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HEALTH LAW VITALS

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CMS Issues Proposed Rule to Implement MACRA

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The Centers for Medicare and Medicaid Services ("CMS") recently issued a final rule establishing key guidelines for the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). Congress enacted MACRA to replace the inefficient Medicare Sustainable Growth Rate framework because its rate schedules yielded regular fee declines and required frequent legislative adjustments to remedy.

MACRA includes two reforms that change how physicians receive pay. First, MACRA increases physician fees by 0.5 percent per year from 2016 to 2019. Second, MACRA creates the Quality Payment Program, a payment model beginning in January 1, 2019 that emphasizes compensating clinicians based on the *value of care received by patients*, rather than the *volume of services provided by physicians*. The Quality Payment Program includes two paths: 1) the Merit-based Incentive Payment System ("MIPS") and 2) the Advanced Alterative Payment Models ("Advanced APMs"). This article discusses each below.

Merit-based Incentive Payment System

The first pathway, MIPS, determines a physician's pay by considering several performance measures reported to the CMS. Specifically, MIPS compresses the Physician Quality Reporting System ("PQRS"), the Value Modifier ("VM"), and the Medicare Electronic Health Record ("EHR") incentive programs into a single system, evaluates clinicians across four categories, and provides a single score. CMS then uses the score output to determine whether a clinician receives a fee increase, a fee reduction, or no change at all. The MIPS categories include:

1. **Quality** accounts for 50 percent of a clinician's score in the first year. Clinicians choose to report six quality measures, which provides the option to accommodate differences in specialties and practice areas.

2. **Cost** (also called "**Resource Use**") represents 10 percent of a clinician's score in the first year. The score is based on Medicare claims, which means no reporting

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requirement for clinicians. This category uses more than 40 episode-specific measures to account for differences among specialties.

3. **Clinical Practice Improvement Activities** constitute 15 percent of a clinician's score in the first year. This metric rewards physicians for clinical practice improvement activities, including those focused on care coordination, beneficiary engagement, and patient safety. Clinicians may select activities that match their practice goals from a list of more than 90 options.

4. **Advancing Care Information** (also known as "**Meaningful Use**") constitutes 25 percent of a clinician's score in the first year. Clinicians report customizable measures that reflect how they use EHR technology in their day-to-day practices, particularly emphasizing interoperability and information exchange. Unlike the existing EHR program, this model does not require all-or-nothing EHR measurement or quarterly reporting.

As mentioned above, a physician's output score determines whether he or she receives a fee increase, a fee reduction, or no change at all. Using 2017 metrics as a performance baseline, MIPS establishes maximum fee increases and reductions of 4 percent in 2019, 5 percent in 2020, 7 percent in 2021, and 9 percent in 2022 and beyond. Importantly, clinicians should note that MIPS is revenue-neutral, which means that when one clinician receives more in fees, another clinician must receive less.

Advanced Alternative Payment Model ("Advanced APM")

The second pathway, Advanced APM, provides an opportunity for eligible clinicians to earn incentives for providing high-quality, efficient, and coordinated care. To qualify as an Advanced APM, a provider must: (1) use certified electronic health record technology; (2) pay clinicians based on measures of quality comparable to those used for MIPS; and (3) adopt a Medicaid Medical Home Model or bear more than a nominal amount of financial risk.

Advanced APMs provide more revenue variability than MIPS because they offer both greater potential financial risk and greater potential financial reward. For example, CMS requires that Advanced APMs link payment to performance for at least 25 percent of a clinician's Medicare revenue in 2019, and increases

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Texas Medicaid & 2017 Legislative Update

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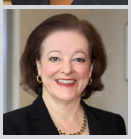

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this to 75 percent in 2022. Additionally, CMS exempts Advanced APM providers from MIPS adjustments and instead gives them a lump sum incentive payment equal to 5 percent of the prior year's estimated aggregate expenditures under the fee schedule. Further, physicians that participate in Advanced APMs will receive an annual across the board fee increase of 0.75 percent in 2026, higher than the 0.25 percent annual increase scheduled for MIPS. Ultimately, because Advanced APMs function to assign more financial risk to clinicians, they incentivize clinicians to find ways to provide health care services more efficiently.

CMS provided a limited list of care models that qualify as Advanced APMs, which are discussed below.

