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Health Law Strategist

Health care reform's impact on payment and delivery models

By Nancy Waite

Health care reform continues the shift away from the fee-for-service payment model toward models that reward coordinated, quality care. The Patient Protection and Affordable Care Act (the Act) includes a series of voluntary pilot programs to explore options for controlling costs while increasing quality. These programs, including a national payment bundling pilot and a pilot that establishes a shared savings program for Accountable Care Organizations (ACOs), encourage providers to collaborate and align their interests.

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The Act also creates the Center for Medicare and Medicaid Innovation (CMI) to test innovative payment and service delivery models to reduce Medicare and Medicaid expenditures while preserving or enhancing quality. The Act includes examples of 18 models for consideration, but CMI has broad authority to select models that will best achieve its objectives.

While awaiting specific guidance on implementation of the Act's provisions on delivery and payment system reform, it is clear that to thrive under these new models, health care providers must become more integrated and more accountable for financial and clinical outcomes.

This article explores how the payment bundling and the shared savings program for ACOs will transform payment and delivery system models, and highlights how health care providers can successfully prepare for these sweeping changes.

National pilot program on payment bundling

The Act directs the Secretary of the U.S. Department of Health and Human Services (HHS) to develop a national, voluntary pilot program for bundled payments by Jan. 1, 2013. Under this pilot program, Medicare will make a bundled payment for services provided during an "episode of care" around a hospitalization. In the Act, an episode of care is defined as the time period that begins three days prior to

admission and ends 30 days following the beneficiary's discharge from the hospital. However, the Secretary may establish a different time period under the pilot program.

The bundled payment will be comprehensive and cover the cost of "applicable services" furnished to an individual during the episode of care. Applicable services are defined as acute care inpatient services, physician services, outpatient hospital services (including emergency department services), post-acute care services and other services the Secretary determines appropriate.

For this pilot program, the Secretary will select up to 10 medical conditions, develop participation requirements and develop payment methods which may include bundled payments and bids from entities for episodes of care. The Secretary will also establish quality measures related to care provided by participating entities. To the extent practicable, providers will submit data on quality measures through the use of a qualified electronic health record.

The pilot program is authorized for five years. However, after Jan. 1, 2016, the Secretary may expand the pilot program's duration and scope if the expansion is expected to reduce spending and improve quality of care.

The current Acute Care Episode (ACE) demonstration provides insight into how the Secretary may implement the bundled payment pilot program.

ACE demonstration. The three-year ACE demonstration is testing a bundled payment for hospital and physician services for inpatient episodes of care for certain orthopedic and cardiovascular procedures. The Centers for Medicare & Medicaid Services (CMS) believes that this bundled payment will better align the incentives for both hospitals and physicians to improve quality and increase efficiency in the care they deliver to Medicare beneficiaries.

Procedures. CMS selected 28 cardiovascular diagnosis-related groups (DRGs) and nine orthopedic DRGs for the ACE demonstration. CMS selected these services because "margins and volumes have historically been high, services are easy to specify and quality metrics are available."

Applicants. Eligible applicants were physician hospital organizations (PHOs). The applicants were required to meet procedure volume thresholds; to have established quality improvement mechanisms; to be located in Texas, Oklahoma, New Mexico or Colorado; and to submit a competitive bid for each DRG in their selected category of cardiovascular and/or orthopedic procedures.

Medicare payment. As payment in full, the ACE sites accept the single bundled payment for physician and hospital services provided during an episode of care. During year one, the time window for the episode of care is the traditional window covered by the current Medicare hospital inpatient prospective payment system (IPPS) rules. After year one of the demonstration, CMS and the demonstration sites may consider expanding an episode of care to include post-acute services.

Medicare beneficiaries. The demonstration applies to inpatient care of fee-for-service beneficiaries with Medicare Part A and Part B. To encourage Medicare beneficiaries to use the ACE demonstration hospitals, CMS shares up to 50 percent of the Medicare savings with the beneficiaries. The exact amount of the payment varies by site and procedure. Medicare sends the payments directly to the Medicare beneficiaries approximately 90 days after their hospital discharge.

Gainsharing. Under this demonstration, physicians can be rewarded for achieving quality and financial standards. CMS established guidelines for these provider incentive programs. For example, incentive payments to physicians may not exceed 25 percent of the amount normally paid to physicians for such cases.

