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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

Supreme Court Agrees to Hear Challenge to IRS Regulation Permitting Eligible Purchasers of Insurance on Federal Marketplaces to Avail Themselves of Premium Tax Credits and Subsidies

On November 7, the Supreme Court agreed to hear a challenge to an IRS regulation that provides premium tax credits and subsides to eligible residents of the states that rely on the federal government to operate their health insurance marketplaces. As discussed in past legal updates, the issue stems from what was likely an error in the drafting of a single section of the Affordable Care Act. That section, which describes how subsidies are calculated, refers to "an exchange established by the state," without specifically providing that subsidies apply to those who purchase insurance on marketplaces run by the federal government instead.

The IRS has issued a regulation providing for subsidies regardless of who runs the marketplace. The challenge alleges that that regulation is inconsistent with the statute. If the challenge succeeds, the Affordable Care Act will remain in effect, but the IRS will be unable to provide premium tax credits to those who have purchased health insurance through the federal health insurance marketplace.

House Republicans Bring New Lawsuit Challenging Administration of the Affordable Care Act

On November 21, House Republicans filed a new lawsuit challenging the Affordable Care Act. The suit alleges that Congress has never appropriated payments to pay for "cost-sharing reductions" to insurers, and hence the payments made to such insurers were an unlawful expenditure of federal funds. Cost-sharing reductions are a provision of the Affordable Care Act that provides reductions in out-of-pocket costs, such as deductibles, co-payments, and co-insurance, to members of households with income between 100% and 250% of the poverty level who purchase certain plans on the health insurance marketplaces. (The lawsuit does not challenge the premium tax credits or subsidies, which households with income between 100% and 400% of the poverty level can receive, as Congress provided in the ACA that the premium tax credits fall within the permanent appropriation for "tax refunds.")

The same lawsuit also alleges that the Obama administration acted unlawfully in postponing the start date of the employer mandate.

FDA Requires Wide Range of Food Vendors to Post Calorie Counts

On November 25, the FDA finalized menu labeling rules requiring a wide range of food vendors with twenty or more locations to post calorie counts for prepared foods. The rules, promulgated under the Affordable Care Act, apply to restaurants, fast-food restaurants, movie theaters, pizza

parlors, vending machines, amusement parks, and even grocery and convenience stores selling prepared foods. The rules are more expansive than expected, and include alcoholic beverages when such beverages are listed on a menu. They take effect on December 1, 2015.

Three-Month ACA Open Enrollment Period Began November 15

In the first week of open enrollment, more than one million people nationally submitted applications for health insurance. Just under half of these people actually chose plans, and of those, about half had existing coverage and the other half did not (including applicants who had had coverage terminated during the year). Although there have been some challenges with individuals revalidating their identities and with individuals who had previously enrolled re-using their usernames and passwords (or resetting such usernames and passwords if they had lost or forgotten them), by and large, the federal health insurance marketplace has not experienced the persistent technical problems that plagued it last fall. As noted in a previous legal update, New Hampshire's marketplace now features five participating insurers, including two cooperative insurance plans that are new to the state.

Federal Appeals Court Rejects Maine's Effort to Drop Medicaid Coverage for Nineteen and Twenty Year Old Members of Low-Income Families

On November 17, the United States Court of Appeals for the First Circuit denied Maine's appeal of a decision by the federal Department of Health and Human Services that had disapproved of Maine's effort to drop Medicaid coverage for nineteen and twenty year old members of low-income families.

After providing Medicaid coverage to 19- and 20-year olds for over two decades, in 2012, Maine proposed a Medicaid state plan amendment dropping that coverage. The federal Centers for Medicare and Medicaid Services (CMS) disapproved that amendment, citing a provision of the Affordable Care Act that contains a "maintenance of effort" provision. This provision, in effect until 2019, requires that states that wish to continue receiving Medicaid funding not change their prior standards for determining the eligibility of any child, which in Maine had been defined to include 19 and 20 year olds. The First Circuit held that even considering the Supreme Court's 2012 decision holding that Congress could not require states to expand Medicaid, Congress could condition states' continuing participation in the existing Medicaid program upon compliance with such a provision.

