AHLA

VOLUME 17 ISSUE 2 November 2015

Health Care Liability & Litigation

A Publication of the American Health Lawyers Association
Health Care Liability and Litigation Practice Group

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Thank You to Rebekah Plowman

The Health Care Liability and Litigation Practice Group (PG) would like to take this opportunity to express its gratitude to Rebekah Plowman (Jones Day, Atlanta, GA), who served so well as chair of our PG over the past three years. Rebekah is a tireless advocate for AHLA, and her work on behalf of the PG has been invaluable. Under Rebekah's leadership, our PG membership grew significantly, and she advocated for and led programming and educational opportunities specifically designed to attract those involved and interested in health care litigation. All of those who have had a chance to work with Rebekah have benefited from her friendship, guidance, and leadership. We all look forward to the next leadership opportunity Rebekah has with AHLA.

Sincerely,

Health Care Liability and Litigation PG Leadership

The False Claims Act Coming Soon to Marketplaces Near You

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This summer brought two U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) reports and one U.S. Government Accountability Office (GAO) investigation which individually and collectively revealed that the processes behind subsidies provided to millions of Americans through the Affordable Care Act (ACA) lacked sufficient internal controls to assure that the public fisc was not defrauded of billions of dollars. At least one of the OIG reports revealed that the Centers for Medicare & Medicaid Services (CMS) was relying on the certifications made by private insurance companies, referred to as Qualified Health Plan (QHP) issuers, that the advance premium tax credit (APTC) subsidies were accurate and that the beneficiaries were eligible for the subsidies. Although the OIG report was quick to point out that their audits did not mean the subsidies were improper, the report's specific findings included examples

demonstrating that the amounts paid out were more than the beneficiary was entitled to receive. CMS' reliance on the issuers' certification could spell False Claims Act (FCA) liability for private insurance companies for the simple reason that false statements, in the form of certifications, clearly fall within the ambit of the FCA.

OIG Reports and GAO Testimony

A June 2015 OIG report found that "CMS's internal controls, (i.e., processes in place to prevent or detect any possible substantial errors) did not effectively ensure the accuracy of nearly $2.8 billion in aggregate financial assistance payments made to insurance companies under the ACA during the first 4 months that these payments were made."[1] The report specifically found that CMS:

- Relied on issuer attestations that did not ensure that advance cost-sharing reduction (CSR)[2] payment rates identified as outliers were appropriate;
- Did not have systems in place to ensure that financial assistance payments were made on behalf of confirmed enrollees in the correct amounts;
- Did not have systems in place for state marketplaces to submit enrollee eligibility data for financial assistance payments; and
- Did not always follow its guidance for calculating advance CSR payments and does not plan to perform a timely reconciliation of these payments.[3]

Based on what OIG identified as "internal control deficiencies," it concluded that CMS was limited in its "ability to make accurate payments to QHP issuers."[4]

With respect to the subsidies paid out as APTCs,[5] OIG concluded that because CMS obtained APTC payment data directly from the QHP issuers on an aggregate basis only, CMS was unable to verify the amounts requested from the QHP issuers' attestations on an enrollee-by-enrollee basis.[6] OIG found that CMS' lack of internal controls prevented it from being able to ensure that APTC payment amounts were appropriately applied on behalf of eligible beneficiaries.[7] Collectively, OIG noted that approximately $2.8 billion in federal funds were at risk without effective internal controls that would ensure financial assistance payments were calculated and applied correctly.[8] Finally, OIG noted that "CMS had the authority to (1) require QHP issuers to restate enrollment totals and payment amounts for prior months to reflect prior inaccurate payments and (2) recoup these payments by offsetting them against future payments *or other means*."[9]

More specifically, according to the OIG report, CMS relied on issuer attestations to ensure that advance cost-sharing payment rates identified as outliers were reliable.[10] Additionally, CMS relied on QHP issuers to submit beneficiary enrollee and payment information in the aggregate, rather than on an enrollee-by-enrollee basis, and then relied on the issuers' attestations that the payments issued by CMS were applied to the appropriate enrollees.[11] Although the OIG report noted that CMS is testing a pilot program to enable CMS to obtain individual enrollment data, it concluded that, "even when this system is fully implemented, CMS stated that QHP issuers will continue to be its source for confirming enrollment data."[12]

Further compounding the risk to insurance companies is an August 2015 report issued by OIG[13] which found that "not all of the federally facilitated marketplace's internal controls were effective in ensuring that individuals were determined eligible for enrollment in qualified health plans and eligible for insurance affordability programs according to the Federal requirements."[14] More specifically, OIG found that the marketplace's controls were not effective in properly verifying annual household income and family size.[15] OIG concluded that without properly verifying an applicant's eligibility, the federal marketplace could not ensure the applicant meets eligibility requirements for insurance affordability programs, nor that the amounts of the APTC and CSRs are determined correctly.[16] In two examples identified in the August report, OIG found that the amounts of the subsidies may have been higher than the applicant was eligible to receive, and in one case the applicant may have been eligible for Medicaid and not at all eligible for the APTC.[17]

