

The question whether a fetus received a vaccine *in utero* was the most significant. The Vaccine Act requires that—except in cases involving unavailable records—each VICP petition contain an affidavit and supporting documentation demonstrating that:

the person who suffered [a vaccine-related injury] or who died . . . received a vaccine set forth in the Vaccine Injury Table [vaccines covered under the VICP] or, if such person

61 42 C.F.R. § 100.3.

62 See, e.g., *Burch v. Sec'y of Health & Human Servs.*, No. 99-946 (Fed. Cl. Apr. 9, 2010) [hereinafter *Burch*] (holding that the receipt requirement could extend to *in utero* injuries as a general matter); *Sumner v. Sec'y of Health & Human Servs.*, No. 99-946V (Fed. Cl. Aug. 13, 2015) [hereinafter *Sumner*] (concluding that petitioners failed to show that the vaccine administered to the child's mother during pregnancy caused the child's condition).

63 See *Schultz v. Sec'y of Health & Human Servs.*, No. 12-234V (Fed. Cl. Aug 30, 2013) [hereinafter *Schultz*].

did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine [OPV]. . . .⁶⁴

Given this requirement that vaccine-injured persons have “received” the vaccine absent one unique set of facts in which persons “did not receive such a vaccine” but “contracted polio, directly or indirectly, from another person who received an oral polio vaccine,” whether vaccines could, as a general legal matter, be received *in utero*, wherein the fetus is not directly administered the vaccine, was a central issue explored in most VICP cases involving allegations of *in utero* injuries. Decisions by special masters and judges at the CFC addressing the issue lacked unanimity. Some concluded that a vaccine administered to a pregnant woman was not “received” by the fetus *in utero* for purposes of interpreting the Vaccine Act,⁶⁵ reasoning, for example, that under the statutory construction principle of *expressio unius est exclusio alterius* if the only type of indirect vaccine injury identified in the Vaccine Act is a category of polio cases contracted through contact with a person who received an oral polio vaccine, other types of indirect vaccine contact are not covered by the Vaccine Act. Other decisions recognized that the Vaccine Act’s language concerning receipt of a vaccine could be interpreted more broadly, for example, that receipt could be indirect if it could be demonstrated that the vaccine’s components passed from the mother’s system to the fetus.⁶⁶ Because this issue

64 42 U.S.C. § 300aa–11(c)(1)(A); *see also id.* § 300aa–11(c)(1)(B)(i)-(ii) (using the phrases “received a vaccine” or “received the vaccine”).

65 *See Di Roma v. Sec’y of Health & Human Servs.*, No. 90-3277V (Fed Cl. Nov. 18, 1993) (concluding that the case lacked a reasonable basis because the Vaccine Act’s receipt requirement clearly does not extend to *in utero* claims); *Melton v. Sec’y of Health & Human Servs.*, No. 01-105V (Fed. Cl. Jan. 25, 2002) (concluding that the receipt requirement does not extend to *in utero* claims, relying on the principle of statutory construction of *expressio unius est exclusio alterius* (“the expression of one is the exclusion of another”). Note, however, that the special master’s decision in *Melton* was vacated by a judge in the Court of Federal Claims on July 3, 2002 and the case was remanded to provide the mother the opportunity to establish that her daughter received the vaccine *in utero*.

66 *See N.H. v. Sec’y of Health & Human Servs.*, No. 11-749V (Fed Cl. Apr. 24, 2012) [hereinafter *N.H.*] (denying the government’s motion to dismiss and holding that, for purposes of that motion, the Vaccine Act’s receipt requirement extended to *in utero* claims); *Burch* (holding that the receipt requirement could extend to *in utero* injuries as a general matter); *Kamkim v. Sec’y of Health & Human Servs.*, No. 10-373V (Fed. Cl. Mar. 29, 2012) (denying the government’s motion to dismiss and holding that certain *in utero* claims may proceed in the VICP); *Rooks v. Sec’y of Health & Human Serv.*, 35 Fed. Cl. 1 (Fed. Cl. 1996) (holding that the receipt requirement extends to *in utero* injuries when petitioners can demonstrate vaccine-related injuries).

was not resolved by any precedential judicial decision, the resolution of such claims within the VICP remained uncertain.

In cases where a CFC judicial officer determined that a maternal immunization claim could proceed, the next question was whether, given the particular facts of a case, a vaccine was in fact received *in utero*.⁶⁷ No precedential court decision existed on this issue. The CFC generally engaged in a case-by-case assessment to determine whether a petitioner had proven that vaccine components passed from a mother's system into a fetus's system *in utero* to demonstrate receipt. Petitioners typically took the position that receipt, for purposes of the Vaccine Act, extended to receipt by a fetus of the vaccine components or the secondary effects of the vaccine (e.g., antibodies produced by virtue of the vaccine) passed through a pregnant woman's system into a fetus's system.⁶⁸ A determination by a special master or a judge that a vaccine was not received *in utero* under the facts of a particular case supported the conclusion that the Vaccine Act's liability protections, and the availability of compensation under the VICP, did not extend to such a claim.

In addition, the Vaccine Act specified that only one petition could be filed with respect to each administration of a vaccine. Although rare, this provision could create barriers in instances in which individuals wished to pursue claims alleging injuries both to a woman who was vaccinated while pregnant and her child *in utero*. One special master avoided this rule by allowing two petitioners (a mother pursuing her own injury claim and parents on behalf of a child's injury claim) to proceed with claims using a single petition.⁶⁹ Nonetheless, no precedential court decision resolved the issue.

The lack of clarity concerning the application of the Vaccine Act to *in utero* injuries undermined the purposes of the Vaccine Act in several ways. First, uncertainties concerning whether *in utero* injuries were compensable in the VICP frustrated the Vaccine Act's purpose of providing a relatively simple,

67 See *N.H.* (in which the special master explained that to demonstrate the vaccine was received *in utero*, petitioner must show by preponderant evidence that the "administered vaccine proceeded through petitioner's system into [the child's] system while he was *in utero*").

68 See, e.g., *Sumner*.

69 See *Schultz*.

no-fault alternative to the tort system for persons pursuing claims of adverse events following vaccination. Compensation cannot be quick, easy, and certain in such an environment.

Second, those uncertainties, together with questions about whether the Vaccine Act would extend to new types of vaccines, appeared to be hindering the development and production of promising new categories of vaccines in development. Vaccine manufacturers were, and continue to be, conducting research and development on new types of maternal immunizations, the benefit of which would inure exclusively to the children born from pregnancies during which the vaccines are administered. These include vaccines to provide protection from Respiratory Syncytial Virus (RSV) and Group B Streptococcus (GBS). Such vaccines may present the best means of conferring immunological protection on newborn children against the threat of serious or life-threatening viruses and bacteria to which newborn children are often exposed.⁷⁰ This raised questions about whether such vaccines, not intended for administration to children after birth, would qualify as covered vaccines under the Vaccine Act (given the statutory requirement for coverage that vaccines be recommended by the CDC for routine administration to children). Vaccine developers and manufacturers indicated that these questions could hinder the further development and production of these promising new vaccines due to unwillingness to invest in bringing such vaccines to market in the face of their uncertain tort liability.⁷¹

Third, there was concern that the uncertainties described above could contribute to less than optimal rates of CDC-recommended vaccination in

70 See THE NATIONAL VACCINE ADVISORY COMMITTEE: OVERCOMING BARRIERS AND IDENTIFYING OPPORTUNITIES FOR DEVELOPING MATERNAL IMMUNIZATIONS 17 (Sept. 2016), available at www.hhs.gov/sites/default/files/nvacmaternalimmunization2016report.pdf [hereinafter OVERCOMING BARRIERS AND IDENTIFYING OPPORTUNITIES]; Helen Y. Chu et al., *Maternal Immunization*, 59 CLIN. INFECT. DIS. 560 (2014), available at www.ncbi.nlm.nih.gov/pmc/articles/PMC4168293; Azure N. Faucette et al., *Maternal Vaccination: Moving the Science Forward*, 21 HUM. REPROD. UPDATE 119 (2014), available at www.ncbi.nlm.nih.gov/pmc/articles/PMC4255605/.

71 Biotechnology Indus. Org., *Maternal Immunization Challenges and Opportunities: Perspective of Vaccine Developers and Manufacturers*, NVAC Meeting, slide 5 (Sept. 9, 2014), available at www.hhs.gov/sites/default/files/nvpo/nvac/meetings/pastmeetings/2014/bio_maternalimmunization_septnvac2014.pdf.

pregnant women. Barriers to the use of existing vaccines for pregnant women, or the addition of new indications for existing vaccines, were attributed, in part, to liability concerns by vaccine administrators and manufacturers. The National Vaccine Advisory Committee (NVAC) concluded that “uncertainties regarding maternal immunizations and liability protections under the VICP represent a barrier that discourages manufacturers and vaccine developers from i) investing in developing new vaccines for use in pregnancy and; ii) pursuing pregnancy-specific indications for vaccines already recommended by the CDC to be routinely administered to women during pregnancy.”⁷²

Advisory Committee and Congressional Activity and Recommendations

For the above-stated reasons, many stakeholders recognized the importance of resolving uncertainties with respect to the applicability of the Vaccine Act to vaccine-injury claims allegedly resulting from maternal immunizations.⁷³ Two HHS federal advisory committees made recommendations on these issues. In December 2013, the Advisory Commission on Childhood Vaccines (ACCV) recommended that the Secretary: (i) work to expand coverage under the VICP to include vaccines recommended for routine administration to pregnant women, but not separately to children and (ii) support eligibility to pursue compensation for injuries sustained by a liveborn infant whose mother receives a vaccine while the infant is *in utero*.⁷⁴ In June 2014, the NVAC

72 OVERCOMING BARRIERS AND IDENTIFYING OPPORTUNITIES FOR DEVELOPING MATERNAL IMMUNIZATIONS, at 17.

73 See, e.g., Nat'l Vaccine Advisory Comm., Maternal Immunization Working Group Phase II—Final Report, slides 10-12 (Sept. 20, 2016) (summarizing public comments received in response to the Maternal Immunization Working Group's Phase II Final Report), available at www.hhs.gov/sites/default/files/Beigi_Omer_NVAC%20MaternalImmunization%20WG_remediated.pdf.

74 See Letter from David King & Michelle A. Williams, Chair & Co-Chair, ACCV, to The Honorable Kathleen Sebelius, Sec'y of Health & Human Servs. (Dec. 3, 2013), available at www.hrsa.gov/advisorycommittees/childhoodvaccines/Proposals/miwgexpandcoverage.pdf; Letter from David King & Michelle A. Williams, Chair & Co-Chair, ACCV, to The Honorable Kathleen Sebelius, Sec'y of Health & Human Servs. (Dec. 3, 2013), available at www.hrsa.gov/advisorycommittees/childhoodvaccines/Proposals/miwgeligibility.pdf; Letter from David King & Michelle A. Williams, Chair & Co-Chair, ACCV, to The Honorable Kathleen Sebelius, Sec'y of Health & Human Servs. (Dec. 3, 2013), available at www.hrsa.gov/advisorycommittees/childhoodvaccines/Proposals/miwgrecommendation.pdf.

recommended that the Assistant Secretary for Health (ASH) support efforts by HHS's Health Resources and Services Administration (HRSA) to address the issue of *in utero* injuries allegedly incurred following maternal immunization within the VICP.⁷⁵ An NVAC Maternal Immunization Working Group further examined this issue and the NVAC issued recommendations in 2016 aimed at developing maternal immunizations, including that:

[t]he ASH should advocate to the Secretary of Health and Human Services to resolve the uncertainties around coverage under the [VICP] for vaccines administered to pregnant women that are not recommended for use in children by the CDC, and for liability protections for live-born infants born to mothers vaccinated during pregnancy.⁷⁶

Members of Congress also urged the Secretary to address *in utero* claims and permit such claims to proceed within the VICP under HHS's existing statutory authorities. The Explanatory Statement for the Fiscal Year 2015 Appropriations Bill provided: "HHS is directed to implement the Advisory Commission on Childhood Vaccines' recommendations on maternal immunization that were adopted in 2013 as HRSA administers the [VICP] under existing authorities."⁷⁷ Then-Congressman Waxman and Senators Hatch, Wyden, and Markey sent a letter to the Secretary on the same day, urging her to adopt the ACCV and NVAC recommendations via the existing authority to administer the VICP. Given the statutory uncertainties described above, however, the authority of HHS at that time to implement these recommendations was very much in doubt.

75 Nat'l Vaccine Advisory Comm., Reducing Patient and Provider Barriers to Maternal Immunization, 130 PUB. HEALTH REP. 10 (2015), available at www.hhs.gov/sites/default/files/nvpo/nvac/reports/nvac_reducing_patient_barriers_maternal_immunizations.pdf?language=en.

76 OVERCOMING BARRIERS AND IDENTIFYING OPPORTUNITIES, Recommendation 2.2.

77 160 CONG. REC. H9307, H9829 (Dec 11, 2014), available at www.congress.gov/crec/2014/12/11/CREC-2014-12-11-pt2-PgH9307.pdf. Per Public Law 113-235, this statement is to be given the same effect as a joint explanatory statement of a committee of conference.

Changes Made by the 21st Century Cures Act

The Cures Act⁷⁸ resolved the liability and compensation issues raised by maternal immunizations in two significant ways. First, the Cures Act added a new category of vaccines to those covered by the Vaccine Act. As noted [above](#), the Vaccine Act previously covered only categories of vaccines subject to a federal excise tax that were recommended by the CDC for routine administration *to children*.⁷⁹ The Cures Act expanded the Vaccine Act to extend to categories of vaccines subject to a federal excise tax that are recommended by the CDC for routine administration *to pregnant women*.⁸⁰ As a result, promising vaccines in development intended exclusively for pregnant women (e.g., RSV and GBS vaccines) will be covered vaccines if and when the CDC recommends such vaccines for routine administration to pregnant women and a federal excise tax is enacted. Between the enactment of the 21st Century Cures Act and June 2017, no vaccines were added under this category because the CDC, as of June 2017, has not recommended any vaccines for routine administration to pregnant women that were not already recommended for routine administration to children. Because this expanded coverage has extended the Vaccine Act's liability protections to vaccine manufacturers with respect to such vaccines, these amendments should remove disincentives in the development of such vaccines. Given that the Vaccine Act's broader liability protections will also extend to vaccine administrators once such vaccines are covered under the Vaccine Act, this change should also minimize the liability concerns of obstetricians and other providers, thereby encouraging them to vaccinate pregnant women with such recommended vaccines and creating opportunities for pregnant women to be vaccinated at higher rates.⁸¹

78 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (Dec. 13, 2016), available at www.gpo.gov/fdsys/pkg/PLAW-114publ255/html/PLAW-114publ255.htm [hereinafter *21st Century Cures Act*].

79 42 U.S.C. § 300aa-14(e)(2); Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13632(a)(3), 107 Stat 312, 646.

80 *21st Century Cures Act*, § 3093(c) (amending 42 U.S.C. § 300aa-14(e) and codifying 42 U.S.C. § 300aa-14(e)(3)).

81 See Asher Mullard, *Making Way for Maternal Immunization*, 15 NATURE REV. DRUG DISCOVERY, 3, 4 (2016) [hereinafter *Making Way for Maternal Immunization*] (noting that only 25% of pregnant women in the U.S. received the TDaP vaccine, even though it is recommended for pregnant women).

Second, the Cures Act resolved undecided issues with respect to categories of vaccines already covered under the Vaccine Act, clarifying the scope of liability protections and eligibility for compensation for claims alleging *in utero* injuries resulting from vaccinations of pregnant women.⁸² Of significance, the Cures Act amended the Vaccine Act to permit VICP claims filed on behalf of children for injuries allegedly sustained *in utero* as a result of maternal immunizations (with respect to covered vaccines), providing that:

[n]otwithstanding any other provision of law, for purposes of this [part 42 U.S.C. §§ 300aa-10-34], both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.⁸³

As a result, the Vaccine Act's liability protections extend to vaccine manufacturers and administrators in relation to such claims.

In addition, the Cures Act modified the Vaccine Act's "one petition rule," which previously provided that "[o]nly one petition may be filed with respect to each administration of a vaccine," by adding new language providing that "[a] covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in [42 U.S.C. § 300aa-11(f)(2)]) who was in utero at the time such woman was administered the vaccine."⁸⁴ As a consequence, the Vaccine Act does not prohibit two VICP injury claims, one on behalf of a woman who was pregnant when vaccinated and one on behalf of her child allegedly sustained *in utero*.

In precise language, the Cures Act's references to children alleging *in utero* injuries extend exclusively to children born alive.⁸⁵ The Cures Act provides that

82 *21st Century Cures Act*, § 3093(c).

83 *Id.* (amending 42 U.S.C. § 300aa-11 and codifying 42 U.S.C. § 300aa-11(f)).

84 *Id.* (amending 42 U.S.C. § 300aa-11(b)(2)).