<u>Other Federal Developments</u>

CMS Issues Final Rule Implementing Provider Enrollment Requirements

On December 3, CMS issued a final rule that will allow it to deny or revoke Medicare enrollment. Specifically, CMS may deny enrollment to providers, suppliers and owners who previously owned a provider or supplier that had a Medicare debt that existed when the latter's enrollment was terminated. This will prevent people and entities that have incurred substantial Medicare debt from exiting the program and then attempting to re-enroll as a new business in order to avoid repayment of the outstanding Medicare debt. Enrollment will be denied if the provider or supplier left the previous organization within one year of the organization's termination or revocation from Medicare. A denial can be avoided if the provider or supplier agrees to a CMS-approved extended repayment schedule for the entire outstanding Medicare debt or repays the debt in full.

Additional restrictions included in the final rule would allow CMS to revoke or deny a provider's billing privileges if a managing employee is found to have been convicted of a state or federal felony within the

previous 10 years, as well revoke Medicare billing privileges if a provider's billing patterns don't meet Medicare requirements.

Sunshine Act Updates

CMS has said that the agency will refresh the 2013 payment data in the Open Payments system by December 31, 2014. The refresh will include newly released data related to records that were in "disputed" status at the close of September 11, 2014. Any records that were disputed after September 11 will not be refreshed until the next data publication in June 2015.

On October 30, CMS announced that applicable manufacturers and group purchasing organizations (GPOs) can now review and revise 2013 payment data that was originally published as "de-identified" on September 30. Applicable manufacturers and GPOs have until the end of the 2014 data submission and attestation period (expected to be March 31, 2015) to submit the corrected reports for the 2013 reporting year.

In addition, on October 17, CMS announced the launch of a search tool where users can search "identified data" in the Open Payments database for physicians, teaching hospitals, or companies using name, city, state or specialty. CMS also indicated that additional interface improvements are expected over the coming weeks, including displays of summary data, data charts, graphs, as well as more detailed data.

OIG Releases 2015 Work Plan

On October 31, the OIG released its Work Plan for FY 2015. The Work Plan provides the OIG's planned reviews and activities with respect to HHS programs and operations during the current fiscal year and beyond. In the Work Plan, the OIG stated that it plans to continue to focus on issues such as emerging payment, eligibility, management, IT security vulnerabilities, care quality and access in Medicare and Medicaid, public health and human services programs, and appropriateness of Medicare and Medicaid payments.

Some notable aspects of the Work Plan include:

- *Hospital Inpatient Admission Criteria – "Two Midnight Rule"*: The OIG intends to review the impact of new inpatient admission criteria on hospital billing, Medicare payments and beneficiary copayments. Specifically, OIG intends to review how billing varied among hospitals in the 2014 fiscal year.

- *Provider-Based Facilities*: The OIG plans to audit and review provider-based facilities' compliance with CMS's compliance criteria. This audit was first identified in the 2013 Work Plan and the OIG anticipates publishing a report of its findings and recommendations in FY 2015.

- *Outpatient Evaluation and Management (E&M) Codes*: The OIG intends to assess whether payments made for E&M services provided during clinic visits and billed at the new patient rate were appropriate, or whether the services should have been identified as services for established patients. This review may result in the OIG recommending recovery of overpayments.

- *Hospital Wage Data*: The OIG will assess the level of hospital control over the reporting of wage data, which is used to calculate wage indexes for Medicare payments. In prior reviews, the OIG identified hundreds of millions of dollars in incorrectly reported wage data that resulted in policy changes by CMS with regard to how hospitals report deferred compensation costs.

- *Oversight of Pharmaceutical Compounding*: The OIG will evaluate the extent to which Medicare's oversight of Medicare-participating acute care hospitals addresses recommended practices for pharmaceutical compounding oversight. The Work Plan notes that most hospitals compound pharmaceuticals onsite and Medicare oversees the safety of those compounded pharmaceuticals through the accreditation and certification process.

- *Ambulatory Surgical Centers – Payment Systems*: The OIG will review the appropriateness of Medicare's methodology for setting ambulatory surgical center (ASC) payment rates. The OIG also intends to review whether a payment disparity exists between the ASC and hospital outpatient department payment rates for similar surgical procedures provided in both settings.

