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Health Law UPDATE

January 2017

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FEDERAL UPDATE

Fraud Tied to Government Health Care Programs Constitutes the Majority of DOJ's 2016 False Claims Act Recoveries

In 2016, the United States Department of Justice (DOJ) had the third-largest year for False Claims Act (FCA) recoveries totaling more than $4.7 billion. Over the past few years, the DOJ has taken a position targeting the health care industry, and the trend continued as $2.5 billion of the 2016 recoveries came from investigations involving fraud, physician compensation, medically unnecessary procedures, misconduct, and kickbacks. The largest recoveries came from drug and device companies. Hospitals, outpatient clinics, nursing homes, laboratories, and physicians also contributed to a sizeable amount of the recoveries. Whistleblower lawsuit recoveries were high. Additionally, 2016 saw an increase in settlements by individuals after the DOJ vowed greater individual accountability for fraud.

Looking to the future in 2017 and beyond, the possibility of the new administration repealing or dramatically amending the Affordable Care Act (ACA) and changing the composition of the Supreme Court will impact the DOJ's enforcement activities going forward.

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HHS Ordered to Clear Medicare Claims Appeal Backlog by 2021

U.S. District Judge James Boasberg ordered The Department of Health & Human Services (HHS) to clear its backlog of Medicare reimbursement appeals by the end of 2020. The order comes by way of a motion for summary judgment, filed by the American Hospital Association (AHA) and other medical centers, who filed suit to compel HHS to meet the statutory deadlines for review of Medicare claim denials within 90 days.

Plaintiffs claim the backlog stems from the Recovery Audit Contractor (RAC) Program, an auditing program implemented to identify and collect improper Medicare payments. Healthcare providers may appeal denied claims before the HHS Office of Medicare Hearings and Appeals (OMHA) in a five-level appeal process. Third-level appeals are brought before administrative law judges (ALJ). The increase in RAC appeals resulted in OMHA suspending new requests for ALJ hearings in December 2013, in violation of statutory deadlines for ALJ review. As of April 2016, OMHA had more than 750,000 pending appeals, but could get through only 77,000 per year.

On December 5, 2016 Judge Boasberg ordered HHS to reduce its backlog incrementally over the next four years. Specifically, HHS is to reduce the backlog by 30% in 2017; 60% by 2018; 90% by 2019 and completely by December 31, 2020. If the Secretary fails to meet the deadlines, the plaintiffs may move for default judgment or to otherwise enforce a writ of mandamus. In addition, the court is requiring HHS to provide 90-day status reports on its progress. HHS asserts that without substantial new resources and authorities from Congress, it has no means to meet the reduction targets without improperly paying claims and violating its fiduciary duty to the Medicare Trust Fund. HHS is currently seeking a motion for reconsideration.

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OIG Revises Safe Harbors under Anti-Kickback Statute

Effective January 6, 2017, the Department of Health & Human Services, Office of Inspector General (OIG) has amended the Anti-Kickback Statute to add new safe harbors that protect certain payment practices and business arrangements from sanctions. OIG also amended the Civil Monetary Penalty (CMP) rules by codifying revisions to the definition of "remuneration."

Specifically, the rule incorporates into regulations safe harbors for payment and business practices permitted under existing law and adds new safe harbors pursuant to OIG's authority to protect practices OIG deems a low risk to federal health care programs. Among the changes are a technical correction to the existing safe harbor for referral services, protection for certain cost-sharing waivers, including emergency ambulance services furnished by state- or municipality-owned ambulance services, and protection for certain remuneration between Medicare Advantage organizations and federally qualified health centers. Additionally, the rule adds a new safe harbor for free and discounted local transportation made available by an "eligible entity" to "established patients," provided certain specific conditions are met. This transportation safe harbor follows numerous OIG advisory opinions on the subject issued over the years. (See the enclosed Alert.)