85 *Id.*

the term “child” shall have the meaning given that term by 1 U.S.C. § 8(a)-(b), except that, for purposes of 42 U.S.C. § 300aa–11(f), “such section 8 shall be applied as if the term ‘include’ in subsection (a) of such section were replaced with the term ‘mean.’”⁸⁶ These definitions provide as follows:

(a) In determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States, the words “person”, “human being”, “child”, and “individual”, shall *include* every infant member of the species homo sapiens who is born alive at any stage of development.

(b) As used in this section, the term “born alive”, with respect to a member of the species homo sapiens, means the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion.⁸⁷

Thus, the Cures Act limits the Vaccine Act’s references to children *in utero* to children born alive, excluding stillborn children. Any claims alleging miscarriages likely would need to be pursued as claims of vaccine-related injuries sustained by women who were pregnant when vaccinated. Very few such claims have been filed in the history of the VICP.⁸⁸

⁸⁶ *Id.* (amending 42 U.S.C. § 300aa–11 and codifying 42 U.S.C. § 300aa–11(f)(2)).

⁸⁷ 1 U.S.C. § 8(a)-(b), the United States Code’s Rules of Construction (emphasis added, punctuation as in original).

⁸⁸ See generally Anna L. Jacobs, *Liability and Maternal Immunization: In Utero Injury Claims in the VICP*, 207 AM. J. OBSTETRICS & GYNECOLOGY S63 (2012) (describing *Spates v. Sec’y of Health & Human Servs.*, 76 Fed. Cl. 678 (2007), in which a judge of the CFC upheld the dismissal of a woman’s injury claims concerning a miscarriage based on a failure to demonstrate that the vaccine caused the miscarriage and raising questions about the possibility of pursuing a related death benefit).

Prior to the Cures Act, numerous stakeholders urged that changes were necessary to resolve the compensation and liability issues arising from maternal immunizations. Some thought these issues could be resolved without statutory amendments (e.g., through regulations or changes in litigative strategy in VICP cases). The Cures Act adopted a legislative mechanism to address these issues, which represented a more comprehensive and simple solution to address the policy concerns identified by stakeholders and federal advisory committees. This approach, more than other alternatives considered, will minimize litigation concerning the application of the Vaccine Act to claims involving maternal immunization and will reduce the likelihood that similar cases will yield disparate outcomes. Given that greater clarity regarding the degree to which vaccine manufacturers will be subject to liability for claims relating to maternal immunization is likely to increase the willingness of manufacturers to develop vaccines intended for pregnant women, this legislative mechanism was the best means to incentivize manufacturers to develop such vaccines. While the Table will need to be amended to include any new vaccines recommended exclusively for routine administration to pregnant women and subject to an excise tax, implementing regulations will not be required to effectuate the changes made by the Cures Act, and covered claims alleging injuries resulting from maternal immunizations may be pursued in the VICP.

While the benefits of the maternal immunization provisions in the 21st Century Cures Act are helpful, they do not resolve other complex issues that may inhibit the development and licensure of vaccines for use in pregnant women. A 2016 NVAC Report on barriers to and opportunities for developing vaccines for pregnant women identified four areas as raising possible barriers:

1. ethical issues;
2. policy issues (including VICP coverage and liability protections under the Vaccine Act);
3. pre-clinical and clinical research issues (including “rather limited knowledge on maternal-fetal physiology and immunology”); and
4. provider education and support issues.⁸⁹

89 OVERCOMING BARRIERS AND IDENTIFYING OPPORTUNITIES, at 18.

For example, although two categories of vaccines are recommended by the CDC for routine administration in pregnant women, no vaccines are specifically indicated for use in pregnant women by the Federal Drug Administration.⁹⁰

Implications of the Amendments Made by the Cures Act

Despite numerous proposals over the years to reopen the Vaccine Act and make clarifications, improvements, or changes, legislators have been reluctant to amend the Vaccine Act. Some have speculated that given the diverse interests of stakeholders, opening up the legislation to changes that may benefit one interest group could result in changes that would impact others with different, perhaps conflicting, perspectives and priorities. The Cures Act represents a rare instance in which the Vaccine Act was amended and these amendments are likely to bring about impactful changes.

Perhaps the most significant potential benefit of these provisions will be to the public health, with a reduction in morbidity and mortality in infants and in pregnant women as a result of newly developed vaccines. The hesitancy of vaccine manufacturers to develop and seek licensure for new vaccines intended for pregnant women, some for the benefit of their later-born children, should be minimized by these legislative changes.

The historic success of the Vaccine Act in minimizing the liability of vaccine manufacturers for covered vaccines should extend to the newly covered categories of vaccines that will be recommended by the CDC for routine administration in pregnant women. Although most civil actions against vaccine manufacturers and administrators alleging vaccine-related injuries are not foreclosed by the Vaccine Act, the benefits of the VICP and the statutory requirement that petitioners exhaust their remedies in the VICP before proceeding with other civil actions in state or federal courts have substantially limited the liability of vaccine manufacturers and administrators

⁹⁰ *Id.* at 3. See also *Making Way for Maternal Immunization* (describing unique challenges posed in trials with pregnant cohorts).

with respect to covered vaccines. The Vaccine Act provides additional protections to vaccine manufacturers in instances in which petitioners pursue litigation after exhausting their remedies in the VICP. The authors expect that this new environment will encourage vaccine manufacturers to develop and seek licensure for new vaccines to be administered to pregnant women, which may substantially minimize the significant harms caused by certain diseases, such as RSV and GBS.

Providers administering vaccines to pregnant women, including obstetricians and general practitioners, should be reassured that the Cures Act fills potential gaps in the liability protections afforded by the Vaccine Act with respect to maternal immunizations. Vaccine administrators are now afforded the Vaccine Act's liability protections with respect to two types of alleged vaccine-related injuries: those sustained by women who were vaccinated while pregnant and those sustained by children resulting from events that occurred *in utero*. In addition, the liability protections of the Vaccine Act now extend to vaccine administrators for new categories of vaccines, namely vaccines recommended by the CDC for routine administration to pregnant women (once subject to an excise tax), even if such vaccines are not recommended for routine administration to children. Per federal law, vaccine administrators must, prior to vaccine administration, distribute Vaccine Information Statements produced by the CDC with respect to vaccines covered under the Vaccine Act.⁹¹ Such Vaccine Information Statements contain concise descriptions of the benefits and risks associated with the vaccines, a statement about the availability of the VICP, and other information determined by the Secretary.⁹²

An additional benefit of covering vaccines recommended for pregnant women under the Vaccine Act may be the generation and collection of safety information, including data concerning any potential adverse events. Federal law imposes recordkeeping and reporting requirements on both vaccine manufacturers and on health care providers who administer vaccines covered

91 42 U.S.C. § 300aa-26(d).

92 *Id.* § 300aa-26(c). See also *Vaccine Information Statements (VISs)*, CTRS. FOR DISEASE CONTROL & PREVENTION, www.cdc.gov/vaccines/hcp/vis/index.html (last visited July 8, 2017).

under the Vaccine Act.⁹³ By law, health care providers and vaccine manufacturers also must report to the federal government certain adverse events relating to covered vaccines.⁹⁴

Further, the Cures Act should provide a more reliable and simple remedy for those pursuing injury claims relating to maternal immunizations. If vaccines administered to pregnant women are shown to cause injuries in the women and/or their later-born children, they will be able to obtain compensation more easily, consistent with the intent behind the Vaccine Act to provide compensation for vaccine-related injuries with ease and generosity within the VICP.⁹⁵ Because many of the issues addressed in the Cures Act were not previously resolved in any precedential judicial decision, the clarity provided by these amendments will minimize litigation concerning previously contentious issues, thereby making the resolution of such claims within the VICP simpler.

A possible, and significant, negative consequence of these amendments is that VICP claims may be filed with respect to common conditions that develop prenatally, as well as other developmental disorders and medical conditions that manifest in early childhood, even in circumstances in which reliable scientific evidence does not support a causal association with the vaccines. For example, women who suffer miscarriages after receiving maternal immunizations might file claims alleging the miscarriages were caused by vaccines. Even if the evidence does not show any association between miscarriages or other conditions and covered vaccines, such claims could leave the public with the impression that vaccines caused those injuries and potentially undermine public confidence in vaccines. Such misperceptions may be exacerbated by the

93 42 U.S.C. § 300aa-25.

94 *Id.* § 300aa-25(b) (requiring each health care provider and vaccine manufacturer to report to the Secretary the occurrence of events included on the Vaccine Injury Table within prescribed time periods, any contraindicating reactions to vaccines specified in manufacturers' package inserts, and any other matters required by the Secretary in regulation).

95 *See Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1325 (Fed. Cir. 2011) (providing that Congress created the Vaccine Program to be "simple, and easy to administer" while also being "expeditious and fair") (citing H. REP. No. 99-908 at 7, 12 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6348, 6353).

fact that a large proportion of VICP cases are resolved through litigative risk settlements, which may be entered into even in circumstances in which the government disputes that vaccines played a role in the alleged injuries and no judicial decision maker has made any causation determination.

Conclusion

To date, only a few claims alleging injuries sustained *in utero* have been pursued within the VICP, and as of seven months following enactment of the Cures Act, no claims had been filed based on the amendments to the Vaccine Act. Petitioners' attorneys are reimbursed for their reasonable fees and costs regardless of whether petitioners receive compensation, so long as the claims were brought in good faith and on a reasonable basis.⁹⁶ This may encourage the filing of VICP claims with respect to injuries in circumstances in which a causal association with vaccines has not been established. Despite these potential concerns, the amendments enacted in the Cures Act with respect to maternal immunization appear to be a beneficial development in protecting the public health, minimizing litigation, and assuring a remedy for those with vaccine-related injuries. **1**

96 42 U.S.C. § 300aa-15(e)(1).



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The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the National Vaccine Injury Compensation Program or the U.S. Department of Health and Human Services.

A Litigation Attorney's Formula for Changing the Factors that Influence a Patient's Decision to Sue

Daniel J. D'Alesio Jr.

What is the issue? Certain risk factors can adversely impact the physician-patient relationship and may launch patients towards litigation when the medical care and treatments provided result in unanticipated and harmful outcomes.

What is at stake? The economic consequences for both providers and patients can be quite significant when medical care and treatments result in unanticipated harm, not to mention the potentially long term physical and emotional toll suffered by the patient and his or her family members.

What do you need to know? Certain protective factors can bolster the physician-patient relationship and help shield the physician from the risk of claims. Establishing a communication pathway that cultivates an environment of safety, honesty, and confidentiality—including protections for both the patient and physician that encourage rather than hinder discussions about how and why the adverse outcome occurred—can go a long way toward defusing a patient's initial reaction to sue for damages.

Daniel J. D'Alesio Jr., *A Litigation Attorney's Formula for Changing the Factors that Influence a Patient's Decision to Sue*, J. HEALTH & LIFE SCI. L., Oct. 2017, at 58. © American Health Lawyers Association, www.healthlawyers.org/journal. All rights reserved.

D'Alesio: Formula for Changing Risk

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Introduction

Certain risk factors can adversely impact the physician-patient relationship and may launch a patient towards litigation. Conversely, certain protective factors can bolster the physician-patient relationship and help shield the physician from risk of claims. This Comment [explores the risk factors](#) that influence a patient's decision to undertake or forego litigation after experiencing a disappointing outcome related to care and [outlines countervailing protective factors and the author's suggested approach](#) by which physicians, hospitals, and the health care attorneys who advise them may reduce the probability of claims and mitigate the adverse economic consequences of claims.

Risk Factors That Increase the Possibility of Medical Malpractice Claims

In the mid-1980s, Moore and O'Connell referred to a survey by the All-Industry Research Advisory Council (AIRAC) that listed eleven possible reasons for the significant increase of medical malpractice lawsuits.¹ Some of the most frequent survey responses that Moore and O'Connell quote from the AIRAC survey include:

- People are more aware that they could sue.
- People want to make money on lawsuits.
- People expect doctors never to make mistakes.
- Doctors see too many patients.

These responses reflected historical changes in the medical and legal environment that parallel the following non-exhaustive list of risk factors which, in the author's opinion and experience, can influence a patient's decision to file suit:

¹ Henson Moore & Jeffrey O'Connell, *Foreclosing Medical Malpractice Claims by Prompt Tender of Economic Loss*, 44 LA. L. REV. 1267 (1984), available at <http://digitalcommons.law.lsu.edu/cgi/viewcontent.cgi?article=4833&context=lalrev> (citing All-[Insurance] Industry Research Advisory Council (AIRAC), *Public Attitude Monitor 1983: A Public Attitude Survey on Drunk Driving, Medical Malpractice, Seatbelts, and Other Insurance and Safety-Related Topics* 24 (Oct. 1983)).

- Lawyer and medical community advertising
- Unrealistic patient expectations of perfect outcomes
- Minimal financial risk for patients to sue, with potential for large financial gain
- The depersonalization of medical practice²

Insurance program administrators and analysis from later surveys and studies corroborate the continuing existence of these risks individually and collectively.³

Advertising by lawyers and increased competition for clients

Until the 1970s, information available to the public regarding the medical and legal professions was quite limited. Lawyer advertising for professional services, for example, was almost generally prohibited as constituting unethical conduct.⁴ Although advertising by lawyers was very limited during this time, motivated patients could locate attorneys through word of mouth, phone books, and signage. In the mid-seventies, the legal environment began to change significantly. In 1977, for example, the United States Supreme Court in the case of *Bates v. State Bar of Arizona* ruled that provisions in the Arizona

² *Id.*

³ See, e.g., Bhanu Prakash, *Patient Satisfaction*, 3 J. CUTANEOUS & AESTHETIC SURGERY 151 (2010), available at www.ncbi.nlm.nih.gov/pmc/articles/PMC3047732; Beth Huntington & Nettie Kuhn, *Communication Gaffes: A Root Cause of Malpractice Claims*, 16 BAYLOR U. MED. CTR. PROC. 157, 157 (2003), available at www.ncbi.nlm.nih.gov/pmc/articles/PMC1201002/pdf/bumc0016-0157.pdf; Richard L. Abbott, *Medical Malpractice Predictors and Risk Factors for Ophthalmologists Performing Lasik and PRK Surgery*, 101 TRANSACTIONS AM. OPHTHALMOLOGICAL SOC'Y 239 (2003), available at www.ncbi.nlm.nih.gov/pmc/articles/PMC1358993/pdf/14971582.pdf; Gerald B. Hickson et al., *Factors that Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries*, 267 J. AM. MED. ASS'N 1359 (1992); Caprice C. Greenburg et al., *Patterns of Communication Breakdowns Resulting in Injury to Surgical Patients*, 204 J. AM. C. SURGEONS 533 (2007); see also CRICO STRATEGIES, MALPRACTICE RISKS IN COMMUNICATION FAILURES: 2015 ANNUAL BENCHMARKING REPORT (2015), available upon request at www.rmhf.harvard.edu/Malpractice-Data/Annual-Benchmark-Reports/Risks-in-Communication-Failures.

⁴ Robert F. Boden, *Five Years After Bates: Lawyer Advertising in Legal and Ethical Perspective*, 65 MARQ. L. REV. 547 (1982), available at <http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=2020&context=mulr>.

Bar ethics rules prohibiting or severely restricting attorney advertising violated the First Amendment right to free speech of attorneys.⁵

Lawyer advertising now saturates the public domain in every media—TV, radio, newsprint, billboards, email, newsletters, and the internet. Multi-media marketing of legal services by litigation firms promotes a variety of themes and messages to the public: more patients are injured or killed by doctors and hospitals than the public realizes; unexpected outcomes equate to medical malpractice; absent attorney involvement, insurance companies try to take advantage of patients when proposing settlements; patients pay nothing for the attorney's services unless and until the attorney wins the case; and the lawyer or firm advertised is the best firm to protect the patient's wellbeing.

As the number of attorneys has grown significantly, so has advertising of legal services. By 2016, the number of attorneys actively practicing in the United States had grown to over 1,350,000, almost quadrupling the number since 1970.⁶ Given the proliferation of attorneys in the marketplace, competition for clients is understandably aggressive, driving advertising campaigns that represent a significant portion of a firm's budget, as well as the need to pursue a greater number of cases to cover costs. Not surprisingly, successful marketing efforts often require significant cash outlays. In 2015, the U.S. Chamber of Commerce Institute for Legal Reform projected television advertising for attorneys in 2015 would reach \$892 million.⁷ In that same year, attorneys spent 68% more on television than they had in 2008.⁸ A handful of law firms today each spend over \$10 million annually on TV advertisements.⁹ The firm of Akin Mears, for example, spends in excess of \$25 million per year, while the firms of Morgan & Morgan and Pulaski & Middleton are close

5 Bates v. State Bar of Ariz., 433 U.S. 350 (1977).

6 AM. BAR ASS'N, ABA NATIONAL LAWYER POPULATION SURVEY: HISTORICAL TREND IN TOTAL NATIONAL LAWYER POPULATION: 1878 - 2016, available at www.americanbar.org/content/dam/aba/administrative/market_research/total-national-lawyer-population-1878-2016.authcheckdam.pdf.

7 U.S. CHAMBER INST. FOR LEGAL REFORM, TRIAL LAWYER MARKETING: BROADCAST, SEARCH AND SOCIAL STRATEGIES 4 (Oct. 2015), available at www.instituteforlegalreform.com/uploads/sites/1/KEETrialLawyerMarketing_2_Web.pdf [hereinafter TRIAL LAWYER MARKETING].