Quality reporting. Sites must report 22 quality measures to CMS every quarter.

Selected Sites. In 2009, CMS selected five health care systems to participate in the ACE demonstration. Currently, three sites are operational.

Editor's Notes

We publish *Health Law Strategist* to keep you informed of current legal developments in the health care industry. *Health Law Strategist* will provide you with practical information to assist in the management of your facility and help facilitate legal compliance.

Thank you for choosing *Health Law Strategist*. Please feel free to contact me if you wish to suggest topics for future issues.
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Hillcrest Medical Center (Tulsa, Okla.)
Sites services: ortho & cardio
Implementation date: May 1, 2009

Baptist Health System (San Antonio, Texas)
Sites services: ortho & cardio
Implementation date: June 1, 2009

Oklahoma Heart Hospital (Oklahoma City, Okla.)
Sites services: cardio
Implementation date: Jan. 1, 2010

Exempla Saint Joseph Hospital (Denver, Colo.)
Sites services: cardio
Implementation date: sometime in 2010

Lovelace Health System (Albuquerque, N.M.)
Sites services: ortho
Implementation date: sometime in 2010

Baptist Health System. Baptist Health System created a new PHO for this demonstration. Although all payments go to the hospital, the new PHO handles the decision-making. To address physicians' fears, Baptist did not require its physicians to reduce their surgical fees. If Baptist physicians meet certain quality and financial criteria, they may receive a 25 percent bonus. According to published reports, in the first month, only a few of the 150 or so eligible physicians received bonuses. That figure has grown steadily to 90 physicians which is indicative of costs coming down and quality going up.

Standardizing options for expensive medical devices and implants has produced the biggest savings, according to Michael Zucker, Chief Development Officer for Baptist. Baptist's quality scores have also improved. For example, post-surgical infection rates have gone down as has length of stay. Zucker believes the gains are due to the demonstration promoting a focus on care protocols and evidence-based medicine.

Hillcrest Medical Center. According to published reports, Medicare is saving 4.4 percent on the base rates for heart and joint surgeries at Hillcrest. According to Hillcrest's Chief Executive Officer, the hospital has cut costs for knee replacement and heart-valve surgery by 5 percent. Hillcrest's doctors are guaranteed their regular surgical fees, but they also get a 25 percent bonus if they keep their costs down while maintaining high quality scores. Hillcrest estimates that it has saved nearly $730,000 since it implemented the ACE demonstration in May 2009.

State and private sector bundling initiatives. States such as Minnesota and Massachusetts have endorsed global payment systems. In addition, private sector initiatives, such as Geisinger Health System's bundled payment program, have been cited by President Obama as models for health care reform. At Geisinger, bundling has been incorporated into a larger pricing program known as ProvenCare, which includes evidence-based practices and rewards physicians for providing quality care. Services for which Geisinger has bundled payments include cardiac artery bypass graft (CABG), hip replacement, cataract surgery, PCI/angioplasty, perinatal care, baratrics, low back pain and erythropoietin management.

In the private sector, the shift toward payment bundling will gain momentum in August when the Integrated Healthcare Association launches a pilot project for bundled payments for total hip or knee replacements for commercial PPO patients in Los Angeles and Orange counties. The bundled charges for hospitals and physician services have not yet been set, but are expected to cover most aspects of the treatment from surgery through 90 days of recovery. Later phases of this pilot will expand the types of procedures and include other areas of California. The program's participants include Aetna, Blue Shield of California, CIGNA, HealthNet, Monarch Health, Cedars-Sinai Medical Center, Hoag Hospital, UCLA Health System, Saddleback Memorial Medical Center and Tenet California.

Conclusion – bundled payments. Because of the increasing prevalence of payment bundling initiatives in the government and private sectors, hospitals will likely encounter bundled payments for certain services (such as orthopedic and cardiovascular services) either as a mandate or as a strategic opportunity.

Medicare shared savings program - ACOs

In addition to payment bundling, the Act includes provisions to encourage delivery system reform through the use of ACOs. An ACO is an integrated health care delivery system that relies on a network of primary care physicians, one or more hospitals and specialists to provide care to a defined patient population. Under this model, the ACO receives bonuses for providing high-quality, low-cost care.