Similarly, in testimony before Congress, GAO Director of Forensic Audits and Investigative Service Seto J. Bagdoyan presented the results of an undercover investigation testing the marketplace's approval of subsidized coverage under the ACA.[18] For 11 of 12 fictitious GAO applicants, the marketplace approved subsidized coverage for a total of $30,000 in annual APTCs.[19] The marketplace also automatically re-enrolled coverage for all 11 fictitious enrollees for 2015[20] and, although it later terminated six of those enrollees based on the failure to provide the necessary documentation, it subsequently reinstated five of those terminated enrollees and increased the PTC subsidies.[21]

FCA Implications for QHP Issuers

The ACA established health insurance exchanges, referred to as marketplaces, to allow individuals and small businesses to shop for insurance and similarly allow insurance companies (issuers) to offer individual private health insurance plans, known as QHPs, and enroll individuals in those plans.[22] CMS operates the federal marketplace and is responsible for reviewing, approving, and generating financial assistance payments, known as advance premium tax credits and advance CSRs, for both the federal and state-based marketplaces.[23] Under what is described as an interim process, CMS requires QHP issuers to submit attestation agreements certifying that all template information is accurate and in compliance with federal policies and regulations before CMS processes payments to the QHPs issuers.[24] As stated

above, CMS has been relying on these issuer attestations to ensure that advance cost-sharing payment rates identified as outliers are reliable and that the payments issued by CMS are applied to the appropriate enrollees.[25]

The FCA prohibits the knowing submission of, or the making of a material false record or statement to secure the payment of, a false or fraudulent claim from the federal government.[26] The application of the FCA to APTCs used to fund an individual's premiums is clearly set forth in the ACA. Indeed, in connection with exchange provisions in the ACA, Congress included express financial integrity provisions to apply civil FCA liability for "[p]ayments made by, through, or in connection with an Exchange . . . if those payments include any [f]ederal funds."[27] As both the two OIG reports and the GAO testimony make clear, not only are APTCs made from federal funds in connection with both the federal and state exchanges, but they are issued by CMS in reliance on the statements of the private insurance plans.

Moreover, the June 2015 OIG report noted that during the four payee group-months audited, CMS did not calculate advance CSR payments using the number of confirmed enrollees reported on issuers' templates, but rather based its payments on the amount of advance CSR payments requested by the issuers. The OIG report also noted that QHP issuers were having difficulty upgrading their systems and producing credible data to reconcile the advance CSR payments to actual amounts, causing CMS to postpone reconciling advance payments until April 2016.[28] Although the postponement provides insurance companies with the opportunity to upgrade their systems, it does not insulate the insurance companies from what OIG concludes is a "significant amount of Federal funds at risk."[29]

Although in the health care sector most FCA cases arise from the submission of an individual claim, there have been an increasing number of FCA cases brought under false certification theories. False certification liability arises in the context of an express or an implied certification. The express false certification theory arises when the entity submitting the claims expressly certifies compliance with the legal requirements imposed by a statute or regulation.[30] The certification may be submitted with the claim for payment or at some other time.

An implied false certification theory arises when the entity submitting the claims implicitly certifies that it has complied with all applicable legal requirements each and every time a claim is submitted.[31] Prior to the processing of any cost-sharing payments, CMS requires the QHP issuers to submit attestations stating that the information submitted was accurate and in compliance with federal policies and regulations. Thus, absent reconciliation, insurers could be liable under either theory of false certification for payments made to them but for which the applicant was either: (1) ineligible or (2) received APTCs in excess of what the applicant was entitled to receive.

Of course, FCA liability does not arise merely on the basis that CMS may have overpaid. Another relevant factor for FCA liability is the element of materiality, particularly under the false statement provisions of the FCA. Specifically, the FCA provides that liability attaches to false statements only if the false statement is material to a false or fraudulent claim.[32] Materiality is defined under the FCA as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[33] As highlighted in the June OIG report, CMS required QHP issuers to submit confirmed enrollee and payment information and relied on issuers to "attest that payments were applied to the appropriate enrollee."[34] CMS' reliance on the issuer's attestation is even greater in the state marketplaces. Indeed, the June OIG report said that although CMS maintains initial enrollment and payment information for QHP issuers in the federal marketplace, in the state marketplaces it "must rely exclusively on issuers to attest to enrollee eligibility for financial assistance."[35] Thus, absent a knowledge defense, it may be difficult for QHP issuers to avoid FCA liability should an investigation reveal that the APTC payments should not have been made and the QHP issuer knew, or should have known, that the payment should not have been made.

On this point the QHP issuers, depending on the circuit, may have a defense. At least three circuits have held that prior government knowledge and approval may prevent the government from establishing the necessary element of "knowledge."[36] For example, the Tenth Circuit in *U.S. ex rel. Burlbaw v. Orenduff* held that the government's authorization of a false claim having possessed knowledge of the facts underlying the claim provides an inference that the defendant did not knowingly present a false claim.[37] Although this defense is available only in case law, the facts on which CMS has issued payments suggest that this defense would be appropriate. Indeed, the OIG reports make clear that CMS is aware its internal controls are ineffective in ensuring accurate eligibility data is available to the QHP issuers and that QHP issuers do not currently possess systems sufficient to produce credible data to reconcile advance CSR payments to actual amounts.

Notwithstanding this defense, and although insurers may take some comfort in the fact that CMS is not currently able to reconcile advance CSR payments, it is important to consider that CMS has only postponed the reconciliation process. As federal budgets tighten and debt spirals out of control, a less ACA-friendly administration may look to private insurers as a deep pocket. In light of CMS' reliance on the attestations of QHP issuers and the fact that the initial reports show significant deficiencies in the information obtained and verified in the marketplaces, insurers would be well served to evaluate the accuracy of the eligibility information associated with their enrollees prior to the anticipated 2016 reconciliation process.