8 *Id.* at 5.

9 *Id.* at 7.

behind, spending over \$24 million per year.¹⁰ According to Lisa A. Rickard, President of the U.S. Chamber Institute for Legal Reform, “The plaintiffs’ bar orchestrates some of the most sophisticated and relentless marketing campaigns in our society.”¹¹ These trends portend increasingly aggressive advertising campaigns to compete for and influence potential clients in their decisions to seek legal counsel for actual or perceived injuries related to their medical care and treatment.

Advertising by physicians/medical institutions and unreasonable expectations

The practice of medicine until the 1970s also had strict codes limiting the exchange of information about practitioners and hospitals. Until 1975, the American Medical Association prohibited physician comparison advertisements as “derogatory to the dignity of the profession” and attempts to advertise could result in sanctions for the physicians involved.¹² Hospital advertising guidelines by the American Hospital Association (AHA) were more liberal, but did not include comparison advertisement until 1984.¹³

Some advertising by the medical community can result in the unintended consequence of manipulating choice, as well as increase the risk of medical malpractice claims and litigation “by presenting limited and biased information that entice rather than to inform.”¹⁴ While advertising campaigns for physicians and hospitals can produce positive notoriety for their practices and entities, they may also encourage unreasonable patient expectations. Adver-

10 *Id.*

11 Press Release, U.S. Chamber Inst. for Legal Reform, Lawyer Spending on TV Ads Growing Six Times Faster than All Others, Report Finds (Oct. 27, 2015), available at www.businesswire.com/news/home/20151027006296/en/Lawyer-Spending-TV-Ads-Growing-Times-Faster.

12 N.D. Tomycz, *A Profession Selling Out: Lamenting the Paradigm Shift in Physician Advertising*, 32 J. MED. ETHICS 26, 26 (2005), available at <http://jme.bmj.com/content/medethics/32/1/26.full.pdf> [hereinafter *A Profession Selling Out*]; see also AMA Code of Ethics (1847), available at www.ama-assn.org/sites/default/files/media-browser/public/ethics/1847code_0.pdf.

13 Lauren Strach, *Hospital Advertising in the Beginning: Marketplace Dynamics and the Lifting of the Ban* 22 ESSAYS IN ECONOMIC AND BUSINESS HISTORY 229, 232 (2004), available at www.ebhsoc.org/journal/index.php/journal/article/viewFile/83/79.

14 *A Profession Selling Out*, at 27.

tisements promising “the perfect physique” or physicians at a certain hospital having made a loved one’s heart “as good as new” and claims of receiving one’s emergency care “faster than Dominos delivers pizza” provide patients with unrealistic expectations of fast, state-of-the-art care with perfect outcomes in every case. Such unreasonable expectations, generated by advertising hyperbole, can result in patient dissatisfaction when expected outcomes do not occur, even if the services provided were within the prevailing professional standards of care. The author has also observed a trend in which plaintiff’s lawyers request defendants’ advertising materials in discovery to address the hyperbolic language used by defendant-physicians/hospital administrators in their advertisements during depositions and at trial. When a bad patient outcome is coupled with promises of outstanding outcomes featured in advertisements, a jury may be influenced to hold the physician to a higher standard of care implied in the advertisement instead of the actual legal standard, which is typically “reasonable” care. In addition, the disappointment experienced by the patient may lead to claims for breach of contract, breach of warranty, failure of satisfaction of a guarantee, and lack of informed consent.¹⁵

Limitations on physician choice and less time spent with patients

In today’s medical practice, insurance plans, managed care programs, and related governmental regulations change on a regular basis, potentially impacting a patient’s choice of physicians and services, which can affect the patient’s perception of trust and confidence in the physician selected.¹⁶ Physicians are also spending less time than they desire with patients in the course of care and

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- 15 See *Faktor v. Lifestyle Lift*, No. 1:09-cv-511 (N.D. Ohio July 22, 2009); *Lovely v. Percy*, 826 N.E.2d 909 (Ohio Ct. App. 2005); *Heffner v. Reynolds*, 777 N.E.2d 312 (Ohio Ct. App. 2002); *Ryan v. Staten Island Univ. Hosp.*, No. 04-CV-2666 (E.D.N.Y. Apr. 13, 2006); *Karlin v. IVF Am., Inc.*, No. 65 (Ct. App. N.Y. May 4, 1999). See also Laura Brockway, *Advertiser Beware: The Do’s and Don’ts of Physician Advertising*, TEX. MED. LIABILITY TRUST, Jan.-Feb. 2005; *Your Advertising for Lasik can Nullify Informed Consent*, AHC MEDIA (Jan. 1, 2001), www.ahcmmedia.com/articles/67800-your-advertising-for-lasik-can-nullify-informed-consent (providing examples outside of medical malpractice that a patient can sue physician for breach of contract, breach of warranty, and lack of informed consent).
- 16 Christopher B. Forrest et al., *Managed Care, Primary Care, and the Patient-Practitioner Relationship*, 17 J. GEN. INTERNAL MED. 270, 276 (2002), available at <http://onlinelibrary.wiley.com/doi/10.1046/j.1525-1497.2002.10309.x/epdf>.

treatment.¹⁷ The length of time spent in a patient visit can play a significant role in the physician-patient relationship. In fact, it is not uncommon to find a correlation between the length of time spent with the patient and the physician's risk of a medical malpractice claim—the shorter the time spent, the greater the risk.¹⁸

Patient expectations of minimized financial risk and major financial gain

The litigation process in the United States grants claimants, regardless of financial status, ready access to the courts to pursue medical malpractice claims. A major component of access is the contingency fee arrangement.¹⁹ Without the burden of an initial monetary outlay, there is little or no financial deterrent to pursue a medical malpractice claim. Further enhancing a patient's expectation of minimized risk is the absence of a “loser pays” rule in the United States, which makes it difficult for physicians who successfully defend themselves in lawsuits to recover litigation fees and costs from the patient.²⁰ Except in very limited circumstances, attorneys' fees and costs will not be awarded to a successful health care provider or hospital litigant.²¹ Even if a health care provider is successful in obtaining an order for fees and costs, financial recovery will not be practical if the patient is judgment proof, i.e., has few, if any, assets to satisfy a judgment of fees and costs.

17 David C. Dugdale et al., *Time and the Patient-Physician Relationship*, 14 J. GEN. INTERNAL MED. S34, (Supp. 1 1999), available at www.ncbi.nlm.nih.gov/pmc/articles/PMC1496869/pdf/jgi_263.pdf.

18 Ezekiel J. Emanuel, *Preserving the Physician-Patient Relationship in the Era of Managed Care*, 273 J. AM. MED. ASSN 323 (1995).

19 An agreement in a civil case between an attorney and client that the attorney will represent the client for a percentage of the amount recovered in a settlement or award.

20 John Leubsdorf, *Toward a History of the American Rule on Attorney Fee Recovery*, 47 L. & CONTEMP. PROBS. 9 (1984), available at <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=3748&context=lcp>.

21 See e.g., FLA. STAT. § 768.79 and FLA. R. CIV. P. 1.442 (Florida's offer of judgment/proposal of settlement law that provides fees and costs to the prevailing party under certain circumstances upon a proposal for settlement prior to trial and rejection by the opposing party.).

The depersonalization of medical practice

As restrictions on managed care and insurance coverage continue to grow, state and federal government programs are increasing in scope, which can limit opportunities for patients and the physicians who treat them to form bonds of trust, confidence, and loyalty.²² Under the federal Emergency Medical Treatment and Labor Act (EMTALA), no patient may be denied emergency care at a hospital, regardless of his or her ability to pay.²³ Patients with low socioeconomic status use more acute hospital care and less primary care than patients with higher socioeconomic status.²⁴ Emergency departments, however, provide little opportunity for a patient to form bonds of trust and loyalty with physicians who rotate through the department in various shifts.

In the hospital setting, depersonalization of care, or the appearances thereof, can creep into the medical culture.²⁵ For example, physicians may unintentionally depersonalize their patients by referring to them as diseases or procedures when speaking with colleagues. Comments such as, “I have a lap chole (gall bladder surgery) scheduled for 1400 in operating room number 1,” can foster a culture of depersonalization. Patients desire and expect to be treated as persons worthy of common courtesy, concern, and respect rather than be defined by a number or a medical condition. Even a physician’s tone of voice can impact whether or not a patient feels he or she is being treated with respect. A 2002 study involving the tone of surgeons’ voices revealed that expressions of dominance and lack of empathy may imply physician indifference, and that failure by surgeons to respond in a timely, reasonable, and respectful manner to patient inquiries thereby enhanced the risk for malpractice claims when outcomes did not meet patient expectations.²⁶

22 Susan Dorr Goold & Mack Lipkin, Jr., *The Doctor–Patient Relationship: Challenges, Opportunities, and Strategies*, 14 J. GEN. INTERNAL MED. S26 (Supp. 1 1999), available at www.ncbi.nlm.nih.gov/pmc/articles/PMC1496871/pdf/jgi_267.pdf.

23 42 U.S.C. § 1395dd.

24 Shreya Kangovi et al., *Understanding Why Patients of Low Socioeconomic Status Prefer Hospitals over Ambulatory Care*, 32 HEALTH AFF. 1196 (2013), available at <http://content.healthaffairs.org/content/32/7/1196.full.pdf+html>.

25 Meghan O'Rourke, *Doctors Tell All—and It's Bad*, ATLANTIC (Nov. 2014), available at www.the-atlantic.com/magazine/archive/2014/11/doctors-tell-all-and-its-bad/380785/.

26 Nalini Ambady et al., *Surgeons' Tone of Voice: A Clue to Malpractice History*, 132 SURGERY 5 (2002).

Communication failures

A 2007 review of data on sentinel events obtained by the Joint Commission suggested that “poor communication contributed to nearly 70% of sentinel events reported in 2005.”²⁷ In a more recent benchmarking report by CRICO Strategies that reviewed almost 24,000 claims and litigation cases filed between 2009 and 2013, poor patient-provider and provider-provider communication were factors that contributed to patient harm in 30% of the cases under review, with communication problems contributing to incurred losses of \$1.7 billion.²⁸ The percentage of cases involving patient-provider communication errors (57%) and provider-provider communication errors (55%) were almost evenly divided, while 12% of the cases reviewed involved breakdowns in both types of communications.²⁹ The communication breakdowns were attributed to multiple causes, including, but not limited to: “[W]orkload pressure, cumbersome [electronic health records], lack of role clarity, distractions, and workplace culture (and hierarchies) . . .”³⁰ Although the benchmarking report noted that communication failures varied by different services, communication failures across all services resulted in misinformation that “can lead to mismanaged care, unmet expectations, and patient harm.”³¹

The Protective Factor Equation: CDC + Compassion = Reduced Exposure to Claims and Suits

Based on years of health law practice and teaching practical legal knowledge courses for health care providers, the author has developed an equation to capture several broad categories of protective factors that can help reduce the risk of a patient’s deciding to assert claims against his or her health care providers or medical institution, and which may also mitigate the costs of

27 Caprice C. Greenberg et al., *Patterns of Communication Breakdowns Resulting in Injury to Surgical Patients*, 204 J. AM. COLL. SURG. 533 (2007).

28 CRICO STRATEGIES, MALPRACTICE RISKS IN COMMUNICATION FAILURES: 2015 ANNUAL BENCHMARKING REPORT (2015), available by request at www.rmfm.harvard.edu/Malpractice-Data/Annual-Benchmark-Reports/Risks-in-Communication-Failures.

29 *Id.*

30 *Id.* at 4.

31 *Id.*

litigation. This simple equation is $CDC + Compassion = \text{Reduced Claims and Lawsuit Exposure}$.

CDC stands for the attributes of competence, diligence, and communication. Under the umbrella of compassion, these attributes are protective factors that can help shield physicians from claims and litigation. While competence and diligence are extremely important in helping physicians successfully defend themselves, communication and compassion are just as important, if not more so, in helping to prevent or minimize the pursuit of claims and lawsuits in the first place. These protective factors are discussed separately below, but they all need to be utilized in combination to provide the best chance of reducing exposure to claims and lawsuits and to otherwise mitigate damages if claims and lawsuits are pursued.

Competence and diligence

In common parlance, competence is the cognitive and technical protective factor in the equation. It is the acquisition of sufficient knowledge and the development of satisfactory technical skills by practicing what is learned. In medicine, a competent physician has acquired knowledge, including expertise, to develop the proper skill sets to practice medicine within the prevailing professional standard of care in delivering health care and treatment. Diligence is the action of putting one's competence into practice. The most brilliant, technically-skilled surgeon may possess the competence to provide excellent inter-operative care and treatment for patients, but if he or she is not diligent in the patient's pre-operative assessment or post-operative management, such lack of diligence can negatively overshadow the surgeon's competence, exposing the surgeon to liability if the surgical results are not optimum. Further, competence and diligence are compromised when not exercised by the entire medical team. It is not uncommon to find that the weakest link in the chain of health care professionals may have been the one to pull an entire medical team into a lawsuit. A consulting physician's sub-par performance, for example, not only reflects negatively on the referring physicians and others treating the patient's medical condition, but can also expose the referring physician to liability if he or she knew or should have known of the consulting physician's

incompetence.³² Having reasonable checks and balances in place to help ensure that care and treatment are delivered in a competent and diligent manner, along with training and proper oversight to implement them, can go a long way toward shielding providers against claims of incompetent care.

It is axiomatic that practicing with competence and diligence also requires that physicians, staff, and their administrators be thoroughly versed in policies relating to their administration of health care to patients. Although courts have held that, without the addition of expert testimony, evidence of the failure to follow policies is insufficient to prove a breach of the standard of care,³³ courts in other states have held that a policy violation may by itself establish such a breach, or may be relevant to establish breaches of administrative or managerial duties a health care institution owes to a patient.³⁴ In the author's experience, in almost all deposition or trial testimony, health care providers and representatives of health care institutions will be questioned by plaintiffs' attorneys regarding the witness's knowledge and understanding of relevant policies and whether or not they had been followed. Answers demonstrating lack of knowledge or understanding and failure to implement relevant policies are often used as leverage in settlement negotiations or at trial to show that patient safety may have been adversely affected by a lack of competence and diligence. This risk can be reduced by taking several proactive steps:

- Conducting a regular review of patient care and administrative policies for relevancy, accuracy, and effectiveness.
- Conducting a legal review of policies to ensure language does not convey requirements of care that would be unreasonable to attain or are otherwise in excess of the recognized prevailing professional standard of care.

32 See e.g., *Estate of Tranor v. Bloomsburg Hosp.*, 60 F. Supp. 2d 412 (M.D. Pa. 1999).

33 See Neil Edwards & Meg Twomey, *Health Care Policies and Procedures As a Basis For Liability*, MEDICAL MALPRACTICE LAW & STRATEGY (July 2015), available at www.lawjournalnewsletters.com/sites/lawjournalnewsletters/2015/07/01/health-care-policies-and-procedures-as-a-basis-for-liability/; see also *Heastie v. Roberts*, 877 N.E. 2d 1064 (Ill. 2007); *Blankenship v. Collier*, 302 S.W. 3d 665 (Ky. 2010).

34 See *McCorkle v. Gravois*, 152 So. 3d 944 (La. Ct. App. 2014); see also, *Heastie*, at 1077-1078.

- Training new staff on policies affecting the scope of their duties, including additional training when policies change.
- Ensuring that witnesses are properly prepared in advance of deposition or trial to respond appropriately to questions posed about the policies at issue.

Communication

Effective physician-patient communication can reduce the risk of claims and lawsuits. In 2003, Huntington and Kuhn commented on several published studies that, despite having used different study techniques, concluded that one of the four most common themes among litigious patients was a need for an explanation as to how their injuries occurred.³⁵ In 2000, the American Academy of Orthopedic Surgeons/American Association of Orthopedic Surgeons issued an advisory statement that patient-centered communication and open, honest dialogue that fosters trust and promotes healing has a favorable impact on “patient behavior, patient care outcomes, and patient satisfaction; [and] as a consequence, it often reduces incidence of malpractice lawsuits.”³⁶ Health care communications take place during evaluation and treatment, when disclosing adverse events and unanticipated outcomes, and when making early offers of compensation.

Communication during evaluation and treatment

During the evaluation and treatment phase of medical care, effectively communicating the potential risks, benefits, alternatives, and expectations to the patient is a major protective factor. Advising the patient of the known and recognized risks of a procedure is essential to dispelling any misconceptions or unrealistic expectations that the patient might have. One study involving primary care physicians showed discernable communicative behaviors that

35 Beth Huntington & Nettie Kuhn, *Communication Gaffes: A Root Cause of Malpractice Claims*, 16 BAYLOR U. MED. CTR. PROC. 157, 157 (2003), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1201002/>.