- *Independent Clinical Laboratory Billing Requirements*: The OIG will review Medicare payments to independent clinical laboratories to determine whether the laboratories have complied with certain billing requirements. The OIG will then use these reviews to identify clinical laboratories that have routinely submitted improper claims and, if improper claims exist, will recommend recovery of overpayments.

- *EHR Incentive Payments*: OIG will review Medicare incentive payments to eligible health care professionals and hospitals for adopting electronic health records (EHRs). As part of this review, the OIG will assess whether those individuals and entities receiving EHR incentive payments are adequately protecting patients' electronic health information.

- *Affordable Care Act implementation*: The OIG also plans to review several aspects of the health insurance marketplaces in FY 2015, including:

    - Determining whether premium tax credits and cost-sharing reductions are being calculated accurately and are going to eligible individuals;

    - Reviewing CMS's internal controls for generating and approving premium tax credit payments;

    - Determining whether nine states made appropriate use of federal funding and complied with federal requirements in the creation of state insurance exchanges;

    - Determining whether insurance exchange navigators complied with federal regulations, such as completing criminal background checks and undergoing training; and

    - Reviewing the internal controls of seven state health insurance exchanges.

2015 OPPS and ASC Final Rule Released

On October 31, CMS published its 2015 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Policy Changes and Payment Rates final rule. This annual rule affects the approximately 4,000 hospitals that are paid under the OPPS and the 5,300 participating ASCs. Some of the key provisions of the rule include:

- *OPPS Payment Rate Increase*: CMS estimates that overall OPPS payments may increase by 2.3

percent based upon a projected hospital market basket increase of 2.9 percent minus adjustments for productivity as required by law.

- *ASC Payment Rate Increase*: ASC payment rates are increasing by 1.4 percent, after a productivity adjustment of 0.5 percent.

- *Physician Inpatient Certification*: The final rule revises the physician certification requirements for most inpatient hospital services. Under the rule, a physician order will still be required for inpatient admissions. However, certification will only be required for patients having inpatient stays of 20 days or more and for outlier cases. CMS currently requires a physician certification, including the admission order, for all inpatient admissions.

- *Medicare Advantage Plan and Part D Additional Recoupment Authority*: CMS established a process, including a three-level appeals mechanism, to recoup overpayments that result from the submission of erroneous payment data by Medicare Advantage (MA) organizations and Part D sponsors where the MA organization or sponsor fails to correct the data.

OCR Delays Issuing Final HIPAA Rule on Disclosing Records Access

On October 10, a representative from the HHS Office for Civil Rights (OCR) announced that the agency will open another round of public comments in the coming weeks on the accounting for disclosures rule and will delay further rulemaking action until 2015. The OCR issued a proposed rule in May 2011 that would require covered entities to generate electronic reports accounting for all disclosures of protected health information under HIPAA.

CMS and the OIG Extend Fraud and Abuse Waivers for Shared Savings Programs into 2015

On October 16, CMS issued a notice that extends fraud and abuse waivers for accountable care organizations (ACOs) until November 2, 2015, at which time a final rule is expected to be in place. The notice extends a November 2011 interim final rule issued by CMS and the OIG that provided fraud and abuse waivers to ACOs participating in the Medicare Shared Savings Program. The interim rule waived certain provisions of several fraud and abuse laws, including the Stark law, the anti-kickback statute and the civil monetary penalty law.

Civil Monetary Penalty Enforcement Actions Against Medicare Advantage Plans Triple

On October 16, CMS released its 2013 Part C and Part D Program Annual Audit and Enforcement Report. In it, CMS states that civil monetary penalty (CMP) enforcement actions in Medicare Parts C and D more than tripled between 2012 and 2013. In 2012, there were 10 instances in which CMS imposed CMPs, the lowest of three enforcement actions the agency may use following an organizational audit. This grew to 33 in 2013, according to the report. Between the two years, CMS imposed nearly $8.4 million in CMPs, ranging from $21,800 to $2.2 million, resulting in an average CMP of $194,410.00. Of the other two enforcement actions, suspension and termination, the number of immediate suspensions rose from two to three and there were no terminations in either year.

