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This New York Healthcare Law Bulletin is written and edited by Robert Schiller and Jacqueline Finnegan.
Reader questions are welcomed.
Practitioners Now Required to Check A Patient’s Controlled Substance History Prior to Prescribing Schedule II, III or IV Controlled Substances

In 2012, Governor Andrew Cuomo signed into law the Internet System for Tracking Over-Prescribing (I-STOP) Act, which requires, with limited exceptions, that all practitioners consult the Department of Health’s (DOH) Prescription Monitoring Program (PMP) Registry prior to prescribing Schedule II, III and IV controlled substances. The PMP Registry contains data that allows practitioners to review their patients’ recent controlled substance prescription history at any time so that they can better evaluate the patients’ treatment with respect to controlled substance prescribing. The I-STOP Act also allows pharmacists to consult the PMP Registry before dispensing a controlled substance, but they are not required to consult the Registry.

As noted in our Client Alert, the regulations implementing the I-STOP Act went into effect August 27, 2013. They require practitioners (or their appointed designees) to (1) consult with the PMP no more than 24 hours prior to the prescribing or dispensing of the controlled substance, and (2) document that they consulted the PMP in the medical record. The regulations set forth the specific circumstances when practitioners are not required to consult the PMP. In such cases, the practitioner must identify the specific exception listed in the regulations and document in the medical record the basis and circumstances for claiming the exception.

The regulations also require dispensing practitioners and pharmacists to file information regarding controlled substances and the patient with DOH’s Bureau of Narcotic Enforcement within 24 hours of the substance being delivered. When no controlled substances have been dispensed, the regulations require that dispensing practitioners and pharmacies submit a “zero report” at least every 14 days to the Bureau of Narcotic Enforcement to inform them that no controlled substances have been dispensed.

In order to access the PMP Registry, practitioners must go through the DOH’s secure Health Commerce System (HCS), which requires each practitioner to have an established HCS account. However, the surge of requests for HSA accounts has resulted in a delay in processing accounts. The DOH and the Bureau of Narcotics Enforcement have acknowledged that this transition period may last through October. As a result, DOH has stated that practitioners who are making a good faith effort to establish an HCS account but have not yet received one should continue to provide treatment to their patients in the same manner as they currently do, including the prescribing of controlled substances without accessing the PMP Registry until the transition period is over.

The text of the regulations can be viewed here.

DOH has issued additional information on the new regulations, which is available here.

DOH Issues Guidance for Hospitals Regarding Compliance with New Sepsis Regulations

The DOH issued a guidance document in June to help hospitals comply with the required components of hospital protocols for severe sepsis and septic shock for adults and children. These new requirements, which are set forth in NYCRR Parts 405.2 and 405.4 and went into effect on May 1, 2013, require hospitals to adopt “sepsis protocols” for the early recognition and treatment of patients with severe sepsis and septic shock.

Specifically, the protocols, which are required to be adopted by the medical staff based upon generally accepted standards of care, must include components specific to the identification, care and treatment of adults and children, and must identify when the components will differ for adults and children.

All hospitals were required to submit protocols on or before September 3, 2013, and once approved, must implement such protocols on or before December 31, 2013. Once implemented, the protocols must be updated and resubmitted to the DOH as requested, but no more often than once every two years, absent hospital-specific concerns by the department.
The text of the sepsis regulations is available [here](#).

The text of DOH’s guidance letter is available [here](#).

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**New Health Care Legislation**

The following health care-related bills were signed into law on July 31, 2013:

*Health Proxy Information To Be Provided on State Agency Websites:* Governor Cuomo signed into law bill A989-B, which amends the technology law to ensure that state agencies that have significant public interactions in the field of public health provide a link on their websites to health care proxy information. The new law takes effect January 1, 2014. The text of the new law can be found [here](#).