36 *Id.* (citing AM. ACAD. OF ORTHOPAEDIC SURGEONS/AM. ASS'N OF ORTHOPEDIC SURGEONS, THE IMPORTANCE OF GOOD COMMUNICATION IN THE PATIENT-PHYSICIAN RELATIONSHIP (2000)).

identified those who were less likely to be sued.³⁷ These physicians demonstrated greater use of orientation statements to educate their patients on the risks, benefits, alternatives, and expectations of care and treatment; they had a better sense of humor and use of laughter; and were more likely to seek out the patient's understanding and opinions about the plan of care by encouraging them to engage in conversation.³⁸

In the author's experience, physicians who discuss the risks, benefits, and alternatives for care in an objective and compassionate manner, using tailored consent forms and accurately charting their discussions with their patients, minimize the risk of the patient and/or the patient's family reacting with anger when complications occur. Such discussions are also likely to promote better dialogue when trying to address the patient's concerns, answer questions, or resolve any complaints.

Adequate documentation of these good practices will help in defending the care provided by the physician if a lawsuit is filed because the documentation will corroborate the nature and extent of the consent process and related conversations. Documentation practices recommended by this author for providers and medical institutions include:

- Have witnesses to conversations regarding risks, benefits, and alternatives.
- Train new physicians, nurses, and other hospital staff on the process of informed consent and the use of standardized forms.
- Conduct periodic review by departments of standardized and tailored-to-procedure informed consent documents for sufficiency of the informed consent advice.
- Avoid overuse of pre-checked entries on forms, which can create confusion where they do not apply.

³⁷ *Id.* at 158 (citing Wendy Levinson et al., *Physician-Patient Communication: The Relationship with Malpractice Claims Among Primary Care Physicians and Surgeons*, 277 J. AM. MED. ASS'N 553 (1997)).

³⁸ *Id.*

- Have a section on forms for free text, which may include documentation of additional information that may be useful in the event of a claim, such as any special concerns presented by the patient and/or addressed by the physician.
- Conduct periodic training for those involved in the informed consent process (e.g., health care providers and administrative personnel) regarding their legal responsibilities.
- Implement and document effective and timely response by the institution to concerns expressed by providers about the form, including assessment of the concerns and actions taken to improve the documentation.
- Ensure that medical records reflecting the informed consent process are consistent with the form used.
- Require and document review by the physician's or institution's health care attorneys for legal sufficiency of the documents.

Communication of adverse events or unanticipated outcomes

Surveys and studies have long shown that when adverse events or other unanticipated outcomes occur, a physician's objective, non-speculative, non-accusatory, and compassionate communication to the patient concerning the outcome may reduce the likelihood of ensuing litigation or reduce the cost of litigation if a claim is made.³⁹ Even when an undesirable event may have been

39 See COMM. ON PATIENT SAFETY & QUALITY IMPROVEMENT, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, COMMITTEE OPINION: DISCLOSURE & DISCUSSION OF ADVERSE EVENTS (Dec. 2016) available at www.acog.org/-/media/Committee-Opinions/Committee-on-Patient-Safety-and-Quality-Improvement/co681.pdf?dmc=1&ts=20170618T1817219850 (citing Charles Vincent et al., *Why do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343 LANCET 1609 (1994); Howard B. Beckman et al., *The Doctor-Patient Relationship and Malpractice: Lessons from Plaintiff Depositions*, 154 ARCHIVES INTERNAL MED. 1365 (1994). See also Lenny Lopez et al., *Disclosure of Hospital Adverse Events and its Association with Patients' Ratings of the Quality of Care*, 169 ARCHIVES INTERNAL MED. 1888 (2009); Bernard Black et al., *The Effects of "Early Offers" in Medical Malpractice Cases: Evidence from Texas*, 6 J. EMPIRICAL LEGAL STUD. 723 (2009), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1112135 [hereinafter *The Effects of "Early Offers" in Medical Malpractice Cases*].

preventable, patients are more likely to consider truthful disclosure of objective facts as being integral to good quality care.⁴⁰ A 1996 article concluded that patients desired acknowledgment of medical errors, regardless of the seriousness of the errors, and that they were more likely to consider litigation when physicians did not disclose errors.⁴¹

Disclosure of adverse events and unanticipated outcomes is not only good practice, but is also the law in a number of states.⁴² In addition to disclosure laws, several dozen states have apology laws that apply to medical situations, and some have both disclosure and apology laws, such as Florida.⁴³ Florida law obligates both hospitals and health care practitioners to notify patients of adverse incidents that result in harm to the patient. Specifically, “[a]n appropriately trained person” designated by each hospital must inform a patient or lawful representative (if the patient is incompetent) “in person about adverse incidents that result in serious harm to the patient.”⁴⁴ A similar statutory provision requires licensed health care practitioners to make the notification.⁴⁵ An “adverse incident,” as defined in other areas of Florida law, is “an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred”⁴⁶ The occurrence of an adverse incident does not necessarily mean that the incident was caused by a breach in the standard of care. Known complications from medical interventions and undesired outcomes can and do occur absent medical negligence. The Florida disclosure statutes implicitly recognize this reality and specifically state that the disclosure of an adverse event to a patient, in and of itself, “shall not constitute

40 *The Effects of “Early Offers” in Medical Malpractice Cases.*

41 Amy B. Witman et al., *How do Patients Want Physicians to Handle Mistakes? A Survey of Internal Medicine Patients in an Academic Setting*, 156 ARCHIVES INTERNAL MED. 2565, 2569 (1996).

42 Anna C. Mastroianni et al., *The Flaws in State ‘Apology’ and ‘Disclosure’ Laws Dilute Their Intended Impact on Malpractice Suits*, 29 HEALTH AFF. 1611 (2010), available at <http://content.healthaffairs.org/content/29/9/1611.full.pdf> [hereinafter *The Flaws in State ‘Apology’ and ‘Disclosure’ Laws Dilute Their Intended Impact on Malpractice Suits*].

43 *Id.*

44 FLA. STAT. § 395.1051.

45 *Id.* § 456.0575.

46 *Id.* § 395.0197(5).

an acknowledgment of admission of liability, nor can it be introduced as evidence.”⁴⁷ Florida also has an apology law, similar to that in other states, declaring that “statements, writings, or benevolent gestures expressing sympathy or a general sense of benevolence relating to the pain, suffering, or death of a person involved in an accident and made to that person or to the family of that person shall be inadmissible as evidence in a civil action.”⁴⁸ A statement of fault, however, whether it is part of the apology statement or in addition to such statement, is admissible as evidence.⁴⁹

Communication and early offers of compensation

Research indicates that even when patients assert claims or suits, there is less cost and earlier resolution of claims and litigation when effective communication of adverse events occur. The Veteran’s Affairs Hospital in Lexington, Kentucky (VA-Lex) and the University of Michigan Health System (UMHS), for example, instituted disclosure programs that require health care providers to communicate with patients whose care and treatment resulted in unexpected, undesired outcomes.⁵⁰ Since VA-Lex instituted its disclosure policy, average settlements substantially decreased compared to other VA hospitals without disclosure policies; claims processing times also were substantially reduced.⁵¹ UMHS realized dramatic reductions in time, cost, and the number of claims and lawsuits over the first five years (2001–2005) of its institutional disclosure program; the average time to resolve claims and lawsuits was cut in half, the number of claims was reduced by more than half, and annual litigation costs dropped by two-thirds.⁵²

47 *Id.* § 395.1051; see also *id.* § 456.0575.

48 FLA. STAT. § 90.4026 (2).

49 *Id.* For other examples and variations, see *The Flaws in State ‘Apology’ and ‘Disclosure’ Laws Dilute Their Intended Impact on Malpractice Suits*.

50 Hillary Rodham Clinton & Barack Obama, *Making Patient Safety the Centerpiece of Medical Liability Reform*, 354 NEW ENG. J. MED. 2205, 2208 (2006), available at www.nejm.org/doi/pdf/10.1056/NEJMp068100 [hereinafter *Making Patient Safety the Centerpiece*]; See also Richard C. Boothman, et al., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, J. HEALTH & LIFE SCI. L., Jan. 2009 at 125.

51 *Making Patient Safety the Centerpiece*.

52 *Id.*

In addition to disclosing medical events that have resulted in harming the patient, taking early steps to minimize the economic damages caused by the error may not only help to reduce the risk of lawsuits, but also may mitigate litigation costs and the amount of settlements or jury awards if a suit is filed.⁵³ Billing patients for situations in which medical mistakes were disclosed can add insult to injury, leaving patients to wonder why they should pay for the provider's mistakes. Coordinating the disclosure of errors with writing off bills for services related to the errors may frequently satisfy the patient and lessen his or her desire to file suit. Attorneys advising physicians and hospitals should be cognizant, however, that billing write-offs may trigger Medicare reporting requirements for Medicare beneficiary patients,⁵⁴ and systematic write-off of only the patient's portion of the bill can run afoul of federal law if the providers' charges are submitted to Medicare or Medicaid for payment.⁵⁵

If verifiable damages resulted from the event, early offers of compensation may help resolve the matter earlier and more cost effectively than litigation. In addition to direct patient-physician, post-incident communication, using early mediation as an alternative dispute resolution effort to resolve medical malpractice claims can help facilitate and support meaningful communication between physicians and patients in a setting where relevant laws and rules of court can ensure confidentiality.⁵⁶ The Florida Patient Safety and Pre-suit Mediation Program (FLPSMP), established in 2008 by the University of Florida J. Hillis Miller Health Center Self-Insurance Program, is one such program that has produced a template for replication beyond the state of Florida.⁵⁷ An eight-year study of the FLPSMP revealed that meritorious patient

53 *The Effects of "Early Offers" in Medical Malpractice Cases.*

54 *Mandatory Insurer Reporting (NGHP): Mandatory Insurer Reporting for Non-Group Health Plans (NGHP)*, CTRS. FOR MEDICARE & MEDICAID SERVS., www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Mandatory-Insurer-Reporting-For-Non-Group-Health-Plans/Overview.html (last visited July 12, 2017).

55 31 U.S.C. § 3729.

56 Randall C. Jenkins et al., *Mandatory Pre-Suit Mediation for Medical Malpractice: Eight-Year Results and Future Innovations*, CONFLICT RESOLUTION QUARTERLY (Apr. 2017), available at http://flbog.sip.ufl.edu/wp-content/uploads/2017/06/Jenkins_et_al-2017-Conflict_Resolution_Quarterly.pdf. Note that not all states have mediation confidentiality privileges. Florida is among a number of states with such a privilege.

57 *Id.*

claims were resolved more quickly than the average resolution time of less than six months required to litigate, and that legal expenses in defending claims were reduced by 87%.⁵⁸ As important as these time and cost savings are, the FLPSMP process gives patients a real sense of being heard and understood. The process also provides an opportunity in a confidential setting to fully discuss why the incident occurred and what steps the physician will take to prevent the problem from reoccurring. The process further presents a platform to help preserve the physician-patient relationship.⁵⁹

These early intervention and mediation programs used by VA-Lex, the University of Michigan, and the University of Florida can serve as blueprints for medical practice groups, hospitals, and academic medical centers nationwide, with appropriate modifications that take into account the laws of the particular jurisdiction in which each program exists.

Compassion: Giving soul to the heart of the protective factors

Competence, diligence, and communication form the heart of the protective factors that reduce lawsuits and damages therefrom, enhance patient safety, and improve the quality of the delivery of medical care to patients. It is the trait and skill of compassion, however, that infuses the soul into these protective factors. Compassion provides the additional incentive to maintain competence for the good of one's patients, and to remain diligent and vigilant, even when faced with daunting workloads and administrative and bureaucratic distractions.⁶⁰ Practicing with compassion extols benefits to all involved, reducing error-causing injury to patients, resulting in better outcomes, and reducing medical malpractice claims.⁶¹

Compassion and empathy are recognized as extremely important skills for physicians, but they may be difficult to develop and exhibit given physicians' busy schedules and limited time with patients in today's medical practice.

58 *Id.*

59 *Id.*

60 See Stephen G. Post, *Compassionate Care Enhancement: Benefits and Outcomes*, 1 INT'L J. PERSON CENTERED MED., 808 (2011), available at www.stonybrook.edu/bioethics/CCE.pdf.

61 *Id.* at 810.

These skills and mindsets are encouraged in medical education and training in classwork, seminars, and online training programs,⁶² but compassion is often best taught by example. One such sterling example is Dr. Richard C. Christensen,⁶³ a former professor in the Department of Psychiatry at the University of Florida College of Medicine. “Dr. C,” as he was affectionately known by his colleagues, resident physicians, and medical students, was a trailblazer in the teaching of effective physician-patient communication. Dr. Christensen was renowned as an expert teacher and was awarded the medical school’s Hippocratic Award, the highest teaching honor bestowed upon the College of Medicine’s faculty. Countless students, residents, and colleagues benefitted greatly by his “clinical pearls,”⁶⁴ time-honored concise teaching advice based on clinical observation and experience. Although his specialty was psychiatry, Dr. Christensen’s pearls assisted all physicians, regardless of specialty, in learning how best to communicate with compassion, especially when physicians were confronted with patients who were angry or hostile or struggling with great internal conflict about their medical condition. Dr. Christensen rendered sage advice with a simple mnemonic, “PEACE,” as an approach that still helps physicians better communicate and engage with patients in a constructive manner to foster better care and better patient compliance.⁶⁵ PEACE recommends that physicians demonstrate Presence, Empathy, Acceptance, Collaboration, and Empowerment. Dr. Christensen opined that physicians can effectively communicate in an empathic and compassionate manner when they:

62 Lisa Pevtzow, *Teaching Compassion: Humanities Courses Help Aspiring Doctors Provide Better Care*, CHICAGO TRIBUNE, March 20, 2013, http://articles.chicagotribune.com/2013-03-20/health/ct-x-medical-school-arts-20130320_1_doctors-students-humanities.

63 Richard C. Christensen M.D. was tragically killed in a hit-and-run incident in 2015 while performing humanitarian services with Habitat for Humanity in Zambia, Africa.

64 See Melinda Fawcett, ‘Christensen Pearls’ Distributed to Psychiatry Clerkship and Interns, UF DEP’T OF PSYCHIATRY: COLL. OF MED. (Aug. 7, 2016), available at <http://psychiatry.ufl.edu/2016/08/17/christensen-pearls-distributed-to-psychiatry-clerkship-and-interns/> (The book was compiled by the University of Florida Department of Psychiatry Editorial Board for use as a teaching tool “to provide medical students and psychiatric interns with information to pass on Dr. Christensen’s legacy of teaching.”).

65 Richard C. Christensen, *Making ‘PEACE’ with Hostile, Unwilling Patients*, 3 CURRENT PSYCHIATRY 78, (2004).

- demonstrate by their Presence that the patient has the physician's undivided attention;
- convey Empathy by trying to understand that the patient may feel powerless, patronized, or coerced;
- show Acceptance of the patient's feelings of distress by acknowledging the patient's struggle and anger regarding his or her care and treatment;
- maintain Collaboration with the patient to form a therapeutic alliance; and
- Empower the patient to make choices in a manner that does not make the patient feel like he or she is being forced into the plan of care.

Conclusion

Today's legal and medical landscape consists of a number of risk factors that have either emerged or otherwise become more pronounced since the 1970s. By establishing effective medical and risk management practices that enhance the protective factors of competence, diligence, and effective, compassionate communication, physicians create a positive practice environment conducive to good physician-patient relationships. These protective factors can play an important role in minimizing the impact of the risk factors and helping to reduce the risk of having unanticipated medical outcomes turn into claims and lawsuits. **J**



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Emerging Duties Under Unsettled Disability Law: Web Access and Service Animals in Health Care

Anne Ruff and Adriana Fortune

What is the issue? Hospitals and health care entities are being challenged over the scope of their emerging responsibilities with respect to providing reasonable accommodation to persons with disabilities who may require the assistance of a service or comfort animal, or who may require assistance accessing a health care entity's website services.

What is at stake? Noncompliance with disability law can interfere with quality patient care, and can result in burdensome and costly administrative investigations and proceedings, bad publicity, economic damages and, in some instances, loss of federal funding (including Medicare reimbursement).

What do you need to know? Health care entities have a legal obligation to accommodate disabled patients and members of the public. That obligation includes ensuring web services are accessible to individuals with disabilities and, in some instances, allowing service animals on site at a health care facility as a reasonable accommodation.

Anne Ruff and Adriana Fortune, *Emerging Duties Under Unsettled Disability Law: Web Access and Service Animals in Health Care*, J. HEALTH & LIFE SCI. L., Oct. 2017, at 80, © 2017 American Health Lawyers Association, www.healthlawyers.org/journal. All rights reserved.

Ruff and Fortune: Disability Accommodations

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Introduction

Hospitals and other health care providers are obligated under federal and state law to provide individuals with disabilities—i.e., patients, companions, visitors, and others accessing the facilities and services—equal access to the health care and other services they provide. Given the increasing incidents of disability in the growing population¹ and the ongoing evolution of federal and state law in the area of disability protection, health care providers should regularly assess their compliance obligations and efforts to ensure they are providing individuals with disabilities with equal access to health care services.

This Practice Resource will: (i) provide a high level [overview of the laws addressing the provision of accessible care to individuals with disabilities](#), (ii) [identify current trends regarding health care accessibility that providers should be aware of](#), and (iii) provide some recommendations and best practices for ensuring accessibility of health care services.

