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Tenacity, Creativity and Results are the three words that best describe Shaheen & Gordon's approach to addressing complex legal issues. Our health care team closely monitors the rapidly changing legal environment so that our clients are prepared to meet the challenges of today as well as tomorrow. Relying on a wealth of experience, we offer practical advice and assist in implementing recommendations tailored specifically to meet the needs of both large and small health care clients.

FEDERAL DEVELOPMENTS

Affordable Care Act Implementation

Close to 2 Million Enroll in Health Insurance Marketplaces

On December 29, the administration announced that more than 1.1 million people had enrolled for private health insurance through the federal health insurance marketplace through December 24, including 975,000 from December 1-24 alone, as compared with 137,000 people who signed up in the entirety of October and November. (The December 23 deadline was extended an additional day to December 24, and those who attempted to enroll by the deadline but were unsuccessful were invited to call the federal marketplace call center starting December 26 to complete their enrollment in time for coverage to begin on January 1). Including enrollment in state exchanges, almost 2 million people have now enrolled for private health insurance through a state or federal exchange. The number of enrollees is below the estimated 3.3 million enrollees that the Department of Health and Human Services predicted would have signed up by this point. Those predictions were made in early September, when officials were unaware of the difficulties that would accompany the rollout of healthcare.gov.

Key ACA Provisions Go Into Effect

On January 1, 2014, various provisions of the Affordable Care Act took effect. In brief:

- Coverage went into effect for the almost 2 million Americans who signed up for new health plans through state or federal marketplaces.
- Premium tax credits and cost-sharing reductions became available for those participating in marketplace plans.
- Medicaid expansion went into effect in those states that chose to expand Medicaid.
- The individual mandate, which requires most people without employer-based coverage to enroll in health coverage or pay a penalty, went into effect. Anyone who signs up for a health plan by the end of March will not be penalized.
- Health insurers can no longer turn down or charge individuals more because of pre-existing conditions, nor can they decline to cover pre-existing conditions for enrolled individuals, except in grandfathered individual health insurance plans.
- Health insurers can no longer charge higher premiums to women than to men for the same coverage.

- Insurers must, in most cases, provide at minimum a standard set of "essential health benefits."

- An expanded small business health coverage tax credit became available. The credit is now available for up to 50% of the costs of premiums for two plan years, as discussed in more detail in past legal updates.

- A new income-based test for determining eligibility for Medicaid for certain groups was implemented nationwide. This test relies on "modified adjusted gross income" and was discussed in detail in the previous legal update.

- Health plans can no longer impose yearly limits for coverage for "essential health benefits," except for grandfathered individual health plans. (Insurers can still impose a yearly dollar limit and lifetime spending limit on spending for health care services that are not considered essential health benefits.) Lifetime limits were previously eliminated for all health plans.

- The mandate that large employers provide health insurance to full-time workers or pay a penalty was supposed to go into effect, but the requirement has been delayed to January 1, 2015.

New Cooperative Health Plan Coming to New Hampshire

On December 12, Minuteman Health, a cooperative health insurance plan based in Massachusetts, announced plans to expand into New Hampshire. Minuteman received a $67 million loan from CMS to facilitate its New Hampshire expansion. Minuteman expects to offer plans in New Hampshire starting in January 2015, including through the federal health insurance marketplace as well as brokers and its own website. Contact information for providers interested in contracting with Minuteman is available at http://minutemanhealth.org/health-professionals.

Enforcement of Contraceptive Coverage Mandate Temporarily Blocked

On December 31, Justice Sonia Sotomayor of the Supreme Court of the United States temporarily blocked the administration from enforcing the contraceptive coverage requirements and related regulations of the Affordable Care Act against a Colorado order of nuns, Little Sisters of the Poor, that has brought a challenge to the law, as well as 486 other Roman Catholic nonprofit groups that use the same health plan. (The Little Sisters challenge is distinct from, although conceptually related to, a separate set of lawsuits being heard by the Supreme Court that involve secular for-profit corporations whose owners object to the requirement to provide contraceptive coverage.)