1 HHS OIG Report, *CMS's Internal Controls Did Not Effectively Ensure The Accuracy of Aggregate Financial Assistance Payments Made to Qualified Health Plan Issuers Under the Affordable Care Act* (Aggregated Financial Assistance Payments Made Under the Affordable Care Act) (A-02-14-02006) (June 2015), Executive Summary at page 9.
2 Cost-sharing reductions "assist certain low-income enrollees with their out-of-pocket costs." *Id.* at ii. "The Federal Government makes an advance monthly CSR payment to QHP issuers to cover the issuers' estimated CSR costs." *Id.*
3 *Id.*
4 *Id.*
5 APTCs are advance payments of premium tax credits. APTCs assist certain low-income enrollees with the cost of their premiums. *Id.*
6 *Id.* at 9.
7 *Id.*
8 *Id.* at 10.
9 *Aggregated Financial Assistance Payments Made Under the Affordable Care Act* (A-02-14-02006), Executive Summary, page iv (emphasis added); p. 10 and MOU Between IRS and CMS, CMS control number MOU 13-150 (effective January 31, 2013); and 45 CFR §§ 156.430(d) and (e).
10 *Aggregated Financial Assistance Payments Made Under the Affordable Care Act* (A-02-14-02006) at 10.
11 *Id.* at 12.
12 *Id.* at 16.
13 *Federally Facilitated Marketplace's Internal Controls Under the Affordable Care Act* (A-09-14-01011).
14 *Id.* Executive Summary at iv.
15 *Id.* at 13.
16 *Id.*
17 *Id.* at 15-16 and 18.
18 *Observations on 18 Undercover Tests of Enrollment Controls for Health-Care Coverage and Consumer Subsidies Provided Under the Act* (GAO-17-702T).
19 *Id.* at Executive Summary.
20 *Id.* According to CMS data, about 11.7 million people obtained a health insurance plan under the ACA and 87% of those using the HealthCare.gov system qualified for the PTC subsidy. *See id. at* 1.
21 *Id.*
22 *Aggregated Financial Assistance Payments Made Under the Affordable Care Act* (A-02-14-02006), Executive Summary at i.
23 *Id.*
24 *Id.* at ii.
25 *Id.* at 10 and 12
26 31 U.S.C. § 3729(a).
27 42 U.S.C. § 18033(a)(6).
28 *Aggregated Financial Assistance Payments Made Under the Affordable Care Act* (A-02-14-02006) at 15.
29 *Id.*
30 *See United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.* 543 F.3d 1211 (10th Cir. 2008) and *Mikes v. Straus* 274 F.3d 687 (2nd Cir. 2001).
31 *See U.S. ex rel. Mikes v. Straus,* 274 F.3d 687, 700 (2nd Cir. 2001) (Although recognizing the implied certification theory, the Second Circuit required that the underlying statute, regulation, or contractual provision expressly condition payment on compliance with the applicable statute, regulation, or contractual provision).
32 31 U.S.C. § 3729(a)(1)(B).
33 31 U.S.C. § 3729(b)(4).
34 *Aggregated Financial Assistance Payments Made Under the Affordable Care Act* (A-02-14-02006) at 12.
35 *Aggregated Financial Assistance Payments Made Under the Affordable Care Act* (A-02-14-02006) at 13.
36 *See U.S. ex rel. Burlbaw v. Orenduff*, 548 F3d 931 (10th Cir. 2008), *U.S. ex rel. Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037 (9th Cir. 2012) and *U.S. ex rel. Ubl v. IIF Data Solutions*, 650 F.3d 445 (4th Cir. 2011).
37 *U.S. ex rel. Burlbaw v. Orenduff*, at 548 F.3d 931, 952-52 (10th Cir. 2008); *see also, U.S. ex rel. Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1050-51 (9th Cir. 2012) and *U.S. ex rel. Ubl v. IIF Data Solutions*, 650 F.3d 445, 452-53 (4th Cir. 2011).

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Insurance Coverage for Health Care Cyber Risks

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Introduction

Data privacy and cybersecurity issues have skyrocketed in importance for health care organizations over the past few years. In that time, providers and vendors have widely adopted electronic health record (EHR) systems, with new requirements to establish and upgrade data systems to comply with privacy rules and regulations and enforcement mechanisms, in particular those implemented and overseen by the Health Insurance Portability and Accountability Act (HIPAA), as amended, and under the Health Information Technology for Economic and Clinical Health (HITECH) Act.[1] This changing data landscape has meant that providers now have far greater responsibility for maintaining compliance protocols and safeguarding the privacy and security of protected health information (PHI)—such as patient records. At the same time, the growing likelihood of a cyberattack or data breach of those records has grown exponentially, greatly expanding the potential liability for organizations.[2]

The resulting costs associated with a cyberattack or data breach could be enormous, and therefore insurance to pay for those costs should be a top consideration. For example, as reflected in The Ponemon Institute's "2014 Cost of Data Breach Study: Global Analysis," the average total cost of a data breach for the companies participating in [its] research [had] increased 15 percent to $3.5 million."[3] The study reported the average cost to a health care organization per record of a health care data breach is $459.[4] Those costs arise on multiple fronts, including but not limited to: repairing damaged or compromised software and hardware systems; reconstructing data;[5] the legal and forensics costs associated with investigating and reporting a data breach notification; reimbursing customers whose PHI was impacted and rebuilding relationships;[6] responding to government inquiries (including the risk of criminal or civil fines or penalties being assessed for HIPAA violations);[7] and defending against third-party lawsuits. A priority for any policyholder is to secure as much insurance coverage as possible to cover these costs.