OIG Announces Extension of Comment Period on Potential Revisions to Permissive Exclusion Authority

On October 29, the OIG announced that the public will have an extra sixty (60) days to comment on potential revisions to the OIG's permissive exclusion authority. Due to a technical problem, the public may have been unable to submit comments by the deadline for the original OIG solicitation, which was published

in the July 11 Federal Register. The July notice asked for public comments on revising the criteria for the OIG's permissive exclusion authority, such as whether the criteria should be different for individuals as opposed to entities and whether an existing compliance program should be considered when making a permissive exclusion decision. Comments are due by December 29.

CMS Releases Final 2015 Physician Fee Schedule

On October 31, CMS issued the final 2015 physician fee schedule, which will go into effect on or after January 1, 2015. Under the final rule, Medicare physician payment rates will be reduced by 21.2 percent after March 2015. This reduction is required under the Sustainable Growth Rate (SGR) formula. CMS noted that in recent years, Congress has taken action to avert a large reduction in the physician fee schedule rates before they went into effect. CMS stated that it will continue to work with Congress to address the SGR "so doctors and beneficiaries no longer have to worry about the stability and adequacy of payments from Medicare."

Some other notable provisions in the final rule include:

- *Primary care and chronic pain management*: Beginning in 2015, CMS will now pay for chronic pain management services separately for Medicare beneficiaries who have two or more significant, chronic conditions. The final rule establishes a payment rate for chronic care management services that may be billed up to once per month for each qualified patient. These services include communication and coordination among a care team, medication management and consistent review of a patient's plan of care.

- *Transparency in setting physician fee schedule rates*: CMS establishes a new process for determining fee schedule payment rates that will allow payment rates to go through notice and comment rulemaking prior to being adopted.

- *Telehealth services*: CMS is expanding the telehealth benefit available to Medicare beneficiaries to include the following services: annual wellness visits, psychoanalysis, psychotherapy, and prolonged evaluation and management services.

- *Improving quality*: The final rule establishes new requirements related to the 2017 Physician Quality Reporting System (PQRS) payment adjustment. To promote reporting of quality information, the PQRS is a pay-for-reporting program that provides incentive payments and payment cuts to eligible professionals. Beginning in 2015, the program will apply a payment adjustment, or cut, to professionals who do not report data on quality measures for particular professional services.

OMB Finishes Review of Final Rule Aimed at Reducing Medicare Fraud

On November 12, the OMB finished its review of a CMS rule that would ensure that potentially fraudulent entities and individuals do not enroll in or maintain their enrollment in the Medicare program. The proposed version of the rule was published in April 2013. The proposed rule would raise the maximum reward for successful Medicare fraud tips from $1,000 to $9.9 million. CMS has said that it believes the proposed rule will increase the incentive for individuals to report information on individuals and entities that have or are engaged in sanctionable conduct and will improve CMS's ability to detect new fraud schemes.

HHS Pulls Proposed Rule on 340B Drug Discount Program

On November 13, HHS withdrew a comprehensive proposed rule on the 340B drug discount program

from review at the Office of Management and Budget (OMB). In a notice posted to its website, HHS's Health Resources and Services Administration (HRSA) said that the agency plans to issue proposed guidance for notice and comment in 2015 "that will address key policy issues raised by various stakeholders." HRSA is also planning to issue proposed regulations where the statute provides explicit rulemaking authority, "pertaining to civil monetary penalties for manufacturers, calculation of the 340B ceiling price, and administrative dispute resolution." This follows a recent court decision where the U.S. District Court for the District of Columbia vacated a narrower 340B rule.

Department of Justice Recovers Record Amount from False Claims Act Cases in FY 2014

On November 20, the Department of Justice (DOJ) announced that it recovered a record $5.69 billion in civil False Claims Act (FCA) settlements during FY 2014, including $2.3 billion for FCA cases involving federal health care programs, such as Medicare and Medicaid. This was the fifth consecutive year that the DOJ recovered more than $2 billion in health care fraud cases due, in part, to the creation of the interagency task force, the Health Care Fraud Prevent and Enforcement Action Team (HEAT) program. Since the HEAT program's inception in 2009, the DOJ has recovered $14.5 billion in federal health care dollars.