A. Comprehensive End Stage Renal Disease Care Model (Large Dialysis Organization arrangement)

Comprehensive End Stage Renal Disease ("ESRD") Care Models are seamless care organizations in which dialysis clinics, nephrologists, and other providers join to coordinate care for beneficiaries suffering from end-stage renal disease. ESRD seamless care organizations may become Comprehensive ESRD Care Models if they possess at least 350 beneficiaries matched to their organization.

Comprehensive ESRD Care Models are noteworthy because organizations become clinically and financially responsible for all care given to their matched beneficiaries, not just for dialysis care or care that relates to ESRD. Further, if organizations successfully offer high value services that decrease the cost of care for Medicare patients, then the organizations will have the ability to share in such savings with CMS.

Special rules apply, however, for Comprehensive ESRD Care Models that include at least one dialysis facility owned by a Large Dialysis Organization ("LDO"). CMS defines LDOs as chains that have 200 or more dialysis facilities. CMS requires Care Models that include an LDO to share liability with CMS for both savings and losses associated with patients' cost of care. This means that Comprehensive ESRD Care Models with LDOs that increase the cost of care for patients are liable for such losses to the CMS.

B. Comprehensive Primary Care Plus

Comprehensive Primary Care Plus ("CPC+") constitutes an innovative payment structure that seeks to support the delivery of comprehensive primary care. CPC+ offers two "tracks," each with different care delivery requirements and payment structures.

For both Track 1 and Track 2, payers provide prospective monthly care management fees to practices based on beneficiary risk tiers. CMS hopes that the increased and non-visit-based compensation will financially support the staffing and training improvements needed to best serve Medicare patient populations. As seen below, Medicare care management fees average to $15 per-beneficiary per-month across four risk tiers in Track 1 and $28 per-beneficiary per-month across five risk tiers in Track 2.

Risk Tier	Attribution Criteria	Track 1	Track 2
Tier 1	1st quartile HCC	$6	$9
Tier 2	2nd quartile HCC	$8	$11
Tier 3	3rd quartile HCC	$16	$19
Tier 4	4th quartile HCC for Track 1; 75-89 percent HCC for Track 2	$30	$33
Complex (Track 2 only)	Top 10 percent HCC OR Dementia	N/A	$100
Average PBPM		$15	$28

CPC+ provides performance-based incentive payments to practices, which depend on their patient experiences, clinical quality, and utilization measures. At the beginning of a performance year, CPC+ pays $2.50 per-beneficiary per-month for Track 1 and $4.00 per-beneficiary per-month for Track 2. Clinicians should note, however, that CMS will recoup such payments if practices fail to meet performance thresholds.

C. Medicare Shared Savings Program (Tracks 2 and 3)

The Medicare Shared Savings Program seeks to reward accountable care organizations ("ACOs") that lower the growth of their health care costs and meet certain quality performance standards for patient care.

CMS allows an ACO to participate in the Shared Savings Program if it meets several requirements. First, the ACO must have at least 5,000 assigned Medicare Fee-For-Service beneficiaries. Second, the ACO must establish a governing body that represents ACO participants and Medicare beneficiaries. Third, ACOs must engage in routine self-evaluation to ensure they continuously improve the care delivered to Medicare patients.

Two of the three financial Shared Savings Program options require ACOs to share in both Medicare savings and losses and, therefore, qualify as Advanced APMs. ACOs share a maximum of 60 percent of risk under Track 2 and a maximum of 70 percent of risk under Track 3. CMS, however, limits the total amount an ACO may save, capping Track 2's savings at 15 percent of the ACO's updated benchmark and Track 3 at 20 percent of the benchmark.

D. Next Generation ACO Model

Next Generation ACO Models constitute the highest risk Advanced APM and are noteworthy for several reasons.

First, Next Generation ACO Models employ a prospectively set benchmark for how much an ACO should spend, which CMS determines by considering historical information, regional trends, and risk scores for the ACO's population.

Second, Next Generation ACO Models test the ability of ACOs to assume almost all financial risk by providing two risk arrangements that determine the portion of the savings or losses that accrue to the Next Generation ACO. In arrangement A, ACOs have an 80 percent sharing rate for years 1-3 and 85 percent for years 4-5. In arrangement B, ACOs have a 100 percent sharing rate. Both arrangements cap total savings or losses at 15 percent of the benchmark.