*Certification of Surgical Technologists:* Governor Cuomo signed into law bill S5185A, which requires surgical technologists working in hospitals and ambulatory surgery centers (ASCs) to complete a nationally accredited educational program for surgical technologists and hold and maintain a certified surgical technologist credential (or complete an appropriate training program for surgical technology in the U.S. military). Surgical technologists must also complete 15 hours of continuing education annually. The law does provide a grandfathering exemption from the certification requirement, and also permits hospitals and ASCs to hire individuals without the certification in certain circumstances, provided the individuals meet the certification requirement within 24 months of employment. The law also provides that surgical technologists may only perform tasks and functions under the direction and supervision of an appropriately licensed health care professional participating in the surgery. The requirements of the new law go into effect on January 1, 2015. The text of the new law can be found [here](#).

*Certification of Central Service Technicians:* Governor Cuomo signed into law bill A878-A, which requires individuals employed as central service technicians to be certified and meet continuing education requirements. Specifically, the law requires that any person who provides the services of decontamination, preparation, packaging, sterilization, and storage and distribution of reusable medical instrumentation or devices in hospitals and ambulatory surgery centers (ASCs) must pass a nationally accredited central service exam, be certified, and complete ten hours of continuing education annually. The law does provide a grandfathering exemption from the certification requirement, and also permits hospitals and ASCs to hire individuals without the certification, provided they meet the certification requirement within 18 months of employment. The requirements of the new law go into effect on January 1, 2015. The text of the new law can be found [here](#).

*Pulse Oximetry Screening To Be Required for All Newborns:* Governor Cuomo signed into law bill A2316B, which adds pulse oximetry screening for critical congenital heart defects to the list of mandatory newborn screening tests that all birthing centers must perform. The new law takes effect January 27, 2014. The text of the new law can be found [here](#). The Governor’s press release on the new law is available [here](#).

*Pharmacists To Administer Meningococcal Vaccine:* Governor Cuomo signed into law bill S4881A, which authorizes a licensed pharmacist, upon a patient-specific or non-patient specific order (i.e., standing order) from a physician or certified nurse practitioner, to administer immunizations to prevent meningococcal disease. The new law takes effect October 29, 2013, 2013. The text of the new law can be found [here](#).

*Smoking Ban on Hospital and Residential Health Care Facility Grounds:* Governor Cuomo signed into law bill A1115-A, which prohibits smoking on the grounds of hospitals and residential health care facilities. The prohibition does not apply to patients and visitors or guests of patients in a residential health care facility, provided they are in a separately designated smoking that is not within 30 feet of any building structure. The new law takes effect October 29, 2013. The text of the new law can be found [here](#).
**2012 Managed Care Legislation Takes Effect**

On July 1, 2013, legislation went into effect that limits a health plan’s ability to deny or reduce payment for emergency admissions in cases where a hospital failed to comply with the health plan’s notice requirement, and provides for a default appeals process in cases where a health plan unilaterally down codes a claim (including DRG reassignment) and reduces its payment to reflect the new coding. A detailed discussion of this legislation was provided in a Client Alert, available here.

**New Regulations Regarding Prevention of Influenza Transmission by Healthcare Personnel**

The New York State Public Health and Health Planning Council (PHHPC) adopted the “Prevention of Influenza Transmission by Healthcare and Residential Facility and Agency Personnel” regulation, which went into effect on July 31, 2013. Pursuant to this regulation, all personnel (defined as persons employed or affiliated with a healthcare or residential facility or agency, whether paid or unpaid) who have not been vaccinated against influenza for the current influenza season will be required to wear a surgical or procedure mask during the influenza season while working in certain areas where patients may be present.

The new regulation, which is set forth at 10 NYCRR § 2.59, applies to the following entities: any healthcare facility, residential facility or agency licensed under Article 28 of the Public Health Law (including but not limited to general hospitals, nursing homes, diagnostic and treatment centers, and adult day healthcare facilities), Article 36 of the Public Health Law (including but not limited to certified home health agencies, long term home healthcare programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies), and any hospice established pursuant to Article 40 of the Public Health Law. In addition to requiring unvaccinated personnel to wear masks while working in areas where patients may be present, these entities must also document the number and percentage of personnel vaccinated against influenza for the current season and provide these data to the DOH upon request.

More information about the new requirements, including the text of the regulation, a Dear Administrator Letter, and Frequently Ask Questions, is available here.