OIG also amended the definition of "remuneration" in CMP rules by implementing and codifying new and existing exceptions. These exceptions include copayment reductions for certain hospital outpatient department services; certain remuneration that poses a low risk of harm and promotes access to care; coupons, rebates, or other retailer reward programs that meet specified requirements; certain remuneration to financially needy individuals; and copayment waivers for the first fill of generic drugs. For more information, contact:

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CMS Announces New Care Delivery Models

Centers for Medicare & Medicaid Services (CMS) has announced two new care delivery models intended to improve patient engagement and decision-making: (i) the Shared Decision Making Model, and (ii) the Direct Decision Support Model. The Shared Decision Making Model allows Medicare beneficiaries to work with their clinicians to choose the best treatment plans and surgeries. Clinicians can participate in the model if they are currently part of the Medicare Shared Savings Program or a Next Generation Accountable-Care Organization. The Direct Decision Support Model relies on engaging beneficiaries about their health outside of the clinical setting. CMS will partner with up to seven Decision Support Organizations, (DSO) organizations that provide health management and decision support services. Each DSO will provide decision support for a core set of preference-sensitive conditions, in addition to proposing a broader range of acute and chronic conditions. The model will encourage the use of decision aids such as pamphlets or brochures that offer treatment options for particular conditions. Both models can be used by Medicare patients with six conditions: stable ischemic heart disease; hip or knee osteoarthritis; herniated disk or spinal stenosis; clinically localized prostate cancer and benign prostate hyperplasia. Organizations and providers interested in both models can apply until March 5, 2017.

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OIG Increases "Nominal Value" Gift Amounts for Medicare & Medicaid Beneficiaries

Under Section 1128A(a)(5) of the Social Security Act, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties of up to $10,000 for each wrongful act. "Remuneration" is defined under the act to include, among other things, waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The act contains a limited number of exceptions permitting Medicare or Medicaid providers to offer beneficiaries inexpensive gifts (other than cash or cash equivalents, e.g., gift cards) or services without violating the law.

Last month, the Department of Health & Human Services, Office of Inspector General (OIG) issued a policy statement clarifying the terms "inexpensive" and "nominal" in order to offer updated guidance to providers and suppliers. In the policy statement, the OIG specified that "nominal value" means having a retail value of no more than $15.00 per item or $75.00 in the aggregate per patient on an annual basis. This is a slight change from the OIG's previous guidance issued in 2000, which defined the term to mean a retail value of $10.00 per item or $50.00 in the aggregate on an annual basis.

Health care entities and individual providers and suppliers should review their corporate compliance policies and practices to ensure that any gifts to beneficiaries are of nominal value as defined in the policy statement, or otherwise meet an exception to the prohibition on inducements. If you need assistance in reviewing or revising your corporate compliance and related policies, please contact us.

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OIG Issues Unfavorable Opinion on Free Laboratory Services

The Department of Health & Human Services, Office of Inspector General (OIG) published an advisory opinion last month regarding a laboratory's proposed arrangement to provide free services to certain dialysis facilities. The OIG concluded that this arrangement could potentially generate prohibited remuneration under the Anti-Kickback Statute and the OIG could potentially impose administrative sanctions against the proposed laboratory-requestor in connection with the arrangement.

Specifically, the laboratory wanted to provide certain dialysis facilities with complimentary services consisting of the labeling of specimen containers and test tubes used by those facilities. In the absence of the laboratory providing this service, the labeling would be performed by the facility's staff. The laboratory would retain sole discretion over which facilities received these free services and they would be provided only to those facilities where it was necessary to do so to retain or obtain a particular facility's business.

The OIG's position on the provision of free goods or services to actual or potential referral sources has been long-standing and clear: such arrangements are suspect and may violate the Anti-Kickback Statute. In this case, the laboratory's provision of free services to selected dialysis facilities at no cost would be a tangible benefit to those facilities. As a result, the OIG opined that the free labeling services are intended to influence the dialysis facility's choice of laboratory. By capturing a dialysis facility's referral stream, the laboratory would be able to generate substantial revenue. As such, providing the free services could be viewed as remuneration in exchange for a referral in violation of the Anti-Kickback Statute.