U.S. Senate Passes Short-Term Delay of Outpatient Supervision Requirement

On November 20, the Senate passed a bill that will delay enforcement for the rest of 2014 of a Medicare supervision requirement for outpatient therapeutic services in critical access (CAH) and small rural hospitals. CMS has had a moratorium on enforcing direct supervision requirements since 2010. However, in the FY 2014 OPPS rule, CMS said that it would end the moratorium for all hospitals beginning in 2014. The bill extends that moratorium for small rural hospitals beds and for CAHs through December 31. The bill passed the House in September and now goes to the president for his signature.

CMS Issues Final Rule on Disproportionate Share Hospital (DSH) Payments

On November 28, CMS released a final rule on the hospital-specific limitation on Medicaid DSH payments. CMS explained that the rule's interpretation and definition of "uninsured" affords states and hospitals maximum flexibility permitted by statute in calculating the hospital-specific DSH limit. Under this limitation, DSH payments to a hospital cannot exceed the uncompensated costs of furnishing services by the hospital to individuals who are Medicaid-eligible or "have no health insurance (or other source of third party coverage) for the services furnished during the year." The rule is designed to mitigate concerns about a 2008 rule requiring state reports and audits to ensure the appropriate use of Medicaid DSH payments, which are paid to hospitals serving a disproportionate share of certain low-income patients. The rule takes effect on December 31.

CMS Proposes Changes to the Medicare Shared Savings Program Regulations

On December 1, CMS issued a proposed rule addressing changes to the Medicare Shared Savings Program, including provisions related to the payment of ACOs participating in the Shared Savings Program. CMS says that the proposed rule will give more flexibility to ACOs seeking to renew their participation in the program. In the fact sheet released with the rule, CMS says the proposed rule addresses changes to several program areas including beneficiary assignment, data sharing, available risk models, eligibility requirements, participation agreement renewals, and compliance and monitoring. Additionally, the proposed rule seeks comment on issues related to financial benchmarking and waivers for program and other payment rules.

OCR Publishes Bulletin on HIPAA Requirements in Emergency Situations

In response to the Ebola outbreak and other current events, the U.S. Department of Health and

Human Services (HHS), Office for Civil Rights (OCR), recently published a Bulletin, *HIPAA Privacy in Emergency Situations*, reminding covered entities and their business associates that their obligations under the HIPAA Privacy Rule do not change during emergency situations, such as the Ebola outbreak. OCR explains that the Privacy Rule requires a balance between the protection of the privacy of protected health information (PHI) against the necessary uses and disclosures of such information "to treat a patient, to protect the nation's public health, and for other critical purposes."

OCR does not introduce any new requirements in the Bulletin, but sets forth the circumstances under which PHI may be shared in emergencies without the patient's permission, including: sharing information on a patient for purposes of treating that patient or to treat a different patient; sharing information with a public health authority such as the Centers for Disease Control and Prevention (CDC); and sharing information with the patient's family and others involved with their care. OCR also states that minimal information on a patient can be shared with the media if the patient has given their approval or if the patient is incapacitated, then if that information is in the public interest. Generally, OCR notes that covered entities must make reasonable efforts to limit the PHI disclosed to that which is the "minimum necessary" to accomplish the purpose.

Health care entities should be aware of these obligations during an emergency. In Nebraska, two employees at the Nebraska Medical Center were fired after they inappropriately accessed the record of an Ebola patient in violation of HIPAA.

OIG Advisory Opinions

On October 14, the OIG released Advisory Opinion No. 14-09, in which it analyzed an existing arrangement under which a township uses tax revenues to cover out-of-pocket costs for basic life support emergency ambulance services received by local residents. Although the ambulance provider bills third-party payers for services provided within the town, it does not bill bona fide residents of the town for any copayments or deductible amounts, including those who participate in federal health-care programs, or for any amounts owed by uninsured or underinsured individuals. The OIG concluded that the arrangement would not lead to the imposition of administrative sanctions for violations of the anti-kickback statute. The OIG's decision was based upon the fact that the township pays the ambulance provider an annual stipend that reasonably approximates the provider's out-of-pocket costs for the town, which it distinguished from prohibited "routine waivers" of cost-sharing amounts.