Under the Affordable Care Act, employers are required to provide coverage for "preventive care" in employee group health plans. By regulation, such care is defined to include coverage for FDA-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. Churches and other religious employers are entirely exempt from the contraceptive coverage requirements, while secular for-profit businesses must comply with it. Nonprofit organizations that hold themselves out as religious and oppose the provision of coverage for some or all contraceptive services on religious grounds may formally opt out of the contraceptive coverage requirement by completing a "self-certification form" and providing that form to its insurer or third-party administrator (TPA). The insurer or TPA then provides coverage and processes claims for contraceptive services that are required to be covered, and obtains payments for those claims (plus an administrative fee) from the federal government.

Challengers around the country have argued in a dozen different cases that signing the certification itself violates their religious beliefs, because the form "directs" a third party to provide contraceptive coverage to which the organization has a religious objection. They chiefly rely on a federal law that provides that the federal government may substantially burden a person's exercise of religion only if it demonstrates that application of the burden to the person is in furtherance of a compelling governmental interest and is the least restrictive means of furthering that interest. Courts around the country considering such cases are evenly split on the question of whether the contraceptive coverage mandate must be enjoined as applied to such organizations. Courts granting injunctions have concluded that the self-certification requirement itself imposes a substantial burden on the religious rights of the challenging organizations. Courts denying injunctions have mostly relied on the fact that the Act does not require nonprofit religious groups to provide contraceptive coverage at odds with their religious beliefs, that the certification form itself merely instructs the insurer or TPA *not* to provide contraceptive coverage as part of the employer's plan, and that the employer cannot raise a religious objection to the acts of separate parties—the insurer/TPA and federal government—in providing contraceptive coverage. Courts are further split on the issue of the obligations of self-insured employers whose TPAs are themselves "church plans" that are not themselves required to provide contraceptive coverage. The deep division in the lower courts and the Supreme Court's latest action in granting a stay suggest that the Supreme Court may take up the issue soon.

CMS Reports Progress in Delivering Accurate Enrollment Information to Insurers

Starting when healthcare.gov opened to public on October 1, 2013, insurers reported problems with the transmission and accuracy of the customer information being conveyed from the exchanges to the insurers. The conveyance of this information is referred to as an 834 EDI transmission or "an 834," and takes place each evening around 6pm. This is not a new process. It is the standard means by which employers communicate with insurers about enrollment in their health plans. On December 14, 2013, CMS reported that the percentage of missing 834s had declined to 0.38% for the period from November 24-December 5, and that accuracy rates had also improved significantly. In early December, CMS provided insurers with a full list of who CMS believed had signed up for each of their plans through the end of November, so that the insurers could reconcile that list with their own internal enrollment records. CMS also planned to provide a similar list for December enrollees following the close of open enrollment in late December.

Covering New Hampshire Website Launched

In late December, Covering New Hampshire, a statewide outreach program for the Affordable Care Act funded by a federal grant and conducted under the auspices of the New Hampshire Health Plan, launched a website for New Hampshire residents to understand their options under the Affordable Care Act. It is accessible online at http://coveringnewhampshire.org/. The website provides detailed information about the marketplace plans available in New Hampshire, including a tool that allows side-by-side comparison of up to three marketplace plans. The site also has information on the locations of "in-person assisters" who can assist with enrollment, and a calendar of enrollment and outreach events being held daily around the state. Finally, the site contains an assistance calculator to help residents estimate whether they are entitled to premium subsidies or cost-sharing assistance. While the website does not permit residents to enroll directly, it provides links to the health insurance marketplace and details alternative means of enrollment. It also links to Anthem's provider directory.

Backlog of Paper Applications Accumulates

As of mid-December, the federal marketplace had accumulated a backlog of 50,000 to 60,000 paper applications, which were particularly popular in October and November for individuals who were unable to access healthcare.gov. Approximately 170,000 paper applications were submitted between October 1 and early December, and it is likely that some individuals who submitted paper applications early on subsequently chose a plan online when healthcare.gov became more functional. An outside contractor, Serco, was hired to handle the applications and was racing to complete processing them by late December. Adding to the challenge, paper applications themselves are not sufficient to complete enrollment in a health plan, but are used only to start the process and determine eligibility for subsidies. Once completed, individuals must either go online or call the call center to choose and enroll in a health plan. It is recommended that individuals enroll directly on healthcare.gov to avoid the delays caused by a paper application.