Third, Next Generation ACO Models also test the effectiveness of alternative payment mechanisms in facilitating investments in infrastructure and care coordination to improve health outcomes. The Model provides four payment mechanism options:

1. Nominal FFS Payment

Next Generation participants and preferred providers have the option of receiving payment from CMS for services through the normal fee-for-service channels at standard payment levels.

2. Nominal FFS Payment + Monthly Infrastructure Payment

Next Generation participants and preferred providers have the option of receiving the normal fee-for-service payment plus an additional per-beneficiary per-month payment to invest in infrastructure to support ACO activities. CMS will make the infrastructure payment at a rate of no more than $6 per-beneficiary per-month, which CMS then recoups in full during the reconciliation process.

3. Population-Based Payments ("PBPs")

Next Generation participants and preferred providers have the option of receiving "population based payments." PBPs constitute an estimate of the aggregate amount by which fee-for-service payments will be reduced for Medicare Part A and B services rendered by PBP-participating Next Generation participants and preferred providers who agree to receive reduced fee-for-service payments when providing care to aligned beneficiaries during the upcoming performance year.

4. All-Inclusive Population-Based Payments ("AIPBP")

Next Generation participants and preferred providers will have the option to receive All-Inclusive Population-Based Payments in 2017. AIPBPs will be determined by estimating the total annual expenditures for care furnished to beneficiaries by Next Generation participants and preferred providers who have agreed to participate in AIPBP. CMS will pay that projected amount to the ACO in a PBPM payment. An organization participating in an AIBP will be responsible for paying claims for its Next Generation participants and preferred providers with which the ACO has written agreements regarding participation in AIPBP.

Conclusion

Industry experts believe that MACRA's dual pathway structure significantly improves previous law. U.S. Department Health and Human Services Secretary Sylvia M. Burwell, for example, described MACRA as "a milestone in our efforts to advance a health care system that rewards better care, smarter spending, and healthier people." Financial projections reflect this optimism, as government estimates project that in 2019 (the first year in which payment consequences will exist for MIPS performance), CMS will distribute $500 million in "exceptional performance payments" to eligible clinicians and around $200 million in APM incentive payments.

Although MIPS and Advanced APMs each establish innovative systems that change how clinicians receive payment, both expose clinicians to significant risk. There is speculation that the effective dates of these systems will be delayed as there has been substantial commentary about the lack of awareness and understanding on behalf of physicians and the lack of clarity around the quality factors.

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Healthcare Employers Should Evaluate Exempt Workers Based on New Overtime Exemption Rules

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The U.S. Department of Labor ("DOL") has issued a final rule, effective December 1, 2016, changing aspects of the Fair Labor Standards Act ("FLSA") regarding overtime exemptions. The FLSA dictates how employees must be paid overtime for working a certain number of hours; however, "exempt" employees who are salaried and who have administrative, executive, or professional job duties do not have to be paid overtime. Previously, these employees had to be paid at least $23,660 per year to quality for the exemption. This salary threshold has been stagnant for over a decade, but now has increased to $47,476 per year ($913 per week) under the new rule. Another exemption for the "highly compensated employee" is increasing from $100,000 to $122,148 per year. In addition to meeting the

threshold salary requirements, employers must also show that exempt employees meet the "duties test" for each respective exemption.

Ultimately, as a result of the changes, employers may elect to change employees to an hourly rate and allow overtime, rather than increase the employee's salary. In the healthcare industry, this change will mostly impact administrative employees, who work in human resources, technology and research workers, social workers, technicians, and information technology workers. Healthcare employers must determine whether to increase the salary for certain employees or elect to change to an hourly rate and pay overtime.

Employers who elect to change employees to an hourly rate should consider the following: 1) the communication regarding the change to employees must be clear and include new training; and 2) the computation for overtime must comply with the FLSA, but employers have options regarding how to compute this time.

First, the change in employment status from salaried to hourly should be communicated to the employee clearly, as a change in compensation may come as a surprise to the employee. The employee may need to undergo additional training specific to hourly employees. The additional training may include, but is not limited to, recording hours worked, policies against under-reporting and over-reporting hours, and how to get approval for overtime.