**Medicaid Provider Enrollment Requirement**

Beginning October 1, 2013, New York State (NYS) Medicaid will begin enforcing the federal requirement that all physicians and other healthcare professionals ordering, prescribing or referring services reimbursed under the Medicaid fee-for-service program be enrolled as a Medicaid participating provider. In other words, Medicaid will not pay for services or items ordered, prescribed or referred by non-enrolled NYS Medicaid providers.

The federal requirement comes from sections 6401(a) and 10603 of the Affordable Care Act (ACA) and the implementing regulations (42 CFR § Section 455.410), which mandates enrollment of all physicians and other healthcare professionals ordering, prescribing or referring services provided under the state plan or under a waiver of the state plan. For institutional claims, the attending professional’s NPI is used for the ordering/referring provider; thus, if the “Referring NPI” field is left blank on the institutional (837I) claim, the attending professional must be enrolled as a NYS Medicaid participating provider in order for the claim to be paid by Medicaid.

Exemptions from this enrollment requirement include:

- Medicaid Managed Care and Family Health Plus encounters and services reimbursed by the plans (Note, however, that if the service is carved out of the plan benefit package and is paid fee-for-service, the requirement applies); and

- Services ordered/referred by residents and other practitioners that NYS Medicaid fee-for-service does not authorize to enroll (these claims must include the NPI of the enrolled supervising physician).
Out of state professionals ordering, prescribing or referring services that will be billed to fee-for-service Medicaid must be enrolled in the NYS Medicaid program.

Providers can enroll by completing the Medicaid Ordering/Prescribing/Referring/Attending (OPRA) Provider form, available here.

Billing providers can verify the Medicaid enrollment status of their ordering/referring providers here.

Medicaid Ordering/Prescribing/Referring/Attending (OPRA) Provider Enrollment Frequently Asked Questions can be viewed here.

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**OMIG Updates Its Compliance Library**

On August 1st, the New York State Office of Medicaid Inspector General (OMIG) announced that it had updated the compliance library section of its website by adding the following documents for providers:

- Bureau of Compliance Identified Compliance Program Best Practices;
- Bureau of Compliance Identified Compliance Program Opportunities for Enhancement; and
- Bureau of Compliance Identified Compliance Program Insufficiencies

These documents are based on what OMIG observed during compliance program reviews of Medicaid providers’ compliance programs, and are current for reviews up through March 31, 2013. Each of the documents breaks down the findings by the required compliance program element. OMIG intentionally did not break the listings down by provider type because it expects that the best practices, opportunities for enhancement, and insufficiencies could apply to all provider types. OMIG expects to update this information periodically.

OMIG’s compliance documents can be viewed here by going to the Compliance Library and clicking the dropdown menu entitled “OMIG Assessment Results.”

A more detailed discussion of these documents is available here.

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**OMIG Recommends Annual Self-Assessment**

In the August 2013 issue of the Medicaid Update, the New York State Office of the Medicaid Inspector General (OMIG) reminded Medicaid providers that it recommends that all Medicaid providers annually conduct a self-assessment of their compliance programs. According to OMIG, a self-assessment will maximize a provider’s opportunity to make improvements, corrections or refinements to their compliance programs prior to the December 2013 certification period. OMIG also informed providers that it will be updating its “Provider Certification of Effective Compliance Programs” form for use in December 2013. OMIG will inform providers when the new form is available in a Medicaid Update and also on OMIG’s website. OMIG expects to present a Webinar on the new certification form for 2014 in November 2013.
Enforcement of New HIPAA Rules Begins

On September 23, 2013, the U.S. Department of Health and Human Services (DHHS) officially began enforcement of the HITECH Omnibus Regulations, which made significant revisions to the privacy requirements of the federal Health Insurance Portability and Accountability Act (HIPAA). Therefore, all covered entities should have, or will need to make immediate changes to, their existing HIPAA compliance programs.

The new rules required covered entities to make a number of changes. As a result, covered entities should now: (1) have revised and implemented new HIPAA privacy policies; (2) be using a revised Notice of Privacy Practices; and (3) have adopted a revised form of Business Associate Agreements. Covered entities have until September 2014 to amend their existing Business Associate Agreements.