Health care organizations and providers should begin with the assumption that there is coverage, even if insurers or brokers state otherwise. For example, the Omnibus Rule's provision for different degrees of culpability and penalty levels under HIPAA means that coverage for fines and penalties may not be excluded, even if it is sought for willful statutory damages.[8] Similarly, different levels of culpability under HIPAA mean that fraud exclusions may not apply. Coverage should be assumed, and not the inverse. To best position themselves for coverage, policyholders should evaluate their entire insurance program, ranging from cyber or HIPAA coverage, to traditional commercial or Directors & Officers (D&O) policies, and pursue a strategy for coverage under those policies. The below considerations highlight some of the complex issues that providers and vendors typically must consider in order to secure insurance coverage that will pay for defense and indemnity costs arising out of cyber issues.

Evaluate and Consider All the Company's Insurance Policies for Coverage of Both Defense and Indemnity Costs

Cyber Policies may Provide Certain Coverage

Cyber coverage is an evolving legal landscape. On the one hand, insurance carriers have developed a slew of new cyber insurance products, and have enlisted insurance brokers to sell those policies in response to the ever-increasing demand. These cyber-specific policies can provide excellent coverage. On the other hand, however, these policies often require considerable rewrites to achieve the desired result. Perhaps an even bigger problem is that insurers are denying coverage under cyber-specific policies as well.

Reliance on cyber coverage demands attention to certain provisions in particular. A recent California case, which was dismissed on other grounds, provides a cautionary tale for reliance on cyber coverage. In *Columbia Cas. Co. v. Cottage*

Health Sys., 2015 WL 4497730, at *1 (C.D. Cal. July 17, 2015) (dismissing for insurer's failure to pursue the alternative dispute resolution process before filing the lawsuit), an insurer sought to avoid its obligation to defend or indemnify a hospital health care system for providing coverage for a class action settlement or regulatory investigation arising out of a data breach that exposed PHI. The insurer disputed whether the insured followed cyber security requirements, invoking an exclusion for failure to follow minimum required cyber practices. Additionally, the insurer disclaimed its obligation on the premise that, under the policy—like many cyber policy forms—"fines and penalties" were not covered damages.

A cyber policy should be tailored to a health care provider's risks and should contain a sufficiently broad definition of "loss" in order to obligate the insurer to pay for damages paid in connection with a failure to comply with HIPAA (or analogous state) requirements. Also, a cyber policy should be tailored to a provider's usage of third-party vendors and of the "cloud," so that it covers the acts and omissions by third parties, or data in the custody of third parties.

CGL Policies Provide Coverage for Losses Arising from a Third-Party Claim

The fact that CGL policies sometimes include specific cyber exclusions is a strong indicator that current standard-form business insurance should not be overlooked and may provide coverage. The arguments for coverage of losses arising from a third-party claim or investigation under CGL coverage are simple and straight forward. Most General Liability policies contain a separate grant of coverage for "Personal and Advertising Injury." This grant affords coverage for any "[o]ral and written publication, in any manner, that violates a person's right to privacy."[9] Accordingly, if someone took private information, and released that to others, coverage should be provided.

Courts addressing coverage under CGL insurance policies for cyber liability have often found coverage.[10] Sometimes a court makes that determination based on whether the information actually was, or could have been, accessed.[11]

Two courts recently have found "publication" where patient information was posted on the internet and publicly available. In *Hartford Casualty Insurance Co. v. Corcino & Associates,* 2013 WL 5687527 (C.D. Cal. Oct. 7, 2013), the court found coverage for a hospital's loss arising out of two class actions alleging disclosure of patients' confidential medical records by "publication"—posting on a public website. Likewise, in *Travelers Indem. Co. of Am. v. Portal Healthcare Solutions, LLC*, 35 F. Supp. 3d 765, 770-71 (E.D. Va. 2014), a health care provider allegedly "failed to safeguard the confidential medical records of patients" where its third-party vendor responsible for the electronic storage and maintenance of those records made some patient records publicly accessible and available on the internet without any security restriction. By posting the information on the internet, there was a potential publication, triggering coverage for an underlying class action.

CGL Policies Provide Coverage for an Insured's Direct Losses

First-party commercial property coverage provides coverage for losses related to property damage and business interruption losses that result from a cyberattack or data theft.

For example, in *Lambrecht & Associates v. State Farm Lloyds*, 119 S.W.3d 16 (Tex. App. 2003), the court found coverage for the replacement costs for the insured's server, operating system, and data damaged by a hacker's computer virus attack. Similarly, in *Southeast Mental Health Center v. Pacific Insurance Co.*, 439 F. Supp. 2d 831 (W.D. Tenn. 2006), where a clinic lost electronic and telephone service as a result of storm damage, resulting in damage to the clinic's pharmacy computer and lost data, and plaintiff was forced to suspend operations, the court found coverage for the resulting loss of business income.