By January 2012, HHS must establish a shared savings program that promotes accountability for a patient population and coordinates physician and hospital care. The program also must encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Under the program, a group of providers must have a mechanism for shared governance, and work together to manage and coordinate care for Medicare fee-for-service beneficiaries.

Generally, ACO providers will continue to receive fee-for-service payments from Medicare. In addition, if the ACO meets quality of care standards established by HHS and reduces the

costs of its patients relative to a spending benchmark estimated by HHS, the ACO will be rewarded with payments for shared savings.

Under the Act, an ACO must:

(1) be willing to become accountable for the quality, cost and overall care of the Medicare fee-for-service Medicare beneficiaries assigned to it;

(2) enter into an agreement with HHS to participate in the program for at least three years;

(3) have a formal legal structure that would allow it to receive and distribute payments for shared savings to participating providers;

(4) include primary care professionals that are sufficient for the number of Medicare beneficiaries assigned to the ACO. At a minimum, an ACO will have at least 5,000 such beneficiaries assigned to it;

(5) provide HHS with certain information regarding its providers;

(6) have a leadership and management structure that includes clinical and administrative systems;

(7) define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care (such as through the use of telehealth, remote patient monitoring and other such enabling technologies); and

(8) demonstrate to HHS that it meets patient-centeredness criteria specified by HHS.

Because key components of an ACO are accountability and coordination of care, a medical home can serve as a critical building block of an ACO. A medical home is not a physical location but is a comprehensive approach to primary care that emphasizes coordination of care and fosters a more collaborative physician-patient relationship.

Under the medical home model, each patient has an ongoing relationship with a personal physician who leads a team that collectively coordinates the patient's care (including acute and chronic care and preventative services). Under this model, patient care is guided by evidence-based medicine and appropriate use of health information technology.

Conclusion – ACOs. By establishing an ACO and participating in the shared savings program, providers can financially benefit from providing high-quality, cost-effective care.

Conclusion

Under the current fee-for-service payment model, providers benefit from the link between service volume and provider revenue. Both government and private sector payers are attempting to break this link by adopting new payment models that reward providers for efficiently delivered, coordinated and high-quality care.

Health care leaders must position their organizations to respond to these new payment models. In order to be successful under the bundled payment initiatives and/or the shared savings ACO model, providers must become more clinically integrated and more accountable, and develop the infrastructure necessary to support such integration and accountability. Some initial steps to consider are:

- Hospitals and physicians should create an entity (such as a PHO) with shared governance and a formal legal structure.
- Hospitals must analyze their relationships with physicians and ancillary providers to determine how to effectively align their interests in providing high quality care while controlling costs. It is important to identify physician leaders who can agree on quality metrics and evidence-based standards of care. Providers must also address how to tie physician compensation to quality and efficiency goals.
- Hospitals must assess their IT systems to ensure that they can collect, analyze and report appropriate utilization, quality and cost data.
- Hospitals should have electronic health records.
- Health care providers must understand and address the legal issues that are raised by this integration.

Schottenstein Zox & Dunn welcomes the opportunity to discuss how health care providers can position themselves to thrive in an environment that rewards clinically integrated providers that provide high quality care while controlling costs.

For questions about accountable care organizations, please contact Nancy Waite at 614.462.5015 or nwaite@szd.com or any member of SZD's Health Care Practice Group. ■

Hospital hit with lawsuit after complying with grand jury subpoena

By Robert Cochran

On Feb. 1, the U.S. District Court in Cleveland issued a significant decision concerning the disclosure of medical information in response to a grand jury subpoena.

The grand jury subpoena was issued to the Cleveland Clinic as part of a criminal investigation of James Turk for carrying a concealed weapon. The Cleveland Clinic complied with the subpoena and supplied the records to a police detective as instructed by the subpoena. As a result of the criminal investigation, Turk was charged with various offenses. A jury eventually acquitted him of one charge and the other charges were dismissed. Turk then filed a lawsuit in federal court against the police and various other defendants, including the Cleveland Clinic. The lawsuit alleged the defendants violated his rights in connection with the criminal investigation.