Second, the employer should consider the various ways of computing overtime. The FLSA provides for hospitals and residential care establishments, under prescribed conditions, an exemption from the general requirement that overtime compensation be computed on a workweek basis: the exemption is called the "8 and 80 Overtime System." To use this exception, an employer must have a prior agreement or understanding with affected employees before the work is performed. The 8 and 80 Overtime System allows employers to pay time and one-half for all hours worked over 8 in any workday and 80 hours in the fourteen-day period. **See the FLSA Fact Sheet here**. In the alternative, healthcare employers can pay at least time-and-one-half their "regular rate" of pay for all hours worked over 40 in a workweek.

Healthcare employers should be particularly mindful of these changes. The DOL's statistics on low wage industries reveal that in 2015 the healthcare industry was one of the industries having to pay the most in back wages in damages for wage and hour violations. To prepare for the changes coming this December, healthcare employers should conduct an FLSA audit now to determine who may no longer be considered exempt as a result of the new rules.

Next Steps for Telemedicine in Texas – Legislative Fix and Medicaid Policy Changes

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Michelle "Missy" Apodaca

In the last several years, Texas has generated significant news stories related to the disagreements between the Texas Medical Board ("TMB") and Teladoc, a telehealth medical provider. The original dispute centered around the right of telemedicine providers to treat Texas residents without an initial in-person visit, which some would argue circumvents the establishment of the practitioner-patient relationship. While the dispute and subsequent corollary issues linger in litigation, some telemedicine/telehealth (referred to generally in this article as "telemedicine") providers have been in a holding pattern with their business operations in Texas. However, there may be legislative and regulatory changes on the horizon.

Legislative Fix

To respond to technological innovation and advances in patient care, stakeholders and advocates met earlier this summer in Austin to start developing telemedicine legislation. Bringing the parties together, including those that have been historically on opposite sides of the issue, to develop legislation prior to the January 2017 convening of the 85th Texas Legislature is significant. It will be important for telemedicine providers and their advocates to get bills passed during the five months of the legislative session—or they will have to wait another nineteen months for the next legislature to take action. For contextual purposes, during the 84th legislative session in 2015, over ten telemedicine bills were introduced, but only one passed.

Some highlights of the draft legislation include:

- Clarifying the appropriate practitioner-patient relationships to be established via telemedicine when certain criteria are met.
- Modifying the definition of telehealth and telemedicine and making conforming amendments to other Texas codes.
- Clarifying that health professionals and physicians must be licensed in Texas.
- Defining the criteria for when drugs can be prescribed through telemedicine.

In addition to the stakeholder legislation, there may be other legislative vehicles providing business opportunities for telemedicine providers. Both the Texas Lieutenant Governor and the Speaker of the House issued interim charges for committees to study improving access to care through telehealth and examining the adequacy of the technology infrastructure for use between healthcare providers.[1] After the committees complete their studies on these issues and draft reports on their findings, legislation is often introduced during the next legislative session. The committees will complete their reports by December of 2016.

Texas Medicaid – Medical Policy Changes & Network Adequacy Consideration

Texas has over four million residents on Medicaid and a conservative legislature, so Texas regulators have been forced to be innovative with their Medicaid program. With the goal of controlling costs and quality improvement, the state has contracted with managed care organizations ("MCOs") to deliver Medicaid services through managed care, while implementing the Texas Healthcare Transformation and Quality Improvement Medicaid Waiver ("1115 Waiver") to incentivize providers to transform their service delivery practices.

Almost 20 years ago, the Texas Medicaid program began providing telemedicine medical services to clients, and has since expanded the services available via advanced telecommunications. A 2014 Texas Health and Human Services Commission ("HHSC") Biennial Report on the effects of telemedicine in Texas Medicaid reported the progress that had been made for Medicaid clients and providers for the previous three years:

- 79 percent increase in the number of clients receiving telemedicine (from 9,748 to 17,416).
- 104 percent increase in the number of providers using telemedicine (from 98 to 200).
- 124 percent increase in expenditures ($1.2 million to $2.8 million).[2]

Further acknowledging the need for alternative healthcare access points, providers implemented over 80 telemedicine, telehealth, or telemonitoring projects

under the state's 1115 Waiver.[3] These projects vary from implementing 24/7 crisis hotlines to extending telemedicine psychiatry services and the funding paid for the equipment, technology, and professional services. These projects will likely remain active until December 2017 or until the 1115 Waiver's extension period ends.