Other Policies may Provide Coverage

A provider or hospital system may have other insurance coverage contained within its insurance program that is tailored to cover losses specific to HIPAA compliance or violations or cyberattacks. For example, a policy provision that excludes coverage for losses arising from fines or penalties may specifically allow for coverage of "HIPAA penalties." A policy also may provide for coverage of the costs to notify patients, for forensic or investigation costs for a "HIPAA proceeding" or proceedings brought by a state attorney general under the HITECH Act, or other regulatory proceeding.

It is further possible that a policy may provide coverage for a third-party act or omission made by a vendor, or "business associate," who is maintaining or storing the data. Such a provision addresses the expanded liability imposed by recent amendments to HIPAA that would hold a provider liable for the violations of its outside vendor even if not aware of any pattern and practice of violations.[12]

Finally, it is possible that there also may be coverage for data losses under other insurance policies, such as D&O, Errors & Omissions, property, or crime policies. An example is a HIPAA subpoena that is simply part of an investigation brought pursuant to authorization under HIPAA, but not specifically related to violations for failing to comply with data security obligations in HIPAA. In that instance, a policyholder may secure coverage under its D&O policy providing for coverage of government investigations.

Pursue Coverage for Statutory Damages

Policyholders seeking coverage are often told by their insurance carriers that their insurance policy does not cover statutory damages. However, policyholders should not accept insurance company coverage denials that are based on an improper labeling of damages. Rather, policyholders should conduct a thorough analysis of policy language and damages alleged, and fight for all of the coverage to which they are entitled.

Damages may be Compensatory or Otherwise Covered

In order to avoid coverage, insurers may label damages as "restitution," or treat them as "punitive" in nature. They also may argue that such damages constitute an allegedly uncovered "fine or penalty." Yet, as recently illustrated, when insurance carriers are challenged on these denials, they are often proven wrong by the courts.[13]

The *Navigators* court held the errors and omissions insurance policy even covered statutory damages for willful violations, even though the policy excluded coverage for fines and penalties. In *Navigators*, it was alleged that the policyholder Sterling willfully violated the Fair Credit Reporting Act (FCRA) by providing false information to employers, who relied on that information to terminate the plaintiffs' employment. Sterling sought coverage under its policy, which covered all sums that the insured became legally obligated to pay as damages, but excluded fines and penalties. The insurer, Navigators, denied coverage and contended that the damages sought under FCRA were excluded penalties. Sterling disagreed and contended that the damages sought were not penalties, but were compensatory in nature.

Notably, the court reasoned that resolution of the coverage dispute depended on the interpretation of FCRA. Under FCRA, a plaintiff can seek either its actual damages or statutory damages between $100 and $1000 per violation, as well as punitive damages. The court noted that the underlying plaintiffs sought only statutory damages for willful violations. The court stated that, depending on the statute, such statutory damages can be compensatory, punitive, or both. Under FCRA, the court found for three reasons "that the statutory damages function primarily as compensation."[14] First, because "actual damages are compensatory, statutory damages that substitute only for those actual damages are also compensatory."[15] Second, statutory damages under FCRA are designed to provide a remedy when actual damages are difficult to calculate. Finally, the court noted that the statute provided a separate remedy for punitive damages, so the other damages sought are more logically considered to be compensatory. The policy provided coverage because damages were compensatory in nature. Hence, they were not subject to the fines or penalties exclusion as Navigators contended.

Similarly, what also matters is determining whether the damages are remedial or compensatory in nature. Courts determining coverage under traditional policies while evaluating how to classify monetary payments due under statutes have looked to the intent behind the remedy and whether the payment is remedial or compensatory in nature. For example, in *Universal Underwriters Insurance Co. v. Lou Fusz Auto Network, Inc.*, 401 F.3d 876 (8th Cir. 2005), the court addressed whether required payments under the Telephone Consumer Protection Act (TCPA) for damages for each separate violation constituted damages where the garage liability policy at issue specifically excluded coverage for fines and penalties. Because the TCPA was meant to be both punitive and remedial, and the payments contained some remedial nature, they were not "penalties," and the court found there was coverage.[16] Similarly, in *Visa Inc. v. Certain Underwriters at Lloyds, London*, 2012 WL 10161619 (Cal. Super. Jan. 6, 2012), a California court held, in an order denying the insurer's motion for judgment on the pleadings, that the statutory damages under the California Invasion of Privacy Act were not "penalties" or "sanctions."

Structure Settlement so Damages Are Properly Characterized for Coverage

The characterization of any damages is particularly important because if they can be characterized as compensatory, they may be covered. Additionally, for HIPAA matters under the new Omnibus Rules, providers may be required to pay even if they had no knowledge of a violation.[17] What this means is that settlement amounts that might previously have been excluded from coverage as fines or penalties for intentional or willful conduct might now be covered. Moreover, many states have held that it is not against public policy for an insurance carrier to pay for fines and penalties. Finally, certain portions of a settlement, such as plaintiffs' attorneys' fees, are traditionally considered covered by insurers. For these reasons, policyholders should keep in mind insurance coverage at all stages of underlying investigations or litigation.

Conclusion

In most cyberattack or data breach situations, there are good arguments that coverage is triggered, and that is often the case under traditional CGL policies. Courts are generally aligned in favor of coverage if data was disseminated to third parties. Experienced coverage counsel's careful examination of insurance policies and the nature of a cyberattack or data breach may be important to preserve coverage. Failure to take this approach could result in an unwelcome and expensive set of costs.