The Growing Population of Individuals with Disabilities

The elderly population in the United States is growing, which is coinciding with the increasing number of individuals with disabilities in this country.² According to the most recent United States Census, approximately 56.7 million people—19 percent of the population—were living with a disability in 2010.³ Medical innovation is helping Americans live longer, but because disability rates increase with age, longer life spans are resulting in an increasing number of disabled individuals.⁴ Statutory changes in recent years also have identified additional impairments that are now treated as a disability under the law,

1 Press Release, U.S. Census Bureau, *Nearly 1 in 5 People Have a Disability in the U.S.*, Census Bureau Reports Report Released to Coincide with 22nd Anniversary of the ADA (July 25, 2012), available at www.census.gov/newsroom/releases/archives/miscellaneous/cb12-134.html.

2 *Id.*

3 *Id.*

4 Robert Preidt, *Americans are Living Longer but More Disabled*, CBS NEWS, Apr. 20, 2016, available at www.cbsnews.com/news/americans-are-living-longer-but-more-disabled/; Eileen M. Crimmins et al., *Trends Over 4 Decades in Disability-Free Life Expectancy in the United States*, 106 AM. J. PUB. HEALTH 1287 (Apr. 14, 2017), available at www.ncbi.nlm.nih.gov/pubmed/27077352.

adding to the already increasing number of individuals who may require accommodation in the health care setting. For example, following the Americans with Disabilities Act Amendments Act of 2008 (ADAAA) and its accompanying regulations, a physical or mental impairment may meet the legal definition of “disability” even if the impairment is temporary,⁵ is in remission,⁶ or can be controlled with medication.⁷

As the number of individuals with disabilities grows, so will their utilization of health care services. Federal and state laws require health care providers to accommodate persons with disabilities and take proactive steps to ensure equal and non-discriminatory access to their services. In light of these obligations, health care providers should properly document information about their efforts to provide good care to patients—including efforts to accommodate disabilities—so that should the need arise, they will be prepared to defend any potential claims of discriminatory provision of services.

The Legal Obligations of Health Care Providers

Health care providers, from large health systems to independent physicians who see patients out of a single office location, are subject to laws that prohibit discriminating on the basis of disability and, with only limited exceptions, create an affirmative legal duty to accommodate the needs of disabled individuals. Protections for individuals with disabilities are addressed in numerous federal statutes, including Section 1557 of the Patient Protection and Affordable Care Act, the Americans with Disabilities Act, and Section 504 of the Rehabilitation Act, as well as in state statutes.⁸

5 29 C.F.R. § 1630.2(j)(1)(ix).

6 *Id.* § 1630.2(j)(1)(vii).

7 *Id.* § 1630.2(j)(1)(vi).

8 As state laws vary widely, a detailed analysis of state statutes pertaining to disability discrimination exceeds the scope of this Practice Resource. Health care entities and providers are strongly encouraged to review applicable state laws and consult with legal counsel as needed when disability accommodation issues arise.

The Patient Protection and Affordable Care Act

Section 1557 of the Patient Protection and Affordable Care Act (ACA)⁹ prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities.¹⁰ The protections provided under Section 1557 apply to any health program or activity that receives federal financial assistance from the U.S. Department of Health and Human Services (HHS), which includes Medicare;¹¹ any health program administered by HHS; and Health Insurance Marketplaces and insurers that participate in them.¹² To prevent discrimination against individuals with disabilities, the Final Rule implementing Section 1557 requires covered entities to ensure:

1. All programs and activities, including those provided through electronic and information technology, are accessible to persons with disabilities.
2. Newly constructed or altered facilities are physically accessible to persons with disabilities.
3. Appropriate auxiliary aids and services are available for individuals with disabilities.¹³

With regard to the provision of auxiliary aids and services, Section 1557 holds health care providers to a higher standard as compared to other entities who also are generally subject to the Americans with Disabilities Act (ADA). For example, most health care providers are subject to Title III of the ADA as

9 Despite almost daily threats of repeal, at the time this Practice Resource was submitted for publication in July 2017, the ACA and Section 1557 remained in effect; Patient Protection and Affordable Care Act, 42 U.S.C. § 18116.

10 *Id.*

11 HHS stated in the commentary that the obligations of Section 1557 do not apply to those providers that only accept Medicare Part B; however, HHS noted that the requirements would “likely cover almost all licensed physicians because they accept Federal financial assistance from sources other than Medicare Part B.” Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376, 31445 (May 18, 2016) (to be codified at 45 C.F.R. pt. 92) [hereinafter *Nondiscrimination in Health Programs and Activities*].

12 HHS, SUMMARY: FINAL RULE IMPLEMENTING SECTION 1557 OF THE AFFORDABLE CARE ACT, available at www.hhs.gov/sites/default/files/2016-06-07-section-1557-final-rule-summary-508.pdf (last visited July 17, 2017).

13 45 C.F.R. § 92.202-.204.

further discussed [below](#); however, those subject to Section 1557 must meet the more stringent Title II ADA standards that generally apply only to state and governmental entities.¹⁴ Title II requires covered entities to give “primary consideration” to the person with a disability’s choice of auxiliary aid, except in limited circumstances.¹⁵

While the current administration has expressed its intent to repeal the ACA, presumably including Section 1557, a repeal would not necessarily eliminate the obligations to prevent disability discrimination and provide the aids identified in Section 1557. Section 1557 is based on longstanding statutes and regulations that independently prohibit discrimination and require health care providers to provide reasonable accommodation to disabled individuals to ensure equal access to available health care services. While the ACA is the most recent law and the subject of considerable publicity and debate, it was not the first federal law to prohibit discrimination in health care facilities on the basis of disability. Those obligations were previously set forth in the [ADA](#) and [Section 504 of the Rehabilitation Act](#). Thus, a repeal of the ACA will not eliminate the pre-existing legal obligations imposed by these federal laws or by state disability law.

The Americans with Disabilities Act

With limited exceptions, most health care providers fall under the jurisdiction of the ADA.¹⁶ Title III of the ADA prohibits discrimination on the basis of disability in the operations and activities of places of public accommodations such as hospitals and health care facilities.¹⁷ Health care entities subject to Title III of the ADA must take steps to provide equal access to health care services, including but not limited to:

- providing goods and services in an integrated setting (a setting that enables individuals with disabilities to interact with nondisabled

¹⁴ *Nondiscrimination in Health Programs and Activities*, at 31421.

¹⁵ 28 C.F.R. § 35.160(b)(2).

¹⁶ 42 U.S.C. § 12101; *id.* § 12187.

¹⁷ 42 U.S.C. § 12182; 28 C.F.R. § 36.

persons to the fullest extent possible), unless separate or different measures are necessary to ensure equal opportunity;

- eliminating unnecessary eligibility standards or rules that deny individuals with disabilities an equal opportunity to enjoy the goods and services of a place of public accommodation;
- making reasonable modifications to policies, practices, and procedures that would deny equal access to individuals with disabilities, unless a fundamental alteration would result in the nature of the goods and services provided;
- furnishing auxiliary aids when necessary to ensure effective communication, unless an undue burden or fundamental alteration of services would result; and
- maintaining accessible features of facilities and equipment.¹⁸

Hospitals and clinics operated by state or local government are subject to Title II of the ADA.¹⁹ While many of the Title II standards parallel those set forth in Title III for places of public accommodation, Title II standards are more stringent and require covered entities to give “primary consideration” to the person with a disability’s choice of an auxiliary aid.²⁰ Thus, under Title II, the disabled individual’s choice must be honored unless the covered entity can prove that (i) an alternative auxiliary aid or service provides communication that is “as effective” as that provided to others; (ii) the requested aid or service would result in a fundamental alteration of the nature of the program, service or activity; or (iii) the requested aid or service would result in an undue financial and administrative burden.²¹

Section 504 of the Rehabilitation Act of 1973

Section 504 of the Rehabilitation Act applies to employers and organizations that receive federal financial assistance from any federal department or agency,

18 *Id.*

19 28 C.F.R. § 35.

20 *Id.* § 35.160(b)(2).

21 *Id.* § 35.164.

including HHS. Covered employers and organizations include “hospitals, nursing homes, mental health centers, and human service programs.”²² Section 504 provides that “no qualified individual with a disability in the United States shall be excluded from, denied the benefits of, or be subjected to discrimination under” any program or activity that either receives federal financial assistance or is conducted by any executive agency.²³ Like the ADA, Section 504 requires health care providers to provide individuals with disabilities full and equal access to health care services and facilities and reasonable modification to policies, practices, and procedures when necessary to make health care services fully available to individuals with disabilities, unless the modifications would fundamentally alter the nature of the services.

State laws

In addition to the federal laws discussed above, many states have disability rights laws that are intended to complement the ADA. Health care providers should be aware of any obligations they may have under such state laws, many of which address issues such as ensuring proper building access and allowing service animals in a health care facility, as well as the consequences of failing to provide necessary access and accommodations.

Despite the longstanding protections afforded by both federal and state laws, new accommodation issues continue to arise. Two of the many emerging examples facing health care providers today involve the increasing use of and dependence on the internet, and increasing requests for service or comfort animals on site in hospitals and health care facilities. These two specific circumstances are discussed at length below.

Emerging Disability Accommodation Issues in Health Care

The remainder of this Practice Resource provides a legal analysis of two newly emerging accommodation issues and provides recommendations for health

22 See HHS, OCR, FACT SHEET: YOUR RIGHTS UNDER SECTION 504 OF THE REHABILITATION ACT (June 2006), available at <https://archive.hhs.gov/ocr/504.pdf>.

23 29 U.S.C. § 794.

care providers to minimize potential disability discrimination claims in each of these areas. These areas, which are experiencing a significant increase in disability discrimination complaints and lawsuits in the health care context (as well as in other industries such as retail, housing, and travel), concern website accessibility²⁴ and access to facilities by support animals.²⁵

The general basis of web accessibility claims is that the individual has been denied the services of, the ability to participate in, or the benefits of a program available on or through a website because the individual was unable, due to a disability, to access the website.²⁶ For example, an individual who is deaf or hard of hearing may claim that he or she has been denied the services or benefits of a program if the program is provided through videos on a hospital's website, but the videos on the website do not contain closed-captions.

Many hospitals and health systems are also struggling with requests from disabled patients or visitors who want to bring an animal with them to health care facilities. While many people, including health care providers, understand the role and rights of identified service animals and their ability to accompany the individuals they serve almost anywhere, an increasing number of requests by individuals wishing to bring their “comfort” or “emotional support” animals onto public transportation, into housing situations that do not generally

24 See generally Lewis Wiener & Alexander Fuchs, *Trending: ADA Website Accessibility Lawsuits*, LAW360, Dec. 15, 2016.

25 See Rebecca F. Wisch, *Summary of Cases Dealing with Emotional Support Animals (ESAs)*, MICH. STATE UNIV. COLL. OF LAW ANIMAL LEGAL & HISTORICAL CTR. (2015), www.animallaw.info/article/summary-emotional-support-animal-cases (last visited July 29, 2017).

26 See Meredith Mays Espino, *Website Accessibility for Persons with Disabilities: The Why & How*, ABA BUS. LAW TODAY (Dec. 2016), www.americanbar.org/publications/blt/2016/12/07_espino.html (last visited July 29, 2017); see Press Release, U.S. Dep't of Educ., Settlements Reached in Seven States, One Territory to Ensure Website Accessibility for People with Disabilities, June 29, 2016, available at www.ed.gov/news/press-releases/settlements-reached-seven-states-one-territory-ensure-website-accessibility-people-disabilities; see Susan Ryan, *ADA Lawsuits up 63% from 2015*, JD SUPRA, July 27, 2016, www.jdsupra.com/legalnews/ada-title-iii-lawsuits-up-63-from-2015-22227/ (noting “a steady increase in lawsuits about websites that are allegedly not accessible to individuals with disabilities.”).

permit animals, and to hospitals and health care centers²⁷ is creating new issues that need to be addressed.

Web Accessibility Issues

As identified [above](#), the ACA, the ADA, and Section 504 all require that health care programs and their operations and activities be accessible to individuals with disabilities. They do not, however, provide explicit guidance on how those regulations apply to websites and online content. For example, Title III of the ADA requires that individuals with a disability be offered the “full and equal enjoyment of the goods, services, facilities, privileges, advantages or accommodations of any place of public accommodation”²⁸ Places of public accommodation must make reasonable efforts to enable disabled individuals to equally utilize the place of public accommodation.²⁹ At the time the ADA was passed in 1990, however, internet use was nonexistent. The statute itself does not contain any express references to websites and certainly does not contemplate a website being a place of public accommodation. In recent guidance, HHS has recommended that “All entities subject to Section 504, Section 1557, and Title II of the ADA should review their EIT [Electronic Information Technology] systems to ensure accessibility of their health programs for all persons with disabilities.”³⁰ Unfortunately, this guidance does not specify any standard that can be adopted to ensure accessibility.

27 The authors have personally observed this trend. *See also* Press Release, U.S. DOJ, Justice Department Reaches Settlement with Kent State University to Resolve Allegations of Discrimination in University-Operated Student Housing (Jan. 4, 2016), [available at www.justice.gov/opa/pr/justice-department-reaches-settlement-kent-state-university-resolve-allegations](http://www.justice.gov/opa/pr/justice-department-reaches-settlement-kent-state-university-resolve-allegations); *see* A. Pawlowski, *Pig on a Plane? The Era of Emotional Support Animals on Flights May be Ending*, TODAY, Sept. 21, 2016, www.today.com/health/pig-plane-era-emotional-support-animals-flights-may-be-ending-t103065 (last visited July 29, 2017).

28 42 U.S.C. § 12182(a).

29 28 C.F.R. § 36.

30 HHS, OCR, GUIDANCE AND RESOURCES FOR ELECTRONIC INFORMATION TECHNOLOGY: ENSURING EQUAL ACCESS TO ALL HEALTH SERVICES AND BENEFITS PROVIDED THROUGH ELECTRONIC MEANS 3 (2016), [available at www.hhs.gov/sites/default/files/ocr-guidance-electronic-information-technology.pdf](http://www.hhs.gov/sites/default/files/ocr-guidance-electronic-information-technology.pdf) [hereinafter GUIDANCE AND RESOURCES FOR ELECTRONIC INFORMATION TECHNOLOGY].

While no concrete guidance has been uniformly adopted to define what is considered “accessible technology,” technology—and particularly the internet—is becoming a necessary component of providing health care in the United States.³¹ Increasingly, health care is provided and coordinated through websites that contain electronic health records, billing services, scheduling services, and e-message communication with health care professionals. Individuals who are unable to utilize websites or access online content that connects them to their health care services or providers are at a disadvantage and may be unable to participate in the health and wellness programs and services electronically available to those without a disability.

If website content or features are not accessible by all intended user populations, these inadvertent barriers may create legal risk if alternatives that can provide equal access are unavailable. Web accessibility issues are wide-ranging and health care providers should consider a variety of accessibility needs when developing website content and platforms.

Scenarios Involving Potential Accessibility Issues When Using Web-based Technology

Scenario 1: An individual with impaired or compromised vision cannot read small text on a computer screen.

Possible Solution: Ensure your website provides the user with the option to enlarge the font size or ensure that the text is compatible with a screen reader.

31 See *E-Health General Information*, CMS, www.cms.gov/Medicare/E-Health/EHealthGenInfo/index.html (last visited July 29, 2017); AGENCY FOR HEALTHCARE RESEARCH & QUALITY, THE CAHPS AMBULATORY CARE IMPROVEMENT GUIDE: PRACTICAL STRATEGIES FOR IMPROVING PATIENT EXPERIENCE: SECTION 6: STRATEGIES FOR IMPROVING PATIENT EXPERIENCE WITH AMBULATORY CARE, 6.D INTERNET ACCESS FOR HEALTH INFORMATION AND ADVICE (July 2015), available at www.ahrq.gov/cahps/quality-improvement/improvement-guide/6-strategies-for-improving/access/strategy6d-internet.html; John Glaser, *How the Internet of Things Will Affect Health Care*, HOSPS. & HEALTH NETWORKS, June 4, 2015, www.hhnmag.com/articles/3438-how-the-internet-of-things-will-affect-health-care (last visited July 29, 2017); *Technology is Becoming Essential to the Health Care Field*, CONNECTED NATION (Jan. 23, 2012), <http://www.connectednation.org/BlogPost/technology-becoming-essential-healthcare-field> (last visited July 29, 2017).

Scenario 2: An individual who is deaf or hard of hearing cannot listen to and/or obtain information from an online video.

Possible Solution: Ensure your website provide closed captioning or other audio transcription.

Scenario 3: An individual with impaired manual dexterity cannot access a website by manipulating a computer mouse.

Possible Solution: Ensure your website allows the user to navigate the content using a combination of computer key strokes.

Scenario 4: A color-blind individual cannot read color-coded charts or other such graphical information that relies on color to communicate a report's findings.

Possible Solution: Ensure your website enables the user to modify the colors or otherwise have the report/charts describe the color-coded information in text format.