As HHSC continues to explore options to improve quality for Medicaid clients, at the beginning of August, it issued draft changes to the Medicaid Medical Policies dealing with Telemedicine and Telehealth services for a short ten-day comment period.[4] While Medicaid providers privately complained that these draft changes did little to allow for alternative methods of telemedicine/telehealth delivery, the changes did provide for facility fee reimbursement for Federally Qualified Health Centers and Rural Health Clinics as patient site providers and did clarify the limited circumstances when telemedicine can be used in a "patient's home" (such as a group or intuitional setting), the requirements relating to the initial and 12-month healthcare provider evaluations for mental health services, and other technical issues. Unless HHSC makes further alterations to these policies, there will be corresponding changes to the Texas Administrative Code in the upcoming months.

As previously mentioned in the July Haynes and Boone *Health Law Vitals*, the Centers for Medicare and Medicaid Services ("CMS") issued new Medicaid managed care rules that require states to consider telemedicine as one of several factors in provider access standards. Specifically, CMS encouraged states to consider how current and future technological solutions including telemedicine, e-visits, and/or other evolving solutions could impact states' network adequacy standards.[5] With the timing of these rules and the upcoming procurement of the Texas Medicaid Managed Care MCOs for the operational start date of March 2019, telemedicine providers will have an important role to play and will want to monitor the progress.

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[1] **Texas Senate, Interim Charges** (Oct. 13, 2015); **Texas House of Representatives, Interim Committee Charges** (Nov. 2015).

[2] Telemedicine, Telehealth, and Home Telemonitoring Texas Medicaid Services – Biennial Report to the Texas Legislature as required by the Texas Government Code § 531.0216, Texas Health & Human Services Commission (Dec. 1, 2014), www.hhsc.state.tx.us.

[3] Presentation to Senate Committee on Health & Human Services: Teleservices in Medicaid, Texas Health & Human Services Commission (June 16, 2016), www.hhsc.state.tx.us.

[4] Draft Texas Medical Medical Policy Under Review for August 2016, www.hhsc.state.tx.us.

[5] Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability (CMS-2390-F), 81 Fed. Reg. 27,497, 27,663, 27,666 (May 6, 2016), **available here**.

Full Federal Trade Commission Reverses ALJ, Holds LabMD Liable for Data Breach, but Declines To Decide Whether Lax Data Security Breaches Section 5

Pierre Grosdidier, Ph.D.

Pierre Grosdidier, Ph.D.

In a unanimous opinion written by Chairwoman Edith Ramirez, the Federal Trade Commission ("FTC") reversed an Administrative Law Judge's ("ALJ") decision that had dismissed Section 5 (15 U.S.C. § 45, the "FTC Act") claims against LabMD for an eight-year-old data breach.[1] The FTC held that the ALJ applied thewrong legal standard and ordered now-inactive LabMD to comply with a number of data-protection measures.[2] The importance of the decision is that it helps set the threshold conditions under which the FTCwill consider that a data breach, or *the risk of a data breach*, constitutes a Section 5 violation.

Section 5 of the FTC Act bars "unfair or deceptive acts or practices in or affecting commerce" and

authorizes the FTC to police such conduct.[3] But the FTC's authority is restricted to acts that, *inter alia*, cause or are"likely to cause substantial injury to consumers."[4] The FTC has used the FTC Act to police companieswhose inadequate or ineffective security measures have resulted in data breaches and, consequently, consumer harm.[5]

The account of the FTC's proceeding against LabMD is convoluted and controversial. LabMD was a medical testing services company that unwittingly granted public access via peer-to-peer software to a large file (the "1718 File") that contained the Personally Identifiable Information ("PII") of some 9,300 patients, including social security numbers and medical data. The FTC filed a complaint against LabMD after Tiversa, Inc., a third-party, found the 1718 File and turned it over to the FTC under contentious circumstances. The ensuing polemic led to a Congressional inquiry and report that cast the FTC and Tiversa in an unflattering light.[6] LabMD eventually unwound its operations in 2014, and the FBI raided Tiversa in March 2016.[7]

The Commission found that the record supported FTC Complaint Counsel's claim that LabMD's data security measures fell substantially short of minimum established norms, especially for a facility that housed medical PII for over 750,000 patients.[8] Unauthorized access protection was very weak and security auditslackadaisical. At least six employees used the password "labmd," for example, and LabMD's IT services failed to detect the peer-to-peer software until the breach occurred. But the record also shows that only Tiversa accessed the 1718 File and no one ever complained, or presented evidence, of a tangible injury because of the data breach.[9]