Federal Legislative Update

Budget Measure Delays Physician Payment Cuts Until March 2014 While Permanent Solution Is Sought

On December 26, as part of a broader budget agreement, President Obama signed the "Pathway for SGR Reform Act of 2013," which delays until the end of March the cut in Medicare reimbursements to physicians that was set to take effect on January 1, 2014. The budget agreement also extended the across-the-board 2% cut to Medicare providers imposed by the Budget Control Act of 2011, but provided a 0.5% increase in reimbursement for claims with dates of service between January 1, 2014, and March 31, 2014, as compared with 2013 rates. The Act extends a number of Medicare provisions through March 31, 2014, including the physician work geographic adjustment floor and the "exceptions" process (using a KX modifier) for medically necessary outpatient therapy furnished in excess of the outpatient therapy caps.

Medicare Physician Payment Legislation Released

On December 19, the Senate Finance Committee, and on December 12, the House Ways and Means Committee, voted similar bills out of committee that address the issue of how Medicare pays physicians. The House Bill would provide physicians with a 0.5 percent annual increase from 2014 to 2018, and a 0.5 percent annual increase starting in 2019 subject to quality adjustments as described below. The Senate Bill would provide no increase for ten years, subject to quality adjustments starting in 2017 as described below.

The Senate Bill proposes to have value-based performance incentives take effect beginning in 2017. These incentives would incorporate and consolidate the Medicare EHR incentive program, the Physician Quality Reporting System, and the value-based payment modifier into one set of incentives. These incentives would be quantified into a "composite performance score" for the year based on the eligible professional's "performance." With the fee schedule amount as a baseline, payments would be decreased or increased by up to 4% of the fee schedule amount in 2017, 6% in 2018, 8% in 2019, 10% in 2020, and 10-12% in 2021 and beyond. In order to have the program be cost-neutral for the government, those with the lowest composite performance scores would have payments decreased by the designated percentage, those with the highest performance scores would have payments increased by the designated percentage, and those with scores in-between would have their payments distributed across the range accordingly—that is, decreased or increased according to the score by a smaller percentage, while those with exactly average performance would have their payments neither decreased nor increased. An eligible professional's composite performance score and corresponding payment rate

would be redetermined each year and would remain unchanged until the following year. The scores themselves would be made public on the Physician Compare website.

The House Bill proposes to have similar but less extensive "quality adjustments" take place beginning in 2019, with adjustments of 1%, 0, or -1% each year depending on the composite score achieved. Those professionals who do not report data for a given year would experience a 5% decrease in reimbursement for that year.

Under the Senate Bill, physicians who participate substantially in "alternative payment models," such as "patient-centered medical homes" and "accountable care organizations," would be eligible for a lump sum annual bonus equal to 5% of the payment amount for covered professional services from 2017 through 2022. Starting in 2024, the Senate Bill would provide participants in such models annual increases of two percent, while other professionals would receive annual increases of one percent.

With the enactment of the Pathway for SGR Reform Act of 2013, lawmakers have until March 31, 2014, to work out a long-term solution to the issue of physician payments.

HHS Extends Protections for EHR Donations Through 2021

On December 27, 2013, the U.S. Department of Health and Human Services (HHS) issued final rules that extend through 2021 legal protections for donations of electronic health record (EHR) products and other health information technologies by hospitals and other health care entities. The rules extend the previously scheduled sunset of an Anti-Kickback Statute safe harbor and Stark Law exception that allow physicians to accept donations of EHRs without running afoul of these anti-fraud laws. The new sunset date of December 31, 2021 coincides with the end of the Medicaid Electronic Health Record Incentive Program, which means that physicians will be able to accept donated software for the duration of the Medicare and Medicaid meaningful use incentive programs so long as the donation is consistent with the Anti-Kickback and Stark laws.