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CMS Finalizes New Medicare Mandatory Bundled Payment Models

Centers for Medicare & Medicaid Services (CMS) recently finalized new alternate payment models that continue the shift of Medicare payments from rewarding quantity to rewarding quality by creating incentives for hospitals and clinicians to work together to avoid complications, avoid preventable hospital readmissions and speed patient recovery. The final rule includes three new payment models that support clinicians in providing care to patients who receive treatment for heart attacks, heart surgery to bypass blocked coronary arteries, or cardiac rehabilitation. The rule also includes a new payment model that will support clinicians in providing care to patients who receive surgery after a hip fracture beyond hip replacement, and also includes updates to the Comprehensive Care for Joint Replacement Model, which began in April 2016. Finally, the new rule provides a new track of ACOs modeled to allow small practices and additional hospitals, including rural hospitals, to participate in alterative payment models.

The payment models will apply to hospital admissions of Medicare patients in certain geographic areas. The models will operate over a period of five years beginning July 1, 2017. The cardiac payment models will apply to participating hospitals located in over 90 metro areas and the surgical hip fracture treatment model will apply to hospitals in 67 metro areas. The rule requires CMS to regularly monitor and evaluate the impact of these treatment and reimbursement approaches on care quality and value.

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Medicare Payments and the Two-Midnight Rule

Centers for Medicare & Medicaid Services (CMS) previously implemented a rule, known as the Two-Midnight rule, to address vulnerabilities in hospitals' use of inpatient and outpatient stay designations, including: (i) improper payments for short inpatient stays; (ii) adverse consequences for beneficiaries of long outpatient stays, including that they may not have the required inpatient nights needed to qualify for skilled nursing facility (SNF) services; and (iii) inconsistent use of inpatient and outpatient stays among hospitals.

The Department of Health & Human Services, Office of Inspector General (OIG), in a report released last month, found that CMS paid an estimated $2.9 billion for short inpatient hospital stays that potentially could have been billed as outpatient stays in FY2014. For purposes of the rule, CMS defines a "short stay" as one that lasted less than two midnights and a "long stay" as one that lasted two midnights or longer. OIG, in reviewing this data, determined whether claims information met CMS's criteria for payment under the rule (e.g. if the stay included an inpatient-only procedure).

The impetus for this review and report boiled down to one main issue: On average, CMS paid three times more for a short inpatient stay than for a short outpatient stay. Conversely, for patients, co-pays are typically higher for outpatient stays.

OIG recommended four modifications to assist CMS in determining the correct designation of stay and payment for such episodes of care: (i) conduct routine analysis of hospital billing and target for review the hospitals with high or increasing numbers of short inpatient stays that are potentially inappropriate under the rule; (ii) identify and target for review the short inpatient stays that are potentially inappropriate under the rule; (iii) analyze the potential impacts of counting time spent as an outpatient towards the required number of impatient nights for SNF services, so that beneficiaries receiving similar hospital care have similar access; and (iv) explore ways of protecting beneficiaries in outpatient stays from paying more than they would have paid as inpatients. OIG believes CMS can improve its oversight of hospital billing under the rule by implementing these recommendations, while at the same time increasing protections, both clinically and financially, for beneficiaries. CMS concurred with OIG's recommendations.

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OIG Issues Review of CMS's Quality Payment Program

The Department of Health & Human Services, Office of Inspector General (OIG) issued an Early Implementation Review of CMS's Quality Payment Program (QPP), a key component of the MACRA law that reforms clinician compensation from a volume-based model to a quality- and value-based model, just ahead of the first performance year for the new payment systems. The OIG found that while Centers for Medicare & Medicaid Services (CMS) has made significant progress in implementing the reforms, some weaknesses exist in the implementation process.

The report does not reflect CMS's management of the QPP or its merits or likelihood of success. Rather, it focuses on five key management priorities regarding the planning and early implementation of the QPP: (i) Adopting integrated business practices to accommodate a user-centric approach; (ii) developing IT systems that support clinician participation; (iii) flexible and transparent Merit-Based Incentives (MIPS); (iv) facilitating participation in alternative payment models (APMs); and (v) fostering clinician acceptance and participation.