The use of health care kiosks poses another challenge to health care providers in terms of making web content accessible. “Healthcare kiosks include, but are not limited to, self-check-in kiosks, physician videoconferencing systems, diagnostic kiosks, health/medication information dispensaries, donor registry kiosks, kiosks that assist patients in taking their vital signs, insurance enrollment kiosks, and pharmacy dispensary kiosks.”³² Achieving kiosk accessibility may include the “installation of tactile interfaces or screen readers, repositioning of kiosks to be within reach of wheelchair users, and options which allow individuals with motor difficulties to independently operate the kiosks, including voice dictation technology.”³³ With equal access, people with disabilities can equally take advantage of the benefits offered by new technologies.³⁴

Because the laws have not contemplated and have not yet caught up with new technologies, the issue of what must be accessible is open to interpretation by the courts. Some courts have found that places of public accommodation

32 GUIDANCE AND RESOURCES FOR ELECTRONIC INFORMATION TECHNOLOGY, at 3.

33 *Id.*

34 *Id.*

are not limited to physical places, explaining that the ADA should be read broadly to accomplish the goals and intent of Congress when it passed the ADA.³⁵ If website accessibility is expected, how can health care providers create websites that are accessible—and what standards will those websites be held to?

WCAG 2.0

No formal standard currently exists to help determine whether a particular website is or is not accessible to disabled users, but the Web Content Accessibility Standards 2.0 (WCAG 2.0) continues to be referenced by courts, administrative agencies, and regulations.³⁶ The WCAG 2.0 are voluntary international guidelines developed by the Website Accessibility Initiative of the World Wide Web Consortium with the goal of providing a single shared standard for web content accessibility that meets the needs of individuals, organizations, and governments internationally.³⁷

WCAG 2.0 is described as a stable, reference-able technical standard with twelve guidelines³⁸ organized under the four principles of being perceivable, operable, understandable, and robust.³⁹

35 See, e.g., *Doe v. Mutual of Omaha Ins. Co.*, 179 F.3d 557 (7th Cir. 1999) (holding that websites are covered by Title III of the ADA); *Carparts Distribution Ctr. v. Auto. Wholesaler's Ass'n*, 37 F.3d 12 (1st Cir. 1994) (holding that insurance offerings fall under Title III of the ADA).

36 See *Nondiscrimination in Health Programs and Activities*, at 31425; Press Release, U.S. DOJ, Justice Department Reaches Settlement with edX Inc., Provider of Massive Open Online Courses, to Make its Website, Online Platform and Mobile Applications Accessible Under the Americans with Disabilities Act (Apr. 2, 2015), available at www.justice.gov/opa/pr/justice-department-reaches-settlement-edx-inc-provider-massive-open-online-courses-make-its-website-online-platform-and-mobile-applications-accessible-under-the-americans-with-disabilities-act (Apr. 2, 2015); Verdict and Order following Non-Jury Trial, *Juan Carlos Gil v. Winn-Dixie Stores, Inc.*, No. 16-23020 (S.D. Fla. June 12, 2017).

37 *Web Content Accessibility Guidelines (WCAG Overview)*, WEB ACCESSIBILITY INITIATIVE, www.w3.org/WAI/intro/wcag (last visited July 29, 2017) [hereinafter *WCAG Overview*].

38 *WCAG 2 at a Glance*, WEB ACCESSIBILITY INITIATIVE, www.w3.org/WAI/WCAG20/glance/ (last visited July 29, 2017).

39 *Introduction to Understanding WCAG 2.0*, WEB ACCESSIBILITY INITIATIVE, www.w3.org/TR/UNDERSTANDING-WCAG20/intro.html#introduction-fourprincs-head (last visited July 29, 2017).

WCAG 2.0 Principles

Perceivable. Information must be presented to users in ways they can perceive (i.e., information cannot be invisible to all of their senses).

Guidelines include:

- Providing text alternatives for non-text content
- Providing captions and other alternatives for multimedia
- Creating content that can be presented in different ways without losing meaning
- Making it easier for users to see and hear content

Operable. Users must be able to operate the interface for a webpage to be considered accessible. Guidelines include:

- Making all functionality available from a keyboard
- Giving users enough time to read and use content
- Not using content that causes seizures
- Helping users navigate and find content

Understandable. Users must be able to understand the information and the operation. Guidelines include:

- Making text readable and understandable
- Making content appear and operate in predictable ways
- Helping users avoid and correct mistakes

Robust. Users must be able to access web page content with a wide variety of user agents, including evolving assistive technologies. Guideline includes:

- Maximizing compatibility with current and future user tools

Each of the twelve guidelines has testable success criteria, which are classified as one of three levels: A, AA, and AAA.⁴⁰ WCAG 2.0 Level AA deals with the

⁴⁰ WCAG Overview.

most significant and most common barriers for disabled users.⁴¹ Level A (the minimum), meets the most basic web accessibility features, whereas Level AAA (the highest level), provides the highest level of web accessibility.⁴²

To be classified as “conforming” to WCAG 2.0 standards, five criteria⁴³ must be satisfied. While technical in nature, the conformance criteria essentially hinges on being able to demonstrate that the complete web page, including all of the information and applicable processes, is available to users in an accessible or otherwise usable format.⁴⁴

Department of Justice rule making and enforcement efforts

The U.S. Department of Justice (DOJ), the enforcement agency with respect to Titles II and III of the ADA, has made some effort to provide formal guidance on a covered entity’s obligation to make websites accessible, but the process has been slow to start and has not yet resulted in any definitive guidance.

On July 26, 2010, the DOJ issued an Advance Notice of Proposed Rulemaking (July 2010 NPRM) on the accessibility of website information and services.⁴⁵ In the July 2010 NPRM, the DOJ proposed that state and local governments subject to Title II, including places of public accommodation subject to Title III, must make their websites and related services accessible to individuals with disabilities to comply with the ADA’s stated purpose of providing disabled individuals with an equal opportunity to participate in, and benefit from, all aspects of life.⁴⁶ The DOJ sought public comment on the proposed adoption of the WCAG 2.0’s Level AA Success Criteria as its standard for website accessibility for entities subject to Titles II and III of the ADA.⁴⁷

41 WCAG 2.0 Conformance, GSA SECTION 508.GOV, www.section508.gov/content/build/website-accessibility-improvement/WCAG-conformance (last visited July 29, 2017).

42 *Id.*

43 *Understanding Conformance*, W3C, www.w3.org/TR/UNDERSTANDING-WCAG20/conformance.html (last visited July 29, 2017).

44 *Id.*

45 Nondiscrimination on the Basis of Disability; Accessibility of Web Information and Services of State and Local Government Entities and Public Accommodations, 75 Fed. Reg. 43460 (proposed July 26, 2010) (to be codified at 28 C.F.R. pts. 35 & 36).

46 *Id.*

47 *Id.*

Interestingly, the DOJ did not finalize the July 2010 NPRM guidance with respect to web accessibility. In 2015, the agency stated it would publish separate NPRMs, with the Title II NPRM expected early in fiscal year 2016 and the Title III NPRM scheduled for some time in fiscal year 2018.⁴⁸

In May 2016, the DOJ issued a Supplemental Notice of Proposed Rulemaking on Accessibility of Web Information and Services of State and Local Government Entities.⁴⁹ The initial comment period deadline was extended from August to October 2016 in an effort to provide more time for the public to submit their comments,⁵⁰ but as of the DOJ's Fall 2016 Statement on Regulatory Priorities, there is no further update and no final rule has been forthcoming.⁵¹

As we await definitive regulations regarding web accessibility standards for Title II state and governmental entities, we can expect additional delays (likely beyond 2018) for any final rule concerning Title III places of public accommodation based on prior DOJ commentary that “The Department believes that the Title II web site accessibility rule will facilitate the creation of an important infrastructure for web accessibility that will be very important in the Department’s preparation of the Title III web site accessibility NPRM.”⁵²

Despite the lack of clear regulatory standards, the DOJ seems to embrace the position that websites must be accessible. In 2014, the DOJ entered into a settlement agreement with Ahold U.S.A. and Peapod, the owners and operators of the internet grocery delivery service, to resolve the agency’s allegations that Peapod’s website, www.peapod.com, “is not accessible to some individuals with disabilities, including individuals who are blind or have low vision, individuals who are deaf or hard of hearing, and individuals who have physical

48 DOJ – Fall 2015: Statement of Regulatory Priorities, www.reginfo.gov/public/jsp/eAgenda/StaticContent/201510/Statement_1100.html (last visited July 29, 2017).

49 Nondiscrimination on the Basis of Disability; Accessibility of Web Information and Services of State and Local Government Entities, 81 Fed. Reg. 28657 (proposed May 9, 2016).

50 Nondiscrimination on the Basis of Disability; Accessibility of Web Information and Services of State and Local Government Entities, 81 Fed. Reg. 49908 (July 29, 2016).

51 DOJ – Fall 2016 Statement of Regulatory Priorities, www.reginfo.gov/public/jsp/eAgenda/StaticContent/201610/Statement_1100.html (last visited July 29, 2017).

52 *Id.*

disabilities affecting manual dexterity.”⁵³ In its statement about the settlement, the DOJ identified WCAG 2.0 AA as “well-established industry guidelines,” and as part of the settlement, the DOJ required that www.peapod.com and its mobile applications “conform to, at minimum, the Web Content Accessibility Guidelines 2.0 Level AA Success Criteria (WCAG 2.0 AA) . . .”⁵⁴

The DOJ also prepared a Statement of Interest in the case of *National Association of the Deaf v. Harvard University* supporting the use of the WCAG standards.⁵⁵ In that case, individuals who were deaf and hard of hearing filed a lawsuit against Harvard University claiming the school violated the ADA and Section 504 by denying them meaningful access to the University’s online curricula by not providing closed captioning to online audio and audiovisual content.⁵⁶ Harvard argued the case should be dismissed or the court should stay the action until the promulgation of a final Title III rule on web accessibility by the DOJ.⁵⁷ The DOJ was not convinced and explained in its Statement of Interest that “both the ADA and Section 504 *currently* obligate Harvard to provide effective communication to ensure equal access to its online programming services.”⁵⁸

Other website regulatory efforts

Outside of the DOJ’s enforcement position with respect to the ADA, the federal government has taken more definitive action to embrace the WCAG 2.0 standards. In January 2017, the Architectural and Transportation Barriers Compliance Board (referred to as the Access Board) published the Final Rule updating requirements for information and communication technology covered by Section 508 of the Rehabilitation Act (dubbed the Section 508

53 Press Release, DOJ, Justice Department Enters into a Settlement Agreement with Peapod to Ensure that Peapod Grocery Delivery Website is Accessible to Individuals with Disabilities (Nov. 17, 2014), available at www.justice.gov/opa/pr/justice-department-enters-settlement-agreement-peapod-ensure-peapod-grocery-delivery-website.

54 *Id.*

55 Statement of Interest of the United States of America, *Nat’l Ass’n of the Deaf v. Harvard Univ.*, No. 3:15-cv-30023-MGM (D. Mass. Nov. 2, 2016), available at www.ada.gov/briefs/harvard_soi.pdf.

56 *Id.*

57 *Id.*

58 *Id.* at 3.

Refresh).⁵⁹ It provides an outline of web accessibility standards for information and communication technology in the federal sector.⁶⁰ Under the Section 508 Refresh, according to digital accessibility consultant Kevin Rydberg, “essentially anything posted onto your website must be accessible to users who need aids and assistive technology to go online.”⁶¹ The Section 508 Refresh incorporates the WCAG 2.0 AA guidelines by reference.⁶²

Section 1557 of the ACA also advocates for use of the WCAG 2.0 standards. Section 1557’s implementing regulations specifically state that health programs or activities provided by covered entities through electronic or information technology must be accessible to individuals with disabilities unless doing so would result in undue financial and administrative burdens or fundamental alteration of the health program.⁶³ In the preamble to the Final Rule implementing Section 1557, the Office of Civil Rights (OCR) specifically used a website as an example of the expectation that electronic or information technology be accessible. The OCR states that “a Health Insurance Marketplace [] creating a Web site for application for health insurance coverage must ensure that individuals with disabilities have an equal opportunity to benefit from the Web site’s tool”⁶⁴

While the ACA may ultimately be repealed or replaced, the obligations imposed by the ADA and Section 504, as well as existing precedent established

59 *About the ICT Refresh*, UNITED STATES ACCESS BOARD, www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-ict-refresh (last visited July 29, 2017).

60 Information and Communication Technology (ICT) Standards and Guidelines, 82 Fed Reg. 5790 (Jan. 18, 2017) (to be codified at 36 C.F.R. pts. 1193 & 1194); Kevin Rydberg, *Explaining the Section 508 Refresh Web Accessibility Regulations*, TECH DECISIONS, May 1, 2017, <https://techdecisions.co/compliance/explaining-section-508-refresh-web-accessibility-regulations/> (last visited July 29, 2017).

61 Kevin Rydberg, *Explaining the Section 508 Refresh Web Accessibility Regulations*, TECH DECISIONS, May 1, 2017, <https://techdecisions.co/compliance/explaining-section-508-refresh-web-accessibility-regulations/> (last visited July 29, 2017).

62 *About the Update of the Section 508 Standards and Section 255 Guidelines for Information and Communication Technology*, UNITED STATES ACCESS BOARD, www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-ict-refresh/overview-of-the-final-rule (last visited July 29, 2017).

63 45 C.F.R. § 92.204.

64 *Nondiscrimination in Health Programs and Activities*, at 31424.

by the DOJ and the courts (which have turned to the WCAG 2.0 standards for website accessibility) will continue.

Reducing risks relating to web accessibility

Despite the lack of formalized regulation, the DOJ continues to pursue consent decrees mandating compliance with WCAG 2.0 standards⁶⁵ while letters from prospective plaintiffs' attorneys continue to demand compensation from health care providers for inaccessible web content. Conforming a provider's website to WCAG 2.0 standards will help reduce the risk of claims alleging inaccessibility. While WCAG 2.0 (including A, AA, or AAA) has not been formally adopted, it does appear that the DOJ defers to WCAG 2.0 as the DOJ's preferred standard, rendering it critical for a provider to be able to demonstrate at least some level of conformance, even where the WCAG is not legally required.

When WCAG 2.0 compliance is not economically feasible, or where it would otherwise result in a major revision to existing websites, health care providers may be able to reduce their risks by taking additional steps to demonstrate accessibility. For example, health care providers can:

- Consider adding an Accessibility Statement or link to the organization's web page which sets forth the organization's commitment to ensuring information is accessible to all users, including users with disabilities.
- Include the name and contact information for a user to call or email if additional assistance is required in accessing website information or services.
- Provide training to all individuals who may receive web access inquiries to ensure they do not turn away disabled users and are prepared to respond to accessibility questions.

65 The DOJ's position on web accessibility dates back more than 20 years and is not expected to change. See, e.g., Letter from Deval L. Patrick, Assistant Attorney Gen., Civil Rights Div., to The Honorable Tom Harkin, U.S. Senate (Sept. 9, 1996), www.justice.gov/sites/default/files/crt/legacy/2010/12/15/tal712.txt (last visited May 14, 2017) ("Covered entities that use the Internet for communications regarding their programs, goods, or services must be prepared to offer those communications through accessible means as well.").

- Be cautious about making any statement on your website that presumes the site is a place of public accommodation or implies the entity is covered by or compliant with any particular law, statute, or guideline, including WCAG 2.0.
- Review your website for obvious usability concerns, with a particular focus on potential users who may have visual, hearing, or mobility (e.g., manual dexterity issues) impairments that may inhibit use of a computer mouse.
- Consult your website designer to discuss building alternate formats for non-accessible information, such as alternative text for photographs and transcripts of audio files and movies. Many of these changes can be implemented for minimal costs.
- Consult counsel immediately if you are contacted by the DOJ or otherwise receive a demand letter claiming your website is inaccessible.

In addition to the above compliance considerations, HHS offers to help entities determine whether their EIT is accessible and what can be done if their EIT is determined inaccessible.⁶⁶

Some Resources to Help Determine EIT Accessibility

- [W3C's Web Content Accessibility Guidelines \(WCAG\) 2.0](#)
- [Guidance for Exchange and Medicaid Information Technology \(IT\) Systems](#)
- [ADA Best Practices Tool Kit for State and Local Governments: Chapter 5, Website Accessibility under Title II of the ADA](#)

66 HHS, OCR, GUIDANCE AND RESOURCES FOR ELECTRONIC INFORMATION TECHNOLOGY: ENSURING EQUAL ACCESS TO ALL HEALTH SERVICES AND BENEFITS PROVIDED THROUGH ELECTRONIC MEANS (2016), available at www.hhs.gov/sites/default/files/ocr-guidance-electronic-information-technology.pdf.