Business Associates were also required to implement a number of changes. Most notably, they were required to adopt their own HIPAA compliance programs including, among other things, written security policies and Business Associate Agreements with their subcontractors.

Enforcement of these new requirements is expected to increase, particularly given that the HITECH Omnibus Regulations dramatically increased the civil monetary penalties that may be imposed on entities that fail to comply (e.g., penalties are now up to $1.5 million per year for any single type of violation). In addition, because Business Associates are now directly liable for HIPAA violations, they will be subject to the same civil monetary penalties as covered entities, such as providers and health plans.

The HITECH Omnibus Regulations are available here.

Congressional Bill Introduced That Would Significantly Limit the Stark Exception for In-Office Ancillary Services

A new bill was introduced in the House of Representatives on August 1, 2013 that, according to its sponsors, seeks to preserve the original intent of the in-office ancillary services (IOAS) exception to the physician self-referral, or “Stark,” law by removing the following complex services from the exception: (1) advanced imaging services (i.e., CT, MRI and PET); (2) pathology services; (3) radiation therapy services; and (4) physical therapy services. If passed, these services, which the bill defines as “non-ancillary services,” would no longer be protected by the IOAS exception, but other services, such as routine clinical laboratory services or simple x-rays that are provided during the patient’s initial office visit, would still fall within the IOAS exception.

In addition to carving out non-ancillary services from the IOAS’s protection, the bill would also enhance enforcement of the Stark law by: (1) increasing civil monetary penalties for improper referrals of non-ancillary services (above those penalties already authorized for other violations of the Stark law), and (2) creating new compliance review procedures to target referrals for specified non-ancillary services, including prepayment reviews, claims audits, focused medical review, computer algorithms designed to identify payment or billing anomalies.

This bill is not the federal government’s only attempt to narrow the Stark law’s IOAS exception. Earlier this year, the Obama Administration’s budget proposal predicted a more than $6 billion savings over 10 years by removing advanced diagnostic imaging, radiation oncology, and therapy services from the IOAS exception unless “certain accountability standards” (which have yet to be defined) are met. To date, there has been no action on the bill or the Obama budget.

The text of the bill can be viewed here.
CMS Issues FY 2014 Inpatient Prospective Payment Final Rule

On August 2, 2013, the Centers for Medicare & Medicaid Services (CMS) released its 2014 Inpatient Prospective Payment System (IPPS) Final Rule for fiscal year (FY) 2014 (the “2014 IPPS Final Rule”). The 2014 IPPS Final Rule included several important policy and coverage changes. Significantly, CMS “clarified” that it is a condition of payment for a physician to certify the medical necessity of inpatient hospital services. CMS also finalized guidelines regarding the so-called “two midnights rule”. More information on the condition of payment and guidelines can be found here.

The IPPS Final Rule also included a provision that allows hospitals to bill Medicare Part B for hospital inpatient services that were inappropriately billed under Part A. Such services may be billed for up to one year from the date of service. Under this new rule, Medicare payment policies allow payment for all hospital services that were furnished and would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient rather than admitted as an inpatient. The revised policy affects admissions with dates of service on or after October 1, 2013.

The 2014 IPPS Final Rule also addressed routine hospital services provided under arrangement. As a result of industry concern, the 2014 IPPS Final Rule delayed the implementation date of a provision in the 2012 IPPS Final Rule limiting the circumstances under which a hospital may furnish services to Medicare beneficiaries “under arrangement” to cost reporting periods beginning on or after January 1, 2015.

The 2014 IPPS Final Rule went into effect on October 1, 2013. The Rule may be viewed in its entirety here.

Other Regulatory Developments Regarding Fiscal Year 2014 Medicare Payment and Policy

- In July, CMS released two proposed fiscal year (FY) 2014 rules for Medicare payment rules: the Hospital Outpatient Prospective Payment System (HOPPS) and Ambulatory Surgery Centers (APCs) Proposed Rule (available here) and the Medicare Physician Fee Schedule Proposed Rule (available here).

- On August 1, 2013, CMS published the Inpatient Psychiatric Facilities (IPF) Prospective Payment System FY 2014 Final Rule updating the prospective payment rates for Medicare inpatient hospital services provided by IPFs. The text of the rule is available here.