In addition to extending the sunset date of the current regulations, the new final rules contain several important revisions to the EHR donation rules, including:

- Eliminating the requirement that the donated EHR technology include electronic prescribing.
- Limiting the scope of protected donors to exclude laboratory companies.
- Updating the definition of interoperability. The rules require that EHR software be "interoperable" at the time it is donated. Software is now deemed to be interoperable if it has been certified by a certifying body authorized by the Office of the National Coordinator for Health Information Technology ("ONC") as meeting current EHR certification criteria on the day that it is donated.
- Clarifying the requirement prohibiting donors from taking any action that limits or restricts the use, compatibility or interoperability of the donated EHR. The final rules modify existing requirements to prevent the misuse of the exception and safe harbor in a way that results in data and referral lock-in and to encourage the free exchange of data.

Phase 2 Claims Editing Begins

As discussed in our previous legal update, Phase 2 claims editing began on January 6, 2014. Medicare will now deny claims for services or supplies if the ordering or referring physician or nonphysician practitioner does not have a valid Medicare enrollment record (including a valid "opt out") and valid NPI, in addition to being members of a specialty that is eligible to order and refer the particular service. CMS has advised that middle names and suffixes of ordering/referring providers should not be included on paper claims; only the first and last name should appear. If the information is invalid or does not match CMS's records, the claim will be denied. (For reference and matching purposes, those records are available online at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/MedicareOrderingandReferring.html.)

The Phase 2 claims edits apply to claims for clinical laboratory, imaging, and DMEPOS services and supplies, as well as Part A claims by home health agencies.

CMS Proposes National Emergency Preparedness Requirements for Participating Providers and Suppliers

On December 27, 2013, CMS published a proposed rule that would establish national emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional and local emergency preparedness systems. It would require 17 types of providers and suppliers to conduct a risk assessment and develop an emergency plan, develop and implement policies and procedures based on the plan and risk assessment, develop and maintain a communication plan, and develop and maintain training and testing programs, including initial and annual trainings. The requirements would vary by type of provider and supplier. While they are not proposed to apply to physician offices, they would apply to most other types of providers and suppliers, including hospitals, ambulatory surgery centers, various forms of inpatient facilities and outpatient clinics, and certain providers of outpatient physical therapy and speech-language pathology services.

OIG Issues Annual Notice Seeking Input on Developing Safe Harbors, Special Fraud Alerts

On December 27, 2013, the OIG published a notice asking for input on what kind of anti-kickback safe harbors and special fraud alerts it should develop in the coming year. Under HIPAA, the OIG is required to publish this notice every year. Comments are due by February 25, 2014.

OIG Releases Report on EHR Fraud Safeguards

The Office of the National Coordinator for Health Information Technology (ONC), which coordinates the adoption, implementation and exchange of electronic health records (EHRs), has contracted with RTI International (RTI) to develop recommendations to enhance data protection; increase data validity, accuracy and integrity; and strengthen fraud protection in EHR technology. In order to assess the extent to which hospitals had implemented RTI's recommended safeguards, OIG sent an online questionnaire to approximately 864 hospitals that received Medicare incentive payments as of March 2012. In December, the OIG published a report analyzing the data, entitled, *Not All Recommended Safeguards Have Been Implemented in Hospital EHR Technology*.

OIG found that while nearly all hospitals with EHR technology had the recommended audit functions in place, they may not be using them to their full extent. In addition, all hospitals used a variety of RTI-recommended user authorization and access controls, with nearly all hospitals using RTI-recommended data transfer safeguards. Almost half of the hospitals had begun implementing RTI-

recommended tools to include patient involvement in anti-fraud efforts. Only about one quarter of hospitals had policies regarding the use of the copy-paste feature in EHR technology, which if used improperly, could pose a fraud vulnerability.

To address these issues, OIG recommends that audit logs be operational whenever EHR technology is available for updates or viewing. To that end, OIG offered two options: (1) ONC could propose a change to its EHR certification criteria to require that EHR technology keep audit logs operational whenever these are available for update or viewing or (2) CMS could update its meaningful use criteria to require providers to keep the audit logs operational whenever EHR technology is available for update or viewing. OIG also recommends that ONC and CMS strengthen their collaborative efforts to develop a comprehensive plan to detect and reduce fraud vulnerabilities in EHRs. Finally, OIG recommends that CMS develop guidance on the use of the copy-paste feature in EHR technology and specifically consider whether the risks of some copy-paste practices outweigh their benefits. CMS and ONC concurred with all of OIG's recommendations.