Service and support animals

Another area in which accommodation issues need to be addressed involves the use of assistive animals.⁶⁷ Service and support animals are increasingly being used to assist individuals with a variety of conditions that go beyond visual and mobility issues. Evidence has shown that animals can help individuals with autism, post-traumatic stress disorder, and anxiety.⁶⁸ Some animals that assist individuals with mental health issues are highly trained psychiatric-service animals. For example, a psychiatric-service animal may help a patient with autism improve her social skills and daily interactions. Other animals may not be specifically trained to assist an individual in a specialized way but rather serve as an emotional support to help relieve, for example, anxiety. Emotional-support animals do not and are not required to receive special training.⁶⁹ To be designated an emotional support animal, a physician must document that the animal assists the patient in this way. Some states designate a separate category of “therapy animals,” which are used to provide therapeutic contact, and to improve an individual’s level of social, emotional, or cognitive function.⁷⁰ It can be difficult, however, for health care providers to identify and categorize whether an animal is a service animal or a comfort/emotional support animal. Correctly identifying the animal’s function is important

67 See Mariko Yamamoto et al., *Registration of Assistance Dogs in California for Identification Tags: 1999-2012*, PLOS One 1 (Aug. 19, 2015), available at <http://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0132820&type=printable> (finding that the number of dogs registered for service and emotional support increased significantly from 1999 to 2009 with minor decreases from 2009-2012); Phil Rogers, *Emotional Support Animals ‘Growing Problem’ on U.S. Flights*, NBC CHICAGO, July 27, 2015 (complaints related to animals on flights increased 1000% from 2004 to 2011).

68 Shirley S. Wang, *Rise in Pets as Therapy for Mental Conditions: Animals Help People with Autism, PTSD, Other Conditions Function Day-to-Day*, WALL STREET J., Nov. 4, 2013, www.wsj.com/articles/rise-in-pets-as-therapy-for-mental-conditions-1383609937; Rick A. Yount et al., *Service Dog Training Program for Treatment of Posttraumatic Stress in Service Members*, ARMY MED. DEP’T J. 63 (Apr.– June 2012); *Service Dog or Therapy Dog: Which is Best for A Child with Autism?*, AUTISM SPEAKS, www.autismspeaks.org/blog/2016/07/15/service-dog-or-therapy-dog-which-best-child-autism (last visited July 29, 2017).

69 DOJ, CIVIL RIGHTS DIV., DISABILITY RIGHTS SECTION, FREQUENTLY ASKED QUESTIONS ABOUT SERVICE ANIMALS AND THE ADA (July 20, 2015), available at www.ada.gov/regs2010/service_animal_qa.pdf [hereinafter FREQUENTLY ASKED QUESTIONS ABOUT SERVICE ANIMALS AND THE ADA].

70 ADA NATIONAL NETWORK, SERVICE ANIMALS AND EMOTIONAL SUPPORT ANIMALS (2014), available at <https://adata.org/publication/service-animals-booklet>.

because different categories of animals receive different protections under state and federal law.

Service animals under the ADA

The 2010 revised ADA regulations specifically define a service animal as a dog⁷¹ that has been individually trained to do work or perform tasks for an individual with a disability.⁷² The task(s) performed by the dog must be directly related to the person's disability.⁷³ Service animals are commonly used for help with seeing, hearing, walking, detecting seizures, and performing other tasks.⁷⁴ As of March 15, 2011, only service dogs are recognized as service animals under Titles II and III of the ADA.⁷⁵ The revised ADA regulations also have recognized that, in some instances, an individual with a disability may utilize a miniature horse⁷⁶ that has been trained to do work or perform tasks for the individual.⁷⁷

Under the ADA, individuals with service animals have the right to the same service and treatment as any other person. While many places do not permit animals, the ADA specifies that a public entity and place of public accommodation must “modify its policies, practices, or procedures to permit the use of a service animal by an individual with a disability.”⁷⁸

State law considerations

While the ADA limits the definition of a “service animal” to a dog or a miniature horse, state law may define a service animal more broadly. The ADA is not intended to displace the rights or remedies provided by other federal laws

71 28 C.F.R. § 35.104; *id.* § 36.104; DOJ, CIVIL RIGHTS DIV., DISABILITY RIGHTS SECTION, ADA REQUIREMENTS: SERVICE ANIMALS (July 12, 2011), available at www.ada.gov/service_animals_2010.htm [hereinafter SERVICE ANIMALS].

72 *Id.*

73 *Id.*; FREQUENTLY ASKED QUESTIONS ABOUT SERVICE ANIMALS AND THE ADA.

74 *Id.*; DISABILITY RIGHTS N.C., SERVICE ANIMALS AT THE DOCTOR'S OFFICE (2010), available at www.disabilityrightsncc.org/sites/default/files/Service%20Animal-MedicalSettings-Self-Advocacy%20Packet%20DRNC.pdf [hereinafter SERVICE ANIMALS AT THE DOCTOR'S OFFICE].

75 SERVICE ANIMALS.

76 “Miniature horses generally range in height from 24 inches to 36 inches measured to the shoulders, and generally weigh between 70 and 100 pounds.” SERVICE ANIMALS.

77 28 C.F.R. § 35.136; *id.* § 36.302.

78 28 C.F.R. § 35.136(a); *id.* § 36.302. See also SERVICE ANIMALS AT THE DOCTOR'S OFFICE.

(including section 504) or state laws (including common law) that provide greater or equal protection to individuals with disabilities.⁷⁹ It is therefore possible that a state law may allow for a category of service animals that the ADA does not (such as cats) and, where the state law offers broader protection, the state law should be followed. For example, Indiana law defines a service animal as an “animal trained as: (1) a hearing animal; (2) a guide animal; (3) an assistance animal; (4) a seizure alert animal; (5) a mobility animal; (6) a psychiatric service animal; or (7) an autism service animal.”⁸⁰ This means a health care provider may need to permit access to a variety of different animals—in addition to dogs or miniature horses⁸¹—that would be considered service animals. These broader protections can present unique challenges to the provider and/or health care facility. Under certain circumstances, however, service animals may be prohibited from entering the facility, such as if:

- the service animal is not housebroken;
- the service animal is not under the owner’s control;
- (for miniature horses) the facility cannot accommodate the service animal’s type, size, and weight; and
- the service animal’s presence will compromise legitimate safety requirements necessary for safe operation of the facility.⁸²

Identifying a service or support animal

Currently, emotional support animals, comfort animals, and therapy animals are not specifically protected under the public accommodation provision of the ADA. To qualify as a service animal, emotional support, comfort, or therapy animals must be individually trained to assist with an individual’s disability.⁸³ Properly identifying the category of the animal (i.e., emotional

79 28 C.F.R. § 35.103(b); *id.* § 36.103(c)

80 IND. CODE § 16-32-3-1.5.

81 Despite the recent addition of miniature horses to the definition of service animal, there are no published cases to date involving an individual’s request to bring a miniature horse to a health care facility as a disability accommodation.

82 SERVICE ANIMALS.

83 *Id.*; FREQUENTLY ASKED QUESTIONS ABOUT SERVICE ANIMALS AND THE ADA; 28 C.F.R. § 35.104; *id.* § 36.104; SERVICE ANIMALS.

support, comfort, therapy, or service) will impact the level of protections allowed for both the animal and the individual under state and federal laws.

While some service animals wear jackets or collars that identify them as service animals, the ADA does not require that they be outfitted with such identifying gear.⁸⁴ Neither does the ADA require that service animals be certified or registered as “designated” service animals.⁸⁵ Adding to the confusion, if an animal is not visibly identifiable as a service animal, health care providers are not permitted under the ADA to require that the individual show proof that his or her animal is a service animal.⁸⁶ Under the ADA, the health care provider may only ask (i) if the animal is required because of a disability and (ii) what work or task the animal has been trained to perform. No other questions are permitted and a hospital cannot require that an individual reveal his or her disability, or provide proof of such disability.⁸⁷

Granting and limiting animal access to health care facilities

Many health care providers understandably have concerns related to disease prevention when considering allowing animals into the health care space. Although there may be some question of bacteria associated with service animals, a report by the Centers for Disease Control and Prevention (CDC) titled *Guidelines for Environmental Infection Control in Health-Care Facilities* found that “[a]lthough animals potentially carry zoonotic pathogens transmissible to man, the risk is minimal with a healthy, clean, vaccinated, well-behaved and well-trained service animal . . .”⁸⁸ The CDC states that “[s]tandard cleaning procedures are sufficient following occupation of an area by a service animal.”⁸⁹ Of note, the ADA specifies that the place of public accommodation

84 FREQUENTLY ASKED QUESTIONS ABOUT SERVICE ANIMALS AND THE ADA.

85 *Id.*

86 *Id.*

87 28 C.F.R. § 35.136(f); *id.* § 36.302(c)(6).

88 Lynne Sehulster & Raymond Y.W. Chinn, *Guidelines For Environmental Infection Control In Health-Care Facilities: Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC)* (2003), available at www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines.pdf [hereinafter *Guidelines For Environmental Infection Control In Health-Care Facilities*].

89 *Id.*

or the public entity may not “impose a surcharge” on an individual with the disability to cover the costs associated with measures and modifications taken in order to provide the individual with nondiscriminatory treatment. A health care provider cannot, for example, charge a patient a cleaning fee for bringing his or her service animal to an appointment.⁹⁰ On the other hand, CDC guidance does identify a larger concern regarding transmission of disease and infection control when it comes to other types of animals and therefore recommends denying access to certain exotic service animals such as reptiles and non-human primates,⁹¹ even if the reptile or non-human primate is a service animal.

While hospitals and health care facilities are required by law to permit service animals in the facility, limiting access to certain areas is permissible where necessary and appropriate in the same way human access is limited. The CDC guidance notes that “[e]xcluding a service animal from an [operating room] or similar special care areas (e.g., burn units, some [intensive care units], [pulmonary embolism] units, and any other area containing equipment critical for life support) is appropriate if these areas are considered to have ‘restricted access’ with regards to the general public.”⁹² If for example a patient’s husband or mother is not typically allowed in the operating room because of increased risk of infection, a service dog may also be prohibited from entering those areas of the hospital.⁹³ In *Branson v. West*,⁹⁴ a physician’s request to use her service animal to pull her wheelchair and perform other tasks for her at the hospital was denied. The physician asked that the service dog “accompany her wherever she went in the hospital, including on her work duties and routine socializing, with the exception of highly sensitive areas such as operating rooms and intensive care units.”⁹⁵ The court ruled that, absent evidence that this would require any financial expenditure or change to hospital operational policies, no reasonable trier of fact could conclude that the service dog was not a reasonable accommodation.

90 28 C.F.R. § 35.130(f); *id.* § 36.301(c); SERVICE ANIMALS AT THE DOCTOR’S OFFICE.

91 *Guidelines for Environmental Infection Control in Health-Care Facilities*.

92 *Id.*

93 *Id.*

94 *Branson v. West*, No. 97 C 3538 (N.D. Ill. 1999).

95 *Id.*

Similarly, in *Day v. Sumner Regional Health Systems*,⁹⁶ the court recognized one's right to a service animal unless the animal created a significant risk to the health or safety of others that could not be eliminated. In *Day*, the patient asked to have her service animal accompany her into the emergency room. The hospital refused and instead treated the patient in the lobby of the Emergency Department. Unable to hold as a matter of law that "allowing Day's service animal into the treatment area posed an actual risk or direct threat to health and safety," the court refused to dismiss her claim.⁹⁷

In addition to limiting a service animal's access based on infection concerns, hospitals and providers may limit access due to safety concerns. For example, a hospital may ask an individual with a disability to remove his or her service animal from the premises if the owner/handler is unable to control the animal or if the animal is not housetrained.⁹⁸ In the case of *Roe v. Providence Health Systems*,⁹⁹ the hospital staff requested that a patient remove her service dog because of its putrid odor that may have indicated a risk of infection, the dog's growling and blocking staff access to the patient, and staff allergic reactions. The hospital had tried using a HEPA filter, shutting the door to the patient's room, and assigning allergic staff to alternative duties. The court concluded the hospital did not violate the ADA given the hospital's legitimate concerns about the animal posing a significant risk to the health and safety of patients, visitors, and staff. According to the court, the hospital had proved the elements of its affirmative defense by showing that the direct threat could not be eliminated by modification of policies, practices, or procedures.

If a service animal is properly excluded, the hospital must provide the patient with the opportunity to receive care without the service animal present.¹⁰⁰ These exceptions are particularly challenging in the context of hospital visits because a hospital environment may cause an otherwise well-trained service dog to act out due to anxiety or concern for the patient. Because the hospital is not responsible for handling the service animal, the animal is only

96 *Day v. Sumner Reg'l Health Sys.*, No. 3:07-0595 (M.D. Tenn. 2007).

97 *Id.*

98 FREQUENTLY ASKED QUESTIONS ABOUT SERVICE ANIMALS AND THE ADA.

99 *Roe v. Providence Health Sys.* – Or., 655 F. Supp. 2d 1164 (D. Or. 2009).

100 28 C.F.R. § 35.136(c); *id.* § 36.302(c)(3).

permitted in the hospital if it remains under the control of the patient or designated handler.¹⁰¹

Best practices for bringing an animal into a facility

Generally, a service animal should be allowed to accompany its handler to areas of the facility where health care personnel, patients, and visitors are permitted without taking added precautions. The authors recommend that health care providers develop a service animal policy and provide education to staff on (i) what constitutes a service animal under the law; (ii) what questions may be asked about the service animal; and (iii) when a service animal may be excluded from the facility or certain areas of the facility.

Conclusion

Numerous federal and state laws and regulatory agencies are focused on ensuring that individuals with disabilities can access services, including health care services, in the same manner as those who do not have disabilities. As we continue developing new cultural expectations and norms—whether they be increased utilization of technologies and web-based services or identifying more ways in which animals can support individuals with disabilities—health care providers will need to understand the legal expectations for accessibility and make necessary adaptations to the services offered by their own practices. **J**

101 FREQUENTLY ASKED QUESTIONS ABOUT SERVICE ANIMALS AND THE ADA.



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Reasonable Limits on Antitrust Liability for Reverse Payment Patent Settlements

Peter A. Hecker

In litigation between drug manufacturers, a patent-holder may end the case by paying the infringer of its patent. Settlements of this nature are known as “reverse payment patent settlements.” They seem strange because under normal circumstances, the infringer pays the patent-holder to end a patent infringement lawsuit. Reverse payment patent settlements arise in the context of the Hatch-Waxman Act,¹ which creates unusual incentives and pressures for the parties involved.

In *F.T.C. v. Actavis*, the Supreme Court held that reverse payment patent settlements could violate antitrust law for being anticompetitive under rule of reason scrutiny.² In doing so, the high court overturned a circuit court ruling that reverse payment settlements could not violate antitrust law as long as they did not extend beyond the scope of the patent or result from sham litigation.³ The case involved a patent-holder paying generic drug companies millions of dollars to withdraw patent invalidation claims and delay market release of a generic version of AndroGel® until a few years before the patent expired.

1 Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984), available at www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf.

2 *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013) [hereinafter *Actavis*].

3 *Id.* at 2238 (reversing and remanding *F.T.C. v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012)).

The Hatch-Waxman Act was intended to increase the number of generic drugs competing with brand-name innovator drugs. In *Actavis*, the court held that the “general procompetitive thrust” of the Act supported its decision to apply antitrust scrutiny to reverse payment patent settlements.⁴ Essentially, the *Actavis* court determined that because the Act was intended to incentivize competition among drug companies, not playing within the rules—e.g., paying millions to competitors so that they withdraw claims and delay release of generic versions—could be anticompetitive. This reasoning may be persuasive, but creating antitrust liability for agreeing to delay marketing of a drug while a patent exists goes beyond the Act’s purpose.

It has been predicted that post-*Actavis* courts will apply a modified version of the rule of reason that presumes antitrust liability at the outset,⁵ and some courts have interpreted *Actavis* to presume antitrust liability merely from a large, unexplained settlement payment.⁶ This Brief Insight argues that the procompetitive thrust of the Act should not be used to presume *anti*-competitiveness under the rule of reason analysis prescribed by *Actavis*. The Hatch-Waxman Act created an artificial route for early generic drug competition, but without further action from Congress explicitly outlawing reverse payment settlements, courts should not assume Congress also intended to create antitrust liability for drug companies that pursue that route without bringing the matter to completion—i.e., without fully litigating the claim and without entering the generic drug into market. Rather, courts should consider the incentives naturally created by the Hatch-Waxman Act, and start with the assumption that it is reasonable for companies to rely on their constitutionally-created patent rights when negotiating settlements.

4 *Actavis*, at 2234.

5 Thomas F. Cotter, *FTC v. Actavis, Inc.: When Is the Rule of Reason Not the Rule of Reason*, 15 MINN. J. L. SCI. & TECH. 41, 43 (2014). For example, the *Actavis* court indicated that an unexplained large settlement would “suggest that the payment’s objective is to maintain supra-competitive prices” and avoid “what might have been a competitive market.” *Actavis*, at 2236.

6 See, e.g., *King Drug Co. of Florence v. Cephalon, Inc.*, 309 F.R.D. 195 (E.D. Pa. 2015), vacated and remanded sub nom. *In re Modafinil Antitrust Litig.*, 837 F.3d 238 (3d Cir. 2016), as amended (Sept. 29, 2016); *In re Cipro Cases I & II*, 61 Cal. 4th 116 (2015), reh’g denied (July 8, 2015).