1 HITECH is a series of statutory provisions within the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No.111-5; *see* ARRA Division A, Title XIII—Health Information Technology, Section 13001.

2 *See* Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule, 78 Fed. Reg. 5566 (Jan. 25, 2013) (Omnibus Rule) (codified at 45 C.F.R. pts. 160 and 164).

3 *See* Ponemon Institute LLC, *2014 Cost of Data Breach Study United States*, at 1 (May 2014) *available at* www-935.ibm.com/services/multimedia/SEL03027USEN_Poneman_2014_Cost_of_Data_Breach_Study.pdf.

4 *See id*, 5 n.4, 7.

5 *See* HITECH Act, Section 13402(h).

6 *See* 78 Fed. Reg. 5587 (Jan. 25, 2013), part 164; HITECH Act, Section 13402(a).

7 For example, HITECH increased the amount of potential civil penalties—which start at $100 per violation and increase up to $50,000 per violation, with a yearly maximum of $1.5 for similar violations—depending on the nature of the violation. *See* 78 Fed. Reg. 5583 (Jan. 25, 2013), discussing section 160.404, HITECH, Section 13410(d).

8 *See* 78 Fed. Reg. 5579-80 (Jan. 25, 2013), discussing section 160.401, HITECH, section 13410(d).

9 *See* ISO standard form CG 00 01 12 07, defining as "oral or written publication, in any manner, of material that violates a person's right of privacy."

10 *See Netscape Commc'ns. Corp. v. Fed. Ins. Co.*, 343 Fed. Appx. 271, 272 (9th Cir. 2009) (sending information to an affiliated entity about users' internet activities without their knowledge violates a person's right to privacy and is therefore a "publication," triggering coverage); *Zurich Am. Ins. Co. v. Fieldstone Mortg. Co.*, 2007 WL 3268460, at *5 (D. Md. Oct. 26, 2007) (finding "publication" triggering coverage from allegations of improper access to credit card information upon which prescreened credit offers were made); *Am. Family Mut. Ins. Co. v. C.M.A. Mortg., Inc.*, 682 F. Supp.2d 879, 884-85 (S.D. Ind. 2010).

11 *See, e.g., Recall Total Info. Mgmt., Inc. v. Fed. Ins. Co.*, 317 Conn. 46, 115 A.3d 458 (2015) (finding that where stolen tapes contained personal information that could not be read by a personal computer, no third party had accessed the information, and no person had suffered injuries from loss of the tapes).

12 *See* 78 Fed. Reg. 5566, 5580-81 (Jan. 25, 2013). The agreement must grant the CE "the authority to direct the performance of the service provided by its business associate after the relationship was established . . ."

13 *See Navigators Ins. Co. v. Sterling Infosystems, Inc.*, Index No. 653024/2013, slip op. at 7 (N.Y. Sup. Ct., N.Y. County July 28, 2015) (Navigators).

14 Slip op. at 8.

15 *Id.*

16 *See id.*

17 78 Fed. Reg. 5566, 5583 (Table 2) and 5586 (Jan. 25, 2013).

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Complying with the Law of Unintended Consequences: How to Minimize the Risks of Liability and Litigation Before Signing MA Plan Shared Savings Agreements

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Reflecting on the problem with applying outdated laws to a changing atmosphere, it has been said that "good intentions can often lead to unintended consequences. It is hard to imagine a law intended for the workforce known to Henry Ford can serve the needs of a workplace shaped by the innovations of Bill Gates."[1] Although Representative Tim Walberg's (R-MI) example was aimed at the impact of applying historical employment laws to a radically different work environment, his observation is equally applicable to the evolving health care industry, both in terms of the way care is provided and the way services are reimbursed. In fact, through unintended consequences, existing and longstanding Medicare Advantage (MA) rules may actually stifle the innovation and collaboration newer laws like the Affordable Care Act (ACA) are meant to encourage.

Whatever the future of the ACA, most experts agree that some changes in the health care sector are here to stay. One change that is rapidly gaining widespread appeal both in governmental and commercial contexts is the move to value-based purchasing. The hybrid governmental/commercial plans—MA plans—are following suit. Unfortunately, outdated MA laws may compromise plans' and providers' ability to maximize the mutual value of value-based reimbursement, thereby reducing both parties' incentives to enter into the arrangements altogether.

MA plans and their contracting physicians should understand the laws affecting their value-based contracts so they can plan ahead and avoid: (1) liability for violating the laws; and (2) future disputes with each other about how to interpret and deal with the impact of the laws on their value-based reimbursement contracts.

One law that is impacting value-based contracts between physicians and MA Plans is 42 U.S.C. § 1395w-22(d)(4) and its implementing regulation 42 C.F.R. § 422.208. These sections govern physician incentive agreements with MA plans. They are intended to reduce any incentive for physicians to limit medically necessary services. While a laudable goal, the laws actually go further.

In addition to prohibiting incentives that reduce the provision of medically necessary services, 42 U.S.C. § 1395w-22(d)(4) and 42 C.F.R. § 422.208 also require any physician or group to have stop-loss coverage if they are at "substantial financial risk" as a result of a physician incentive plan. These substantial risk thresholds and stop-loss requirements have MA plans and physicians at odds with each other when negotiating and performing under shared savings agreements.