OIG Issues its Fall Semiannual Report to Congress

On December 23, 2013, OIG issued its Fall semiannual report to Congress, summarizing its activities from April 1, 2013 through September 30, 2013. Some of the highlights of the report include:

- OIG expects to recover more than $5.8 billion for fiscal year 2013, consisting of about $850 million in audit receivables and approximately $5 billion in investigative receivables.

- OIG reported exclusions of 3,214 individuals and entities from participation in Federal health care programs; 960 criminal actions against individuals and organizations engaged in crimes against federal health care programs; and 472 civil actions, including False Claims Act cases and civil monetary penalty settlements.

- Over the course of FY 2013, Medicare Fraud Strike Force teams filed charges against 274 individuals or organizations, worked on 251 criminal actions and recovered $333 million. Strike force teams are currently operating in nine cities.

In a foreword to the report, the Inspector General said that HHS faces significant challenges in implementing the Affordable Care Act, especially the health insurance exchanges. Going forward, OIG will focus on core risk areas associated with the marketplaces, such as eligibility systems, payment accuracy, IT security and contracting.

NPDB Announces Publication of a Draft of the Revised User Guidebook

The Health Resources and Services Administration will accept comments through January 10, 2014 on draft revisions to the National Practitioner Data Bank (NPDB) Guidebook. The revised Guidebook incorporates legislative and regulatory changes since the 2001 edition, including the merger of the NPDB with the Healthcare Integrity and Protection Data Bank, and includes links to statutes, regulations and the NPDB website. The revised Guidebook also offers Data Bank users additional and clearer examples of when and how to report and query the Data Bank, and useful tables explaining Data Bank policies. Requests for an electronic PDF copy of the draft Guidebook can be obtained by emailing NPDBPolicy@hrsa.gov.

NEW HAMPSHIRE DEVELOPMENTS

Annual New Hampshire Insurance Department Report on Health Insurance Costs Released

In mid-December, the New Hampshire Insurance Department released its annual report on health insurance costs in New Hampshire. The report contains many statistics on the state of health care and health insurance in New Hampshire. According to the report:

- Health care prices in 2014 are set to increase about 8.1%, while they increased 8.7% in 2013.
- Premiums in fully insured private plans increased 1.1% in 2012, less than the 3.8% increase in 2011. According to the report, premium increases would have been approximately 4% to 6% were it not for a movement to increased member cost sharing (higher deductibles, copayments, and coinsurance) within the insurance plans.
- In fully-insured plans, utilization decreased 3.5%, but costs increased 6.4%, for a net increase in overall claims of 2.7%.
- The share of claims paid by members of fully-insured health plans increased from 18.2% in 2011 to 20.1% in 2012 due to increases in member cost sharing.
- In fully-insured plans, actual claims consumed only 79.5% of premiums in 2012. The ACA requires a minimum 80% loss ratio in the individual and small group markets, and 85% in the large group market. (New Hampshire received a waiver temporarily allowing for lower loss ratios in the individual market of 72% in 2011 and 75% in 2012, but carriers are required to meet the 80% threshold in 2013 and beyond). Two New Hampshire carriers—Cigna in the large group market and Time Insurance Company (Assurant) in the individual market—were required to pay $1.2 million in premium rebates for failing to meet the required threshold.
- Insurers' operating profit margins, known as the "underwriting gain percentage," rose from 3.1% in 2011 to 3.4% in 2012.
- Census data from 2010 and 2011 report that New Hampshire residents receive health insurance coverage as follows: 61% Employer-Sponsored, 15% Medicare, 7% Medicaid, 5% Individual, and 1% Other Public, leaving 11% of New Hampshire residents uninsured. Certain of these percentages are quite different from national averages, where 49% have Employer-Sponsored Coverage, 16% have Medicaid, 16% are Uninsured.
- In the fully-insured private market in 2012, Anthem held a 62.8% market share, followed by Harvard Pilgrim with 22.5%, CIGNA with 5.6%, MVP with 4.9%, and others with the remaining 4.3%.