Although OIG applauded CMS in certain areas, OIG highlighted several areas where CMS needs to focus efforts to ensure a continued successful implementation of the program. Specifically, OIG calls for CMS to focus on small, solo and rural providers who are historically less likely to participate, as well as the need to build and test the complex IT systems necessary to support full implementation of the program. CMS has replied that it will focus its efforts on the IT systems necessary for the rollout and is working with clinicians to ensure the program is accessible and user friendly. 2017 will be the first performance year for the QPP, with any payment adjustments taking place on January 1, 2019.

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STATE UPDATE

New Safe Care Camera Program

On December 22, 2016, the New Jersey Attorney General and the New Jersey Division of Consumer Affairs (DCA) unveiled the "Safe Care Cam" Program. The program provides for loans of micro-surveillance cameras to New Jersey residents who suspect that a health care provider may be abusing a family member. New Jersey residents will have access to the latest technology in micro-surveillance cameras, which can be easily hidden, to detect abuse and protect patients.

Individuals can borrow cameras for free for up to 30 days if they suspect that a family member is being abused or neglected by home health aides or other in-home caregivers who spend long hours alone with a disabled or elderly person. Typically, these micro-surveillance cameras may be too expensive for individuals to purchase on their own. The mission behind the program is to address the public's growing concern regarding caregiver abuse as more consumers choose in-home care as a more affordable alternative to long-term care facilities. Individuals who lodge complaints against home care providers are increasingly backing up their complaints with hidden camera footage, which greatly increases the chance of substantiating any wrongdoing.

New Jersey residents who want to participate in the Safe Care Cam program must complete a brief training program conducted by the (DCA). It is up to the individual who borrows the camera to monitor the recorded footage and report any issues of concern to the DCA or appropriate authorities.

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Legislative Update

On December 19, 2016, the New Jersey State Senate passed a bill (NJ S2156) that would require physicians to discuss with a parent or guardian the addiction risks associated with certain drugs prior to issuing a prescription to a minor patient. Doctors would also be required to include a note in the patient's medical record confirming that the discussion took place. The bill, which passed unanimously in the State Assembly, is awaiting Governor Christie's signature.

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Brach Eichler In The News

As announced last month, Brach Eichler welcomes **Debra W. Levine** and **Cheryll A. Calderon** to the Health Law Practice Group. Debra W. Levine served 27 years as a Deputy Attorney General, Assistant Section Chief and counsel to the NJ State Board of Medical Examiners. Her unparalleled experience in professional licensing, credentialing, state regulatory and disciplinary matters, involving all of the professional licensing boards, is an invaluable resource for our physician and facility client bases. See the press release at: *http://www.bracheichler.com/C3F493/assets/files/News/HealthlawNewAttorneysDec2016%20FINAL%2012-14.pdf*

Lani M. Dornfeld authored an article in the September 2016 edition of *Outpatient Surgery* magazine, entitled "No. 1 HIPAA Privacy Risk? Snooping Staff." *http://magazine.outpatientsurgery.net/i/726435-or-excellence-awards-2016-september-2016-subscribe-to-outpatient-surgery-magazine/33*

Mark Manigan was quoted in NJBIZ on "Health Care Predictions 2017: Preparing For Another Upheaval." *http://www.njbiz.com/article/20170104/NJBIZ01/301039991/health-care-predictions-2017-preparing-for-another-upheaval*

HIPAA CORNER

OCR Issues Fact Sheet Regarding Disclosure to Public Health Agencies

The Department of Health & Human Services, Office for Civil Rights (OCR) and the Office of the National Coordinator for Health Information Technology issued a fact sheet that provides guidance through the use of hypothetical situations as to a covered entity's (CE) obligations under HIPAA related to disclosure to public health agencies. HIPAA provides that a CE may disclose protected health information (PHI) to public health agencies, such as the Centers for Disease Control and Prevention, who are authorized by state or federal law to collect such information.