On October 21, the OIG released Advisory Opinion No. 14-10, in which it concluded that a proposed arrangement between an insurer and a hospital organization for discounted Medigap plans would not lead to the imposition of administrative sanctions for violations of the anti-kickback statute. Under the proposed arrangement, the insurer would indirectly contract with hospitals for discounts on otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay. The OIG said the proposed arrangement would be unlikely to increase utilization and would present a sufficiently low risk of fraud or abuse under the anti-kickback statute.

STATE DEVELOPMENTS

Update on Medicaid Expansion

Less than six months after New Hampshire expanded its Medicaid programs, officials announced that New Hampshire is already close to meeting its first-year enrollment target. State officials had expected that 30,000 to 40,000 of the estimated 50,000 eligible adults would sign up for the expanded Medicaid in its first year. As of early December, just fewer than 25,300 had enrolled.

In addition, the State has submitted a waiver request to CMS to allow the State to use private health insurance plans to cover newly eligible Medicaid recipients under the Affordable Care Act. The federal government pays all of the cost for those who qualify under the expanded Medicaid program through December 31, 2016, and then reduces its share by two percent annually for the following five years. Those eligible for Medicaid under the expanded eligibility are currently on the State's Medicaid Managed Care program. This waiver will allow those individuals to choose private insurance through the health insurance marketplace. If CMS approves the waiver, qualified individuals will begin enrolling in private plans through the health insurance marketplace in October 2015.

Law on Registration of Medical Technicians Took Effect October 1

As of October 1, the law requiring that anyone employed as a "medical technician" register with the New Hampshire Board of Registration for Medical Technicians, RSA chapter 328-I, went into effect. The law defines "medical technician" broadly as a health care worker who is not licensed or registered by another New Hampshire regulatory board; who assists licensed health care professionals in the diagnosis, treatment, and prevention of disease; who has access to controlled substances; and who has access to or contact with patients in a health care facility or in a medical establishment. Anyone who fails to register may be guilty of a misdemeanor and subject to administrative fines.

The new law also imposes obligations on health care facilities licensed under RSA chapter 151 and "medical establishments", which is defined broadly to include most health care offices that are not licensed under RSA chapter 151, including physicians' offices. Those facilities and medical establishments must ensure that medical technicians are registered prior to employment. The health care facilities must report any "disciplinary or adverse action" against the technician to the Board within 30 days, even where the misconduct is resolved by voluntary resignation. Health care facilities that fail to comply with the provisions of the law will be subject to fines and penalties pursuant to RSA chapter 151.

Legislature Approves Medical Marijuana Treatment Center Rules

On November 19, the Joint Legislative Committee on Administrative Rules met to approve regulations for the alternative treatment centers that will be certified to sell cannabis for therapeutic purposes. Under the proposed rules, the State would seek to have four treatment centers across four "geographic areas" in New Hampshire, including one for Belknap, Rockingham and Strafford counties; a second for Hillsborough and Merrimack counties; a third for Cheshire and Sullivan counties plus Hanover and Lebanon; and a fourth for Carroll, Coos and the remainder of Grafton county. The Department for Health and Human Services has stated that the fees for the fourth treatment center will be offered at a reduced price to "increase the likelihood" of attracting a potential operator in that region. The request for applications for the treatment centers will be released in early December and the selections will be made by late January.

Elections May Impact Healthcare Policy on Federal and State Levels

On November 4, New Hampshire voters went to the polls in the mid-term elections. Governor Maggie Hassan was elected to a second term as was Senator Jeanne Shaheen. Incumbent Representative Ann McLane Kuster also retained her seat while Representative Carol Shea-Porter was defeated by Republican Frank Guinta in their third matchup. At the state level, Republicans increased their majority in the Senate and took back control of the House. The first legislative sessions of the new term will be held on January 7, 2015. We will continue to summarize and track legislation that bears on healthcare in this State.

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

BIOS

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