Regarding his medical records, Turk claimed the Cleveland Clinic violated his privacy rights by releasing privileged medical records in response to the grand jury subpoena. The clinic argued the claim should be dismissed because the clinic was responding to a grand jury subpoena. The clinic argued that Ohio courts do not extend the physician-patient privilege to records subpoenaed by the grand jury because the disclosure to the grand jury is not a public disclosure. The clinic also argued that the disclosure was required because there is a countervailing interest in investigating criminal activity.

The trial court rejected both arguments and overruled the clinic's motion to dismiss. The court ruled that there is no statutory privilege permitting disclosure of medical records in response to a grand jury subpoena. Additionally, the court rejected the public policy argument that the government's interest in investigating criminal activity outweighed Turk's interest in maintaining the confidentiality of his medical records. The court concluded that no such public policy exception to the physician-patient privilege exists under Ohio law.

The court also addressed the applicability of the Health Insurance Portability and Accountability Act (HIPAA) to the disclosure of Turk's medical records. HIPAA authorizes (but does not require) a hospital to release a patient's medical records in response to a grand jury subpoena. HIPAA preempts state law unless the state law relates to the privacy of individually identifiable health information and is more stringent than HIPAA. The court concluded that Ohio Revised Code §2317.02 (Ohio's physician-patient privilege statute) is more stringent than HIPAA, and therefore is not preempted.

When deciding whether to disclose medical records, health care providers need to consider Ohio Revised Code §2317.02 as well as HIPAA. A disclosure authorized by HIPAA may be prohibited under Ohio Revised Code §2317.02. In addition, special attention should be paid to requests for records from law enforcement, including grand jury subpoenas and criminal trial subpoenas. The public's interest in investigating criminal activity is not necessarily more important than the public's interest in preserving the confidentiality of medical records. Providers should consult legal counsel when necessary.

For questions about HIPAA and grand jury subpoenas, please contact Robert Cochran at 614.462.2248 or rcochran@szd.com or any member of SZD's Health Care Practice Group. ■

New timely filing requirements for Medicare fee-for-service claims

Section 6404 of the Patient Protection and Affordable Care Act (the Act) amended the timely filing requirements to reduce the maximum time period for submission of all Medicare fee-for-service claims to one calendar year after the date of service.

Under the Act, claims for services furnished on or after Jan. 1, 2010, must be filed within one calendar year after the date of service. In addition, Section 6404 mandates that claims for services furnished before Jan. 1, 2010, must be filed no later than Dec. 31, 2010.

According to CMS, the following rules apply to claims with dates of service prior to Jan. 1, 2010:

- Claims with dates of service before Oct. 1, 2009, must follow the pre-Act timely filing rules.
- Claims with dates of service Oct. 1, 2009 through Dec. 1, 2009, must be submitted by Dec. 1, 2010.

Section 6404 of the Act also permits the Secretary of the U.S. Department of Health and Human Services to make certain exceptions to the one-year filing deadline. At this time, no exceptions have been established.

For questions about Medicare reimbursement, please contact Robert Cochran at 614.462.2248 or rcochran@szd.com or any member of SZD's Health Care Practice Group. ■

Medical homes improve primary care delivery

By Nancy Waite

Medical homes have emerged as a leading model for improving the quality and accessibility of health care. A medical home is not a physical location, but rather it is a comprehensive approach to primary care that emphasizes coordination of care and fosters a more collaborative physician-patient relationship.

Fee-for-service reimbursement has encouraged physicians to focus on the episodic treatment of disease. In contrast, a medical home takes a holistic, coordinated view of patient care which results in healthier patients and a reduction in avoidable health care costs.

Specifically, in a medical home:

- Each patient has an ongoing relationship with a personal physician who leads a team that collectively coordinates the patient's care (including acute and chronic care and preventative services).
- The practice utilizes information technology to support performance measurements, patient education, disease registries, enhanced communication and optimal patient care.
- Patient care is guided by evidence-based medicine and clinical decision-support tools.
- The practice educates patients and encourages patient involvement to increase compliance with care management plans.
- Patient access to care is improved by utilizing open access scheduling, expanded hours and new options for patients to communicate with their physician-led team.