Shared Savings Payments Are Subject to Section 422.208

First, the parties often dispute whether the statute and regulation apply to shared savings contracts at all. The laws encompass virtually any incentive plan, including a shared savings plan. The statute defines "physician incentive plan" as "any compensation arrangement between a Medicare+Choice [nka Medicare Advantage] organization and a physician or physician group *that may directly or indirectly have the effect of reducing or limiting services* provided with respect to individuals enrolled with the organization under this part."[2] The regulation defines physician incentive plan substantially the same as in the statute.[3] Shared savings plans by design are intended to reduce unnecessary services and, therefore, fall within the definition of "physician incentive plan." As such, they must comply with the substantial risk thresholds and stop-loss requirements set out in the regulation at Section 422.208.

The regulation sets the following limits, among others: if a bonus payment is 33% or higher of all other payments to the physicians, or any "other incentive payment" is 25% or higher of all payments to the physicians, then the physicians are at "substantial financial risk."[4] There is no prohibition against physicians being at substantial financial risk and therefore agreeing to incentives in excess of the percentage thresholds.[5] However, once physicians are at substantial financial risk, they must have "adequate" stop-loss coverage, as detailed in the regulation, to curtail any monetary incentive they may have to withhold medically necessary services.[6]

So, is a shared savings payment a bonus or "other incentive payment?" Bonus is defined broadly as "a payment made to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold."[7] Although a shared savings payment may fit this definition, a Centers for Medicare & Medicaid Services (CMS) representative confirmed that CMS does *not* consider shared savings payments to be "bonuses."[8] However, the representative also stated that where the shared savings payment relates to the use or cost of referrals outside the physician's own group, CMS would consider it to be an "other incentive payment" subject to the 25% threshold.[9] CMS' interpretation that shared savings payments are subject to the substantial risk thresholds is consistent with the regulatory history of Section 417.479, a sister regulation governing physician incentive payments from prepaid health care organizations and the

model for Section 422.208,[10] which suggests that the U.S. Department of Health and Human Services (HHS) intended to subject shared savings plans to the regulatory analysis and stop-loss safeguards.[11]

There are no cases or CMS guidelines pertaining to the application of Section 422.208 to shared savings arrangements. In fact, according to the CMS official, the regulation's application to shared savings agreements is an issue of first impression for CMS, growing out of the recent focus on shared savings agreements as a result of the Medicare Shared Savings Program and out of the fact that the enabling statute and regulation were enacted well before this new era of shared savings.[12] Only recently have interested parties started to inquire about the regulation's relationship to shared savings payments.

Exceptions to the Stop-Loss Coverage Requirements

Despite the broad interpretation of the types of payments that are subject to the statute and regulation, Section 422.208 is meant to provide safeguards so that *medically necessary* services are not limited or reduced in the process. The regulation, therefore, carves out certain incentive payments that are *not* subject to its stop-loss requirements.

First, payments that do not meet the applicable substantial risk thresholds are not subject to the stop-loss requirements.[13]

Second, payments that are not based on the use or cost of referrals *outside of the contracting physician group* (such as incentives based *solely* on the quality of care provided, patient satisfaction, and participation on committees or reduction of medically unnecessary services *within the group*) are not subject to the regulation.[14] Ancillary services are not considered referral services if they are performed by the physician group.[15] When a contract relates to both services furnished by the physician group as well as referral services, the contract is subject to the regulation, even though it may be hard to separate the two types of services.[16]

Third, physician groups serving panels of more than 25,000 patients are not at substantial financial risk.[17] In determining the panel size, the group may pool commercial, Medicare, and Medicaid enrollees or the enrollees of several MA organizations with which a physician or physician group has shared savings contracts.[18]

Minimizing Section 422.208 Disputes and Liability

In addition to understanding Section 422.208 to reduce the parties' risk of liability for government enforcement, addressing the regulation early can also curtail disputes between the parties. These party disputes occur at two primary points of the relationship:

- During negotiations when the MA plan wants to set a ceiling on the amount of savings the physician can receive under the shared savings plan by reference to the statute and regulation. A ceiling that does not measure up to the physician's expected efforts necessary to generate the savings could be an impediment to reaching a final agreement at all.
- After the fact when the shared savings payment is due. This timing is particularly ripe for disputes because the physician will have already expended resources generating the savings and may feel that the MA Plan is retroactively and improperly interpreting the physician incentive laws in an effort to rewrite the parties' agreement and retain more of the savings.

If the parties understand the requirements of, and exceptions to, Section 422.208 up front, the risk of these disputes can be minimized. Here are some ways to address Section 422.208 at the outset:

- If the provider intends to achieve cost savings *solely* through reductions, efficiencies, or quality improvements in its *own practice*, rather than through reductions in the cost or use of services *outside of the provider*, the agreement should reflect this fact because the savings generated and the corresponding payment will not be not subject to Section 422.208.
- If the contract relates to both services furnished by the provider (such as quality or satisfaction goals) as well as referral services, the contract is subject to the regulation, but the physician should be permitted to use only the portion related to referral services outside the provider to determine if the payment reaches the threshold. If the parties are able to estimate the portion of the savings attributable to referral services, and that amount does not reach the threshold, then no stop-loss should be required. Consider incorporating into the contract a procedure for calculating such an estimate, either in advance or when the payment is due, to avoid future disputes. CMS has also suggested that parties seek preapproval of the attribution process and their intent to apply some, but not all, of the payment to the threshold determination. The CMS representative expressed a willingness to grant the parties leeway in structuring the deal to avoid stop-loss requirements.[19]
- In addition, MA plans have the option to include a contract provision that would require the physician to specify the level of potential risk for referral services only.[20] Thus, the contract could be drafted to limit the physician's risk related to referral services outside of the physician's practice to less than the threshold, and leave the remainder of the shared savings payment unlimited, except as it relates to how the parties will share the savings.