Importantly, while HIPAA requires CE's to provide the minimum amount of information necessary, a CE may reasonably rely that a public health authority's request for information satisfies this requirement. Examples of when public health authorities collect information include: disease reporting and surveillance information; public health investigations; public health interventions; studies; medical device recalls; viral outbreaks and communicable disease exposure; and workplace medical surveillance. The fact sheet may be found at: *https://www.healthit.gov/sites/default/files/12072016_hipaa_and_public_health_fact_sheet.pdf*

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- Changes to Safe Harbors Under the Anti-Kickback Statute: OIG Adds Exception for Local Transportation
- Congress Makes Big Move to Repeal Affordable Care Act

HEALTH LAW ALERT

JANUARY 2017

Changes to Safe Harbors Under the Anti-Kickback Statute: OIG Adds Exception for Local Transportation

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On January 6, 2017, the Department of Health & Human Services, Office of Inspector General (OIG) revised and added certain safe harbors available under the Anti-Kickback Statute. The safe harbors under the statute protect certain business arrangements from liability under the law, so long as the particular arrangement fits "squarely within" the applicable safe harbor. Perhaps the most significant of the new safe harbors is one that permits for the provision of free or discounted local transportation services that meet specific criteria.

Free or Discounted Local Transportation

As of January 6, 2017, pursuant to 42 CFR § 1001.952(bb), "eligible entities" will be permitted to offer free or discounted local transportation services to "established patients" for the purpose of obtaining medically necessary items or services, provided that certain specific conditions are met. These conditions include:

- The entity cannot shift the cost of providing transportation services onto any federal health care programs, payers, or individuals
- The entity must set forth a policy for the provision of services that is applied consistently and uniformly
- The services cannot be determined in a manner that relates to the past or anticipated volume or value of federal health care program business
- The modes of transportation cannot be luxury, air, or ambulance level transportation
- The entity cannot publicly market or advertise the service nor can any advertising for medical services or items take place during the transportation
- Drivers and/or any entity providing transportation cannot be paid based on the quantity or volume of riders.

Who qualifies for this "safe harbor"?

For purposes of this new safe harbor, an "eligible entity" is defined broadly as any individual or entity, except ones

that primarily supply health care items. Thus, because pharmacies, durable medical equipment (DME) suppliers, and pharmaceutical companies provide only health care items and not medical services, they are excluded from the definition of "eligible entities." Entities that provide both medical services and items, such as hospitals with pharmacies on site, are deemed eligible entities. Other examples of eligible entities include home health agencies, ambulatory surgery centers, physical therapists, and dialysis centers.

"Established patients" are those patients that have selected a provider or supplier, initiated contact, and scheduled an appointment. This definition includes current patients of the provider as well as new patients, as long as they have scheduled an appointment. To minimize the possibility that the offer of transportation would be used as a recruiting tool, entities are prohibited from advertising the service, but they are permitted to inform patients of the service when they contact the provider to make an appointment. Also, the service cannot be limited to only individuals who receive federal health care program benefits.

Scope of transportation

Free and discounted transportation can be provided only for medically necessary services or items. It can come in the form of transportation offered by the entity directly or through a third party provider, such as a taxi cab or public transportation. If through a third party provider, payment may be made through direct payment by the entity or via a voucher given to the patient. It cannot, however, come in the form of luxury, air, or ambulance services. Additionally, a set schedule is not required and services can be offered on an ad hoc basis. While a set schedule is not required, an eligible entity must have a consistent policy in place for offering the service. While OIG declined to mandate specific parameters, entities offering free or discounted transportation to their patients must comply with the terms of this safe harbor.

What does "local" mean?