Transforming into a medical home. After assessing the practice's current operations, the practice should formulate a plan to transition to a medical home that manages and coordinates comprehensive patient care. Such a plan will include:

- Building a team of clinical and non-clinical providers who will manage and coordinate patient care, and identifying specific responsibilities for each team member.
- Implementing electronic health records that are linked with the hospital and specialty referral physicians.
- Ensuring that the practice has appropriate IT capabilities (e.g., disease registries, patient tracking, patient communication).
- Implementing evidence-based standards for delivering patient care.
- Enhancing patient outreach and education programs (particularly for patients with chronic conditions).
- Expanding patient access to care.
- Working with specialty referral physicians and hospitals to strengthen their relationships.

Impact on hospitals. Because medical homes keep patients healthier, hospitals have raised concerns about the impact on hospital volume. Initial studies indicate that medical homes can lower emergency department visits, urgent care visits and "preventable hospitalizations;" however, such admissions are often the least profitable admissions.

Payment. As payment continues to shift from fee-for-service to reimbursement methods that reward coordinated and cost-effective care, medical homes will be well-positioned for financial success. Medical homes can also proactively negotiate with payers for reimbursement that reflects the added value of coordinated patient care. In addition, many states have multi-payer medical home initiatives and, under the newly passed federal health care reform legislation, Centers for Medicare & Medicaid Services may test medical home models for certain individuals.

Part of a larger integration strategy. Medical homes offer a comprehensive approach to primary care that benefits patients and providers, while helping to reduce avoidable health care expenses. Further, the medical home can invigorate the local providers' integration strategy and serve as a building block for the creation of an Accountable Care Organization.

For questions regarding transforming primary care practices into medical homes, contact Nancy Waite at 614.462.5015 or nwaite@szd.com or any member of SZD's Health Care Practice Group. ■

Health care reform enhances fraud and abuse laws

By Robert Cochran

The Patient Protection and Affordable Care Act includes new fraud and abuse provisions. Some of the key fraud and abuse provisions include:

- Requires all providers and suppliers to implement compliance programs. The U.S. Department of Health and Human Services (HHS) is required to determine a timeline for implementation and to develop the core elements for a compliance program.

- Requires providers to report and return overpayments within 60 days of identifying the overpayment (or the date any corresponding cost report is due). Providers must state in writing the reason for the overpayment.

- Clarifies that an overpayment retained after the deadline for reporting and returning the overpayment is an "obligation" for purposes of the False Claims Act (FCA). This means a provider who knowingly retains an overpayment faces civil prosecution under the FCA.

- Allows HHS to impose Civil Monetary Penalties, including exclusion, on any individual or entity that:

    - knows of an overpayment and does not report or return the overpayment;

    - knowingly makes a false statement, omission or misrepresentation of material fact in any application, agreement, bid or contract to participate or enroll in a federal health care program; and

    - fails to grant timely access to the Office of Inspector General for the purpose of audits, investigations, evaluations or other statutory functions.

- Clarifies that services performed and billed as a result of kickbacks are false claims under the FCA. Relaxes the intent requirement of the Anti-Kickback Statute. To violate the Anti-Kickback Statute, a person need not have actual knowledge of the statute or a specific intent to commit a violation of the statute.

- Allows the Centers for Medicare & Medicaid Services to suspend Medicare payments to providers pending an investigation of a credible allegation of fraud against the provider.

- Requires long-term care facilities receiving at least $10,000 in federal funds to report to HHS, and one or more law enforcement entities where the facility is located, any reasonable suspicion of a crime against a resident. If the event giving rise to the suspicion results in serious bodily injury, the report must be made within two hours. If the event does not result in serious bodily injury, the report must be made within 24 hours. A violation of the reporting requirement can result in civil penalties up to $300,000 and exclusion.

- Requires HHS to screen all providers and suppliers, including advanced screening procedures for certain types of at-risk providers and suppliers.

- Requires HHS to establish within six months a self-disclosure protocol for Stark violations.

- Expands the Recovery Audit Contractors program to Medicaid.

The Act also increases funding to fight fraud and abuse. With these new provisions and increased funding, providers should anticipate an increase in government audits and investigations. To avoid the potentially ruinous consequences of an audit or investigation, providers should review and strengthen their compliance programs.