- The physician group should consider whether it can pool patients to reach the 25,000 patient exception.

Complying With Stop-Loss Coverage Requirement

A practical difficulty of complying with the stop-loss requirements is that shared savings agreements do not lend themselves to a determination of the final payout amount in advance such that the parties would know whether the provider will meet the substantial risk threshold and need stop-loss coverage.

Another problem is that when stop-loss is required, the parties may dispute who is responsible for the cost of purchasing it. Under 42 C.F.R. § 422.208(d), the MA plan "must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection."[21] There is an argument that the plan must purchase or reimburse the provider for the cost of stop-loss. However, this position, though once embraced by CMS, has since been rejected by it. According to the regulatory histories of 42 C.F.R. § 422.208 and the related 42 C.F.R. § 417.479, and communications directly with CMS, its position now is that neither party is specifically obligated to purchase stop-loss protection—the parties are free to negotiate who must purchase the stop-loss coverage and the plan must determine and report whether and to what extent the provider has stop-loss protection.[22]

Faced with the prospect of a more limited payment than expected (perhaps not enough to cover the costs of performing under the contract) or the need to purchase stop-loss coverage, some physicians may choose not to enter into a shared savings agreement with an MA plan. This is discouraging because these arrangements have been proven to provide medical benefits as well as monetary savings. While complying with the laws as written, interested parties should also encourage lawmakers to remedy the disconnect between today's goals and yesterday's laws.

1 Education and the Workforce Committee Statement by U.S. Representative Tim Walberg, July 14, 2011, at the Hearing on "The Fair Labor Standards Act: Is It Meeting the Needs of the Twenty-First Century Economy?"
2 42 U.S.C. § 1395w-22(d)(4).
3 *See* 42 C.F.R. § 422.208(a).
4 *Id.* at (d)(3)(iii).
5 *Id.* at (c).
6 *Id.* at (c) and (f).
7 *Id.* at (a).
8 December 10, 2014 conference call with CMS Representative Marty Abeln.
9 *Id.*
10 *See* 63 Fed. Reg. 123, 35002 (Jun. 26, 1998); 65 Fed. Reg. 126, 40325 (Jun. 29, 2000).
11 *See* 61 Fed. Reg. 60, 13432 (Mar. 27, 1996). *See also* 61 Fed. Reg. 60, 13440 (Mar. 27, 1996) ("this final rule allows for continued, but limited, risk sharing beyond the point at which the stop-loss protection begins."); 61 Fed. Reg. 252, 69040 (Dec. 31, 1996) (referring to risk-sharing arrangements) (describing shared savings payments as bonuses). When commenters complained that withholds and bonuses should not be subject to the regulation, HHS responded that the laws broadly required stop-loss protection for *all forms of incentive arrangements* that put physicians at substantial financial risk. *See* 61 Fed. Reg. 252, 69045 (Dec. 31, 1996).
12 December 10, 2014 conference call with CMS Representative Marty Abeln.
13 42 C.F.R. § 422.208(c)(2).
14 61 Fed. Reg. 60, 13433 and 13447 (Mar. 27, 1996).
15 61 Fed. Reg. 252, 69041 (Dec. 31, 1996).
16 *See* 61 Fed. Reg. 60, 13439-40 (Mar. 27, 1996) (relating to § 417.479).
17 42 C.F.R. § 422.208(d)(3), (f)(2)(iii), and (g). *See also* 61 Fed. Reg. 60, 13439 (Mar. 27, 1996).
18 42 C.F.R. § 422.208(g).
19 December 10, 2014 conference call with CMS Representative Marty Abeln.
20 61 Fed. Reg. 252, 69040 (Dec. 31, 1996).
21 42 C.F.R. §§ 422.208(c)(2), (f)(1).
22 *Compare* Establishment of the Medicare+Choice Program, 63 Fed. Reg. 123, 35087 (Jun. 26, 1998) (requiring MA Plan to "provide" stop loss coverage) to Medicare+Choice Program, 65 Fed. Reg. 126, 40325 (Jun. 29, 2000) (replacing requirement that MA Plan "provide" stop-loss with duty to "assure" that physicians at substantial risk have stop-loss). *Compare* Requirements for Physician Incentive Plans in Prepaid Health Care Organizations, 61 Fed. Reg. 60, 13433 and 13448 (Mar. 27, 1996) (requiring plan to provide stop-loss protection directly, purchase it, or reimburse the cost if the physician group purchased it) and 61 Fed. Reg. 60, 13441 (Mar. 27, 1996) (CMS rejects requests to eliminate plan's responsibility for covering the stop-loss premium because doing so would be inconsistent with enabling statute) to 61 Fed. Reg. 252, 69036 and 69046 (Dec. 31, 1996) (eliminating requirement that the plan pay for stop-loss protection).

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