In addition to limiting the modes of transportation, OIG also has limited the distance allowed. Specifically, transportation may be provided only within a 25 mile radius in urban areas and a 50 mile radius in rural areas. The mileage can be measured directly, which would include any route within that radius even if such route is more than 25 or 50 miles when driven. Entities would be permitted to provide transportation services to providers and suppliers within their network of providers and suppliers as long as there is an established patient relationship between the eligible entity providing the transportation and the patient being transported, as well as an established patient relationship between the patient and the provider to which the patient is transported.

Shuttle Services

The OIG separately protected a second form of transportation akin to a shuttle service. The provision of a shuttle service is subject to the same conditions as other modes of transportation permitted under the safe harbor, except that entities are not required to limit the service to established patients only. The OIG believed it was too burdensome to require a shuttle driver to determine at each instance whether an individual was an established patient for purposes of this amendment. The shuttle service can make as many stops along its route as the entity sees fit, as long as the stops are within the 25 or 50 mile radius mandated by the OIG.

Should you need more information about understanding the requirements to qualify for this new safe harbor, reviewing your current policies and procedures, or deciding whether further action is necessary, please contact a member of our health law team listed on back.

Congress Makes Big Move to Repeal Affordable Care Act

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On a vote almost entirely along party lines, the House of Representatives approved a budget resolution on January 13, 2017, which begins the process of dismantling the Affordable Care Act (ACA). The Senate approved the same budget measure the previous day. The budget resolution instructs certain Congressional committees to draft legislation to effectively repeal the Affordable Care Act. However, Republicans have yet to agree on any concrete proposals to replace the ACA. While the Republican leadership, including the administration of President Elect Donald Trump and Speaker of the House Paul Ryan, have repeatedly stressed that the ACA will not be repealed without replacement legislation soon to follow, no consensus on legislation has yet to emerge.

With the passage of the budget resolution by both the House and the Senate, Senate Republicans can now use a procedural tactic known as "reconciliation" to prevent Senate Democrats from being able to block an ACA repeal. Reconciliation, a complicated process first introduced by the Congressional Budget Act of 1974, expedites Senate consideration of bills related to the budget and limits debate to 20 hours, which effectively prevents Senate Democrats from filibustering the proposed legislation. Without the ability to filibuster, Democrats cannot prevent a bill from passing with a majority vote. Thus, the Senate can pass legislation to repeal the ACA with a simple majority of 51 votes rather than the 60-vote super-majority required for most major bills. Republicans currently control 52 seats in the Senate.

The budget reconciliation process only works for fiscal measures in the ACA, such as tax credits for example. Other provisions of the ACA, such as the provision allowing children to stay on their parent's healthcare until the age of 26, cannot be repealed by the reconciliation process and thus will most likely still need a 60 vote super-majority. With little cooperation expected between Republicans and Democrats in the Senate, the ability to completely repeal the ACA is unlikely at the present time. Furthermore, since a number of moderate Republicans have expressed concern about repealing the ACA without replacement legislation ready, there is no guarantee that even the required 51 vote minimum can be achieved without some form of compromise. Members of both parties have expressed grave concerns about the effects on their constituents if the ACA is repealed without concrete replacement measures in place.

While Congressional Republicans have not come to agreement on replacement legislation, many replacement proposals are currently being floated. For example, the conservative Republican Study Committee re-introduced legislation this week, the American Healthcare Reform Act, which provides for tax deductions for individuals to purchase their own insurance, removes state boundaries on insurance offerings, removes antitrust exemptions for insurance companies and adds a malpractice safe harbor for doctors who follow clinical guidelines. In addition, Kentucky Senator Rand Paul introduced a replacement plan on January 15, 2017 which proposes to legalize the sale of inexpensive health insurance policies and

expand the use of health savings accounts and tax credits. Since health care regulations and insurance contracts are already in place for 2017, consumers should see very little impact from any changes this year. Changes could begin as early as 2018. People who purchase their insurance individually or through a healthcare exchange could see the most impact from any changes. In addition, people who gained coverage through the expansion of Medicaid could lose their coverage. People who get health insurance through their employer or through Medicare would most likely be impacted the least.

If you would like additional information, please contact a member of our health law team below.

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