If you have any questions about fraud and abuse laws, please contact Robert Cochran at 614.462.2248 or rcochran@szd.com or any member of SZD's Health Care Practice Group. ■

News and Notes

In February, **Kevin Hilvert** presented: "Navigating Legal Complexities of Physician Marketing" before The Advisory Board.

On May 13, **Robert Cochran** presented: "New Fraud and Abuse Laws in the Health Reform Legislation" at the Columbus Bar Association, Health Law Committee Meeting.

On June 1, **Kevin Hilvert** presented: "Physician Integration Strategies Under Health Care Reform" for Equity's National Health Care Group.

On June 16, **Stephen Kleinman** and **Kevin Hilvert** presented: "Transformation to Accountable Health Care, How Existing PHOs Can Operate as ACOs" at the Kettering Physician Hospital Alliance Annual Meeting.

On July 27, **Kevin Hilvert** presented: "Form 990 Compensation and Related-party Transaction Reporting, the Legal Do's and Don'ts" in Cincinnati, Ohio.

On Aug. 20, **Kevin Hilvert** will present: "Hospital-Physician Integration Strategies in the Midst of Health Care Reform" for the Healthcare Financial Management Association in Columbus, Ohio.

64 percent of appealed RAC claims decided for providers

By Robert Cochran

According to a recently released report from Centers for Medicare & Medicaid Services (CMS), providers won 64.4 percent of appealed claims during the three-year Recovery Audit Contractors (RAC) demonstration project. Providers appealed 76,000 claims and received favorable decisions on 49,000.

Providers can win a RAC appeal. Preparedness is the first step to surviving a RAC audit. Providers must be prepared to respond to RAC demand letters and requests for medical records. Because RAC audits are generally unannounced, the appropriate time to prepare for an audit is now. Providers should consider the following to prepare for an audit:

- ***Not responding is not an option.*** Providers have a narrow window in which to respond to an audit. Providers have 45 days to respond to a RAC request for medical records. If a provider fails to respond, RACs are authorized to render an overpayment determination on the underlying claims. Failure to timely respond could also result in the loss of valuable appeal rights.

- ***Designate someone as the contact person for all audits.*** Providers should designate appropriate personnel to respond to all audit requests. RACs are required to communicate with providers by email, telephone, letters and in-person. Accordingly, administrative personnel must be available to process correspondence and respond to the RAC's various requests. Training personnel and cultivating a working relationship with the regional RAC may mollify interactions and aid in the timeliness of communications.

- ***Collect relevant documents and records.*** Providers should ensure that the records they produce to the auditor are complete. This will help show the appropriateness of the treatment, billing and reimbursement. The relevant records include not only medical records, but billing information as well.

- ***Contact legal counsel.*** Providers are well served to engage legal counsel to help navigate RAC audits and appeals. Lawyers can help train employees on the details of RACs, including an overview of the regulatory history, "hot button" issues RACs are likely to focus upon, and how to respond appropriately.

- ***Investigate the claims at issue.*** Providers should undertake a careful review of the materials investigated during an audit. RACs are sometimes perceived as overly aggressive in identifying overpayments largely because they are paid on a contingency fee basis. Staying abreast of the scope of the audit may reveal issues that are ripe for appeal.

- ***Keep a written record of all contact with auditors and a set of all documents sent to auditors.*** Because the audit findings can be appealed, providers should retain a copy of all documents provided to the RAC. Providers should also memorialize the date, time and a brief description of all communications during the audit. Keeping accurate records will protect providers if a problem arises regarding the conduct of the audit. It will also help the provider appeal an adverse audit finding.

- ***Become familiar with the appeals process.*** RAC denials are subject to the Medicare Part A and Part B appeals process with two differences. First, providers are given 15 days from the date they receive an improper payment letter from a RAC to rebut the RAC's findings, although providers are not required to go through this rebuttal process before filing an appeal. Second, a provider appealing a RAC determination must file an appeal to its fiscal intermediary within 30 days of the date that the provider receives the fiscal intermediary's notice indicating the amount of overpayment identified by the RAC. Given the number of appeals decided in the provider's favor, the importance of audit preparation and understanding your appellate rights cannot be understated.

For questions about RAC audits, please contact Robert Cochran at 614.462.2248 or rcochran@szd.com or any member of SZD's Health Care Practice Group. ■

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