The Hatch-Waxman Act and the Incentives It Creates

The Hatch-Waxman Act facilitates early challenges against innovator drug patents.⁷ The first generic drug applicant to certify under Paragraph IV that an approved drug's listed patents are invalid or not infringed upon by the new generic drug will receive 180 days of exclusivity during which the Food and Drug Administration (FDA) will refrain from approving any other generic versions.⁸

Paragraph IV certification is statutorily defined as an act of patent infringement.⁹ Within 45 days of a Paragraph IV certification being made, a patent-holder must bring suit to assert its patent against the “infringing” generic drug company to delay approval of the generic drug for up to 30 months.¹⁰ If the patent-holder does not bring suit within the 45-day period, the FDA may approve the generic drug immediately.

In this scenario, the generic company has little to lose because no damages will be awarded if it loses the suit. On the other hand, the innovator company is not driven by the usual monetary damage awards available in most suits, but is instead induced by the Act to bring its own suit within 45 days to assert its patent and delay approval of the generic drug, which is opposite of the typical patent case where a patent-holder sues an infringer for damages.¹¹ The Supreme Court has noted the “highly artificial” nature of this situation.¹²

The artificial nature of Paragraph IV certification leads to unintended consequences. While the Act requires patent holders to file suit within 45 days, it does not require the parties to *remain* in litigation until the questions of patent validity and infringement are fully decided. The innovator company

7 Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353, 1356 (Fed. Cir. 2008).

8 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (5)(B)(iv).

9 35 U.S.C. § 271(e)(2)(A).

10 21 U.S.C. § 355(j)(5)(B)(iii).

11 See Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On “Probabilistic” Patent Rights and False Positives*, ANTITRUST 68, 69–70 (2003), available at www.jonesday.com/files/Publication/795d0f33-6127-461b-809f-c4ff08aabe16/Presentation/PublicationAttachment/d2c9acfd-d891-49f2-9d01-c330f5c5382b/hatchwaxman.pdf.

12 See, e.g., *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

may naturally find it is advantageous to pay the generic company to withdraw its generic drug application and patent invalidation claim until the patent expires. The patent-holder also may offer more money than the generic company would make selling its generic drug because the patent-holder would lose more in lost sales during the patent term than the generic company would make on selling its generic version.

Did Congress Intend to Create Anticompetitive Liability?

This Brief Insight argues that companies that enter into reverse payment patent settlements are merely following the natural path created by the Hatch-Waxman Act and should not be punished for it. The Hatch-Waxman Act was intended to promote competition; however, this does not mean a company's behavior is anticompetitive if the Act's intended process—fully resolving questions of patent validity and infringement—is not followed.

Further, the Hatch-Waxman Act artificially creates new competition by facilitating early challenges to patentability and infringement. This competition is artificial because without these early patent challenges in which generic drug companies cannot be sued for damages, generic drug companies would be less willing to enter the market. It is inaccurate to assume that Congress intended to hold companies liable if they choose not to compete where the would-be competition is artificially created by the Act.

If a generic company embarks on Paragraph IV certification fully intending to add a new generic drug to the market, but is then offered to discontinue its quest by the innovator company in return for a larger sum than it would otherwise obtain through the sale of its generic drug, both drug companies are simply reacting to pressures and following the incentives that will benefit them most. It is counterintuitive to assume Congress intended to *require* companies to compete by that process and yet, that is precisely what imposing antitrust liability on reverse payment patent settlers would do.

Overall, it is not clear if Congress intended that that companies pursuing Paragraph IV certification continue to the end of litigation. Encouraging

parties to settle rather than litigate is generally preferred,¹³ so it would be inaccurate to assume that Congress intended a different outcome—i.e. the parties litigating to the very end—without clearly stating so.

It assumes too much to say that Congress intended to hold liable those who pursue Paragraph IV certification but later decide to abandon the journey because incentives created by the Hatch-Waxman Act are more advantageous. As Justice Roberts said in dissent in *Actavis*, although “the point of these provisions is to encourage competition[,] . . . ‘no legislation pursues its purposes at all costs’ and that ‘it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute’s primary objective must be the law.”¹⁴ Courts applying a rule of reason analysis should therefore not assume Congress’s intent to create more competition makes reverse payment patent settlements unreasonable.

Congress Should Give Clear Notice if the Hatch-Waxman Act Should Trump Patent Rights

The procompetitive thrust of the Hatch-Waxman Act encourages generic drug companies to challenge innovators’ patents, but it does not explicitly deny patent rights. Patent rights are constitutionally mandated¹⁵ and the courts should not weaken them in the context of negotiated settlement agreements in the absence of clearly established Congressional intent. Courts applying the rule of reason from *Actavis* should remember that it is reasonable to choose not to enforce one’s patent during the patent’s term. For example, in *Actavis* the patent holder and generic drug companies had entered into a settlement agreement in which the generic drug companies agreed to withdraw their patent challenges and delay marketing a generic drug until a few years *before* the patent expired.¹⁶ Thus, the patent would have been active during the entire reverse payment settlement agreement. Normally a patent-holder has the right

13 See *Actavis*, at 2239 (Roberts, J., dissenting).

14 *Id.* at 2242 (Roberts, J., dissenting) (quoting *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987)).

15 U.S. CONST. art. I, § 8, cl. 8.

16 *Actavis*, at 2229.

to a monopoly during the term of its patent despite the existence of antitrust law, and can choose whether to enforce that monopoly.¹⁷

The *Actavis* court relied on statements by Senator Hatch and Representative Waxman to show an intent to specifically limit reverse payment patent settlements when Congress passed the 2003 amendments to the Hatch-Waxman Act.¹⁸ The 2003 amendments created a requirement that the terms of any Paragraph IV litigation settlement must be reported to the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice. However, stating that a bill is intended to deter companies from entering into reverse payment settlements and actually outlawing reverse payment settlements are very different matters. A mere requirement to *report* settlement agreements to the FTC does not deny the rights of patent-holders to enjoy the monopolies granted by their patents, even if those who sponsored the bill intended that result.

Regardless, the reporting requirement created by the 2003 amendments is compatible with an intent to deter only anticompetitive arrangements that go beyond the scope of patent rights. For example, if the settlement agreement in *Actavis* had required the generic companies to refrain from marketing generic versions of AndroGel® even *after* the AndroGel patent expired, then this would have been reported to the FTC and the FTC could have taken appropriate action. Such an agreement would likely be deemed illegal even in the pre-*Actavis* Eleventh Circuit because it would exceed the scope of the patent.¹⁹ The settlement agreement in *Actavis* did not, however, require the generic companies to refrain from marketing generic versions of the drug after the patent

17 *Id.* at 2239 (Roberts, J., dissenting) (citing HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 7.3, 7-13 – 7-15 (2d ed. 2010)).

18 *Id.* at 2234 (quoting 148 Cong. Rec. 14437 (2002) (remarks of Sen. Hatch) (“It was and is very clear that the [Hatch–Waxman Act] was not designed to allow deals between brand and generic companies to delay competition”); 146 Cong. Rec. 18774 (2000) (remarks of Rep. Waxman) (saying the amendments were intended to deter companies from “strik[ing] collusive agreements to trade multimillion dollar payoffs by the brand company for delays in the introduction of lower cost, generic alternatives”).

19 See *F.T.C. v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012), rev’d and remanded sub nom. *Actavis*.

expired.²⁰ Instead, the terms ended a few years before the patent expired, and while the reporting requirement would have made the FTC aware of this arrangement, it did not necessarily mean that the FTC should find that the arrangement violated antitrust law. Thus, although the terms of the *Actavis* court did not go beyond the scope of the relevant patent, the reporting requirement created by the 2003 amendments enabled the FTC to detect reverse payment settlements that do.

Even if a few members of Congress wanted the Hatch-Waxman Act to deter all reverse payment patent settlements rather than only anticompetitive arrangements that extend beyond the scope of a relevant patent, it would be improper to impute that intent to the entire legislature that passed the bill unless that intent was included in the language of the statute itself.

It is not even dispositive that a statement was made by an author or sponsor of a bill. For example, Giles Rich coauthored the Patent Act of 1952 and held (as a member of the U.S. Court of Customs and Patent Appeals) that the new § 103 obviousness requirement replaced old non-statutory patent doctrines.²¹ However, rather than deferring to Judge Rich, the Supreme Court held that the new § 103 obviousness requirement codified, instead of replaced, the old doctrines.²² Likewise, statements by Senator Hatch and Representative Waxman are not necessarily authoritative or representative of the entire Congress. Rather, the collective intent of the group that passed the bill is made manifest by the language of the statute itself.

Congress Has the Ability to Create Antitrust Liability If It Wants To

Congress has the ability to charge those who engage in reverse payment patent settlements with antitrust liability. Several bills have been introduced that

20 *Actavis*, at 2229.

21 *In re Gustafson*, 331 F.2d 905, 909 (C.C.P.A. 1964); Peter A. Hecker, *How an Old Non-Statutory Doctrine Got Worked into the § 101 Test for Patent Eligibility*, 99 J. PAT. & TRADEMARK OFF. SOC'Y 4, 8–9 (2016).

22 *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 3–4 (1966).

would explicitly create antitrust liability for those who engage in reverse payment patent settlements, but none of them has been passed.²³ In fact, Congress has successfully amended the Hatch-Waxman Act in the past and considered reverse payment patent settlement issues when making those amendments. When introducing the 2003 amendments, Representative Waxman cited reverse payment settlement agreements as a reason for the bill.²⁴ Congress was therefore aware of these settlements and their related issues, but chose not to attribute antitrust liability to those who entered into them. This suggests that Congress intended to allow reverse payment patent settlements to occur. Thus, courts considering antitrust liability in reverse payment patent settlement cases should not assume Congress intended to create liability where it did not.

Conclusion

Congress's goal in establishing the Hatch-Waxman Act was to create more generic drug competition, and the Act has been successful in doing so.²⁵ That some companies choose to wait until applicable patents expire instead of completing Paragraph IV litigation should not be considered unreasonable by courts applying rule of reason scrutiny. ■

²³ *Actavis*, at 2242 (Roberts, J., dissenting).

²⁴ *Id.* (quoting 146 Cong. Rec. 18774 (2000) (remarks of Rep. Waxman)).

²⁵ Garth Boehm et al., *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 298 (2013).



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Cybersecurity Report Identifies Unique Challenges to Tackling Cybersecurity in Health Care

Deborah R. Farringer

After a year of deliberation, the Health Care Industry Cybersecurity Task Force (Task Force) issued a report regarding the preparedness of the health care industry to respond to ever increasing cybersecurity threats.¹ Formed under Section 1533 of the Cybersecurity Information Sharing Act of 2015 (CISA),² the Task Force was charged with examining cybersecurity risks specifically within the health care industry and further identifying who will lead and coordinate efforts, how divisions and subdivisions³ will divide responsibilities, and how they will communicate amongst one another.⁴

With increasing incidents of large-scale data breaches due to hacking and growing occurrences of ransomware attacks across all industries, the U.S. Congress enacted the CISA to encourage the sharing of cyber threat information across various sectors in an effort to thwart, or at least diminish, the

1 HEALTH CARE INDUS. CYBERSECURITY TASK FORCE, REPORT ON IMPROVING CYBERSECURITY IN THE HEALTH CARE INDUSTRY (June 2017), available at www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf [hereinafter REPORT].

2 Cybersecurity Information Sharing Act (CISA) was passed as part of the Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, 129 Stat. 2242 (Dec. 18, 2015).

3 HHS has eleven operating divisions, eight agencies within the U.S. Public Health Service, and three human services agencies. For a complete list, see *HHS Agencies & Offices*, HHS.gov, www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html (last visited July 3, 2017).

4 6 U.S.C. § 1533(b).

incidence of data breaches. While the sharing of information under the CISA is entirely voluntary, the CISA encourages sharing by preempting existing laws that stood as a barrier towards sharing by making such sharing ostensibly illegal, including privacy laws such as the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH).⁵ Realizing the complexity and unique challenges of the health care industry, the Task Force brought together experts from various areas of the industry, including members who represent hospitals, insurers, patient advocates, security researchers, pharmacy and pharmaceutical companies, medical device manufacturers, health information technology developers and vendors, and laboratories.

Issued on June 5, 2017, the [96 page report](#) identifies threats to the industry and provides a number of recommendations, along with accompanying action items, for what can be done to ensure the security of patient data and electronic health systems. The report acknowledges from the start that certain aspects of the industry are challenging. Regardless, the report states unequivocally that “health care cybersecurity is a key public health concern that needs immediate and aggressive attention.”⁶

Among the challenges, the report identifies the following potential barriers: the expense of in-house information security personnel or IT staff; lack of infrastructure related to identification, tracking, and ability to prevent threats; lack of information regarding new technology threats; unsupported legacy systems (replete with vulnerabilities); lack of awareness regarding vulnerability; and historic low prioritization of cybersecurity. In response, the report identifies what it refers to as “six high-level imperatives by which to organize its recommendations and action items . . . :

1. Define and streamline leadership, governance, and expectations for health care industry cybersecurity.
2. Increase the security and resilience of medical devices and health IT.

5 The Privacy Rule and Security Rule are combined in the HIPAA Administrative Simplification Regulations found at 45 C.F.R. §§ 160, 162, and 164.

6 REPORT, at 2.

3. Develop the health care workforce capacity necessary to prioritize and ensure cybersecurity awareness and technical capabilities.
4. Increase health care industry readiness through improved cybersecurity awareness and education.
5. Identify mechanisms to protect research and development efforts and intellectual property from attacks or exposure.
6. Improve information sharing of industry threats, weaknesses, and mitigations.⁷

In preparation for the report, the Task Force consulted with sectors in the financial services, transportation, and energy industries. While there were some similarities, the Task Force quickly realized that health care organizations could not adopt wholesale any of these approaches due to existing infrastructure challenges. In addition, the “unique culture” of health care,⁸ the manner in which the industry has adopted a digital platform, the complicated regulatory environment of the industry, the exceedingly variable size (and wealth capacity) of organizations, the vast amounts of patient data collected purposes unrelated to patient care, and the complex reporting vulnerabilities and breaches all serve as major barriers and reasons why the health care industry is unlike any other industry when it comes to combatting cybersecurity.

What then does the report recommend for health care entities given all of these unique barriers? First and foremost, the Task Force believes that the health care sector requires its own single source for sharing cybersecurity threats and a single reporting framework. The health care industry is simply too complex and too distinct from other industries to contemplate that cybersecurity could be addressed by a leader or frameworks across multiple industries. Importantly, the report identifies the Stark Law and the Anti-Kickback Statute as potential barriers to success and “strongly encourage[s]

⁷ *Id.* at 21.

⁸ *Id.* at 9. The report characterizes the culture as both a benefit because sharing information is already a vital and primary part of the culture of health care, and also a hindrance because the need for rotating staff to immediately access data on a 24/7 basis make the protection of such data difficult in clinical environments.

Congress to evaluate an amendment to these laws specifically for cybersecurity software that would allow health care organizations the ability to assist physicians in the acquisition of this technology, through either donation or subsidy.”⁹ Other specific recommendations include securing legacy systems; increasing lifecycle (from concept generation through disposal) security for electronic health records and medical devices; increasing training and education; establishing a Medical Computer Emergency Readiness Team; increasing IT staffing; creating more low-cost shared-savings program models to encourage more interface and collaboration across organizations; developing more assessment and evaluation tools; dedicating more research and development in this area; and simplifying and tailoring information for easier consumption when sharing.

The number of recommendations and the various areas for increased readiness makes it clear that cybersecurity in the health care sector will not be an easy task. Implementation will be extremely difficult to coordinate; the report makes clear that no one sector of the industry can begin the process of increasing readiness on its own. The report calls on lawmakers and policymakers, including the U.S. Congress and Centers for Medicare & Medicaid Services (CMS), to change laws and regulations to enable greater integration and provide greater protections. The report also calls on health care IT vendors to make certain improvements and updates regarding security of existing systems and legacy systems, medical device manufacturers to make improvements to existing devices to provide better security and integration, and providers and suppliers (among others) to increase training and IT support and dedicate more resources to achieve the constant vigilance required for cybersecurity.

Indeed, part of what the Task Force identified as why the health care industry needs a different approach to cybersecurity than in other industries—namely the complexity of the health care industry and its existing infrastructure—creates challenges in implementation of an effective cybersecurity response. Given that reality, what is the take away for anxious hospital administrators or insurance executives trying to figure out how best to prevent the next ransomware attack or massive medical records data breach? First, imple-

⁹ *Id.* at 27.

mentation will require significant time and resources. Health care entities will need to acknowledge and plan for the “new normal” to include a robust IT staff and a larger percentage of the budget dedicated to maintenance and operation of electronic health records. Additionally, there must be a more concerted effort on the part of entities across the industry to think about IT and cybersecurity, approaching the challenge not as an individual issue—how can I protect *my* data—but as a coordinated effort. Entities will have to work together to make necessary structural and technical changes and adjustments and, given the current political environment, may have to make those changes independent of legal and regulatory amendments. The report is a helpful tool for identifying the areas that will require attention, but the difficult task of industry working across sectors to try to implement change has just begun. **J**



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