Updates to New Hampshire Business Corporation Act Enacted

As of January 1, 2014, the revised and updated New Hampshire Business Corporation Act ("NHBCA"), RSA ch. 293-A, went into effect. The new NHBCA replaces the previous version of the Act, which was enacted in 1993. New Hampshire businesses may want to consult with corporate counsel to understand the changes in the law and, if necessary, to adapt their governance documents. The following is a description of some of the more notable provisions of the Act:

- The new law includes several provisions that address developments in technology. These provisions allow for the electronic transmission of corporate notices and allow shareholders to participate in annual and special meetings remotely.

- The NHBCA changes the standard for when a sale of assets by a corporation requires shareholder approval by providing a bright line test for what constitutes a sale of "all, or substantially all" of a corporation's assets. Under the new Act, shareholder approval is required if the sale would leave the corporation without significant continuing business activity, and defines when that is considered to happen.

- The NHBCA contains a new chapter dedicated to the conversion of various business entities. The chapter sets forth a process for allowing foreign business corporations and other entities to become New Hampshire corporations by filing a simple set of documents with the Secretary of State.

- The NHBCA allows more types of entities to serve as registered agents.

- The NHBCA makes several changes to when shareholders have the right to dissent from corporate action. Under the updated NHBCA, shareholders do not generally have the right to dissent from changes to a corporation's articles of incorporation unless dissenters' rights are specifically provided for in the articles of incorporation. In addition, the rights of preferred shareholders to dissent can, in certain circumstances, be eliminated to the extent expressly provided for in the articles of incorporation.

- Claims against a dissolved corporation must now be brought within three years, and not five. The law also provides a procedure by which dissolved corporations may file an application with the Superior Court to determine the amount and form of security to be provided for payment of contingent or other unknown claims.

Challenges to Medicaid Enhancement Tax Continue

Arguments are taking place soon in two lawsuits challenging the constitutionality of the Medicaid Enhancement Tax, one in Rockingham County Superior Court, and the other in Hillsborough County Superior Court. In addition, three pieces of proposed legislation will seek to make changes to the MET. One proposed bill would allow hospitals to make MET payments on a quarterly basis; a second would exempt specialty rehabilitative hospitals from the MET; and a third would seek to reduce the rate of or eliminate the MET and replace the revenue with another funding source.

Stolen Thumb Drive Costs Massachusetts Dermatology Practice $150,000

On December 26, 2013, HHS announced that a Massachusetts-based dermatology practice – with two locations in New Hampshire – agreed to pay $150,000 to settle claims that it violated the HIPAA Privacy, Security and Breach Notification Rules. In addition to the fine, the practice will also be required to implement a corrective action plan to correct deficiencies in its HIPAA compliance program. According to HHS, this marks the first settlement with a covered entity for not having policies and procedures in place to address the breach notification provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act.

The HHS Office for Civil Rights opened an investigation into the practice after receiving a report that an unencrypted thumb drive containing the electronic protected health information (ePHI) of approximately 2,200 individuals was stolen from a staff member's vehicle. The thumb drive was never recovered. The investigation revealed that the practice notified its patients of the theft of the thumb drive within 30 days and provided media notice at that time. However, the practice did not conduct an accurate and thorough analysis of the potential risks and vulnerabilities of the confidentiality of ePHI as part of its security management process until a year later. It also did not have written policies and procedures in place as required under the HIPAA Rules.

REMINDERS

Annual Reports Are Due to the Secretary of State's Office by April 1, 2014

For individuals or groups organized as a corporation, professional corporation or professional association, limited liability company, or professional limited liability company, annual reports are due to the Secretary of State's Office by April 1, 2014. Reminders were sent last week. The Secretary of State has issued an alert that some for businesses whose name starts with the letter "T" (including those business names that begin with the word "The") and continuing through the end of the alphabet, the annual report reminder notice may contain the wrong Business Identification Number. A corrected annual report reminder notice will be sent to those affected businesses with their correct Business ID number.

Deadline to Notify HHS of All Breaches Affecting Fewer Than 500 Individuals is March 1, 2014

To comply with HITECH breach notice requirements, HIPAA covered entities are required to report all breaches that affected fewer than 500 individuals that occurred in 2013 to the U.S. Department of Health and Human Services by March 1, 2014. Notifications must be submitted online at http://ocrnotifications.hhs.gov/.

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Cinde Warmington, Clara Dietel, and Benjamin Siracusa Hillman contributed to this month's Legal Update.

BIOS

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