In its action against LabMD, Complaint Counsel took the position, inter alia, that a company's lax computer security measures are actionable under the FTC Act even in the absence of a data breach.[10] According tothis argument, Section 5 liability can be imposed merely based on the risk that inadequate security measures will cause a data breach resulting in future consumer harm.[11] In its Initial Decision dismissing theFTC's complaint, the Administrative Law Judge ("ALJ") specifically rejected this argument because it required too many speculative steps between the lax security and actual consumer harm. In dismissing Complaint Counsel's claim regarding the 1718 File, the ALJ also held that "Complaint Counsel ha[d] proven the 'possibility' of harm, but not any 'probability' or likelihood of harm."[12]

In reversing the ALJ, the Commission held that the release of the 1718 File, which contained sensitive personal medical information, caused sufficient consumer injury to satisfy the Section 5 threshold.[13] Thiswas so even though only Tiversa accessed the 1718 File. The Commission also held separately that the exposure of the 1718 File for 11 months on a peer-to-peer file-sharing site was in and of itself actionable under Section 5 because it created a "significant risk" of substantial consumer injury.[14] The unauthorizedrelease of one file containing PII to one party is, therefore, actionable under Section 5, as is publicly exposing such a file through peer-to-peer software, even in the absence of evidence of actual copying.

But, significantly, the Commission expressly declined to address Complaint Counsel's "broader argument" that inadequate security measures that potentially expose PII to a breach constitute a Section 5 violation in and of themselves:

> We note that Complaint Counsel argues that LabMD's security practices risked exposing the sensitive information of all 750,000 consumers whose information is stored on its computer network and therefore that they create liability even apart from the LimeWire incident. We find that the exposure of sensitive medical and personal information via a peer-to-peer

> file-sharing application was likely to cause substantial injury and that the disclosure of sensitive medical information did cause substantial injury. Therefore, we need not address Complaint Counsel's broader argument.[15]

The Commission, therefore, saw no need to opine on Complaint Counsel's most reaching argument. However, companies that host large quantities of PII would be ill-advised to find solace in the Commission's restraint, given the zeal that the FTC showed in policing the LabMD breach. This is especially so considering the ever-growing sophistication of hackers which, arguably, constantly shifts what constitutes a "significant risk" of data breach and, therefore, consumer injury. Meanwhile, the controversy continues: LabMD has already stated its intent to appeal the Commission's decision to a Court of Appeals.[16]

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[1] Opinion of the Commission, *In re LabMD, Inc.*, FTC No. 9357 (July 29, 2016) [hereinafter "Commission Opinion"). The *In re LabMD* pleadings are **available here**. *See also* Pierre Grosdidier, *Speculative Data Breach Damages Might Be Actionable*, excerpted from State Bar of Texas, Computer and Technology Section's Circuits Newsletter, May 2016, **available here**.

[2] Final order, *In re LabMD, Inc.*, FTC No. 9357 (July 28, 2016).

[3] 15 U.S.C. § 45(a)(1)—(2).

[4] *Id.* § 45(n).

[5] Commission Opinion at 10 n.21 ("[t]o date, using both its deception and unfairness authority, the Commission has brought nearly 60 data security cases.").

[6] *Tiversa, Inc.: White Knight or Hi-Tech Protection Racket?*, Comm. on Oversight and Gov't Reform, U.S. House of Rep., 113th Cong. (Jan. 2, 2015) ("Committee Report").

[7] http://www.theregister.co.uk/2016/03/18/fbi_raids_cybersecurity_firm_tiversa/.

[8] Commission Opinion at 11-16.

[9] Tiversa also shared the 1718 File with an academic researcher.

[10] Complaint Counsel's Appeal Brief, *In re LabMD, Inc.*, FTC No. 9357, at 5-7, 10-12 (Dec. 22, 2015).

[11] Initial Decision, *In re LabMD, Inc., FTC No. 9357, at 84—85 (Nov. 13, 2015).*

[12] Initial Decision at 14.

[13] Commission Opinion at 17-19.

[14] *Id.* at 20-25

[15] *Id.* at 16

[16] Allison Grande, *FTC Revives LabMD Data Leak Suit, Finds Consumer Harm*, Law360 (July 29, 2016).

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