- On August 6, 2013, CMS published the FY 2014 Medicare Inpatient Rehabilitation Facility (IRF) Final Rule. The text of the rule is available here.

- On August 6, 2013, CMS published the Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNF) Final Rule for FY 2014 to update the PPS rates and make other updates to SNF reimbursement policy. The text of the rule is available here.

- On August 7, 2013, CMS published the final rule updating the hospice payment rates and policies and the wage index for FY 2014. The text of the rule is available here.

CMS Issues Guidance On Policy Regarding Hospital Inpatient Admission Orders and Certifications

On September 5, 2013, CMS released a guidance document entitled “Hospital Inpatient Admission Order and Certification” which interprets its new requirements for admission and medical review criteria for hospital inpatient services under Medicare Part A that were finalized in the 2014 IPPS Final Rule. A discussion of this guidance is available here.
CMS Delays Enforcement of its DME Face-to-Face Requirement

CMS has delayed enforcement of regulations requiring a face-to-face encounter as a condition of Medicare payment for certain durable medical equipment (DME) items from July 1, 2013 to October 1, 2013. The regulations, which implement Section 6407 of the Affordable Care Act, require that a physician document and communicate to the DME supplier that the physician (or a physician assistant, a nurse practitioner, or a clinical nurse specialist) has had a face-to-face encounter with the beneficiary. The encounter must occur within the six months before the order is written for the DME.

CMS delayed the compliance date due to concerns that some providers and suppliers may need additional time to establish operational protocols necessary to comply with face-to-face encounter requirements.

The complete list of DME items subject to the face-to-face requirement is available in Appendix A of MLN Matters Number: MM8304, available here.

Our blog alert summarizing the face-to-face requirement is available here.

New Regulation Requires Written Agreement Between Long Term Care Facilities and Hospice Providers

Effective as of August 26, 2013, long-term care (LTC) facilities, such as skilled nursing facilities (SNFs) and nursing facilities (NFs), must enter into written agreements (or revise existing agreements) with hospice providers to clearly delineate which services each entity will provide to nursing home residents who are receiving hospice care. The new regulation, which was contained in the Medicare and Medicaid Programs; Requirements for Long Term Care Facilities; Hospice Services final rule and is codified at 42 CFR § 483.75(t), also heightens patient transfer notification requirements for LTC facilities, requiring LTC facilities to notify their hospice counterparts about a need to transfer a resident from the facility for any condition.

The text of the final rule is available here.

OIG Issues Report on Hospitals’ Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries

On July 29, 2013, the OIG issued report number OEI-02-12-00040 entitled “Hospitals’ Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries.” This report was issued as a result of concerns raised about hospitals’ use of observation stays and short inpatient stays and concern about improper payments for short inpatient stays when the beneficiaries should have been treated as outpatients.

While the report contained no formal recommendations, it did conclude that CMS’s proposed policy changes (regarding the so called “two midnight rule” and Part B billing for hospital inpatient services, both of which were subsequently finalized in the 2014 IPPS Final Rule) would substantially affect how hospitals bill for observation stays, long outpatient stays, and short inpatient stays and address many of the concerns about improper payment. The OIG also noted that its results raised concerns about SNF services for beneficiaries in observation stays, long outpatient stays, and short inpatient stays, and that CMS should consider how to ensure that beneficiaries with similar post-hospital care needs have the same access to and cost-sharing for SNF services.

The report can be viewed here.

OIG Issues Final Rule on Data Mining by State Medicaid Fraud Control Units

On May 13, 2013, the OIG published a final rule that amends 42 C.F.R. §1007.19, which prohibited State Medicaid Fraud Control Units (MFCUs) from using federal matching funds to identify fraud through screening and analyzing State Medicaid
data (known as data mining). In the final rule, OIG permits federal financial participation (FFP) in costs of defined data mining activities under specified circumstances in order to support and modernize MFCU efforts to effectively pursue Medicaid provider fraud. In addition, the OIG finalized requirements that MFCUs must annually report costs and results of approved data mining activities to the OIG. The rule went into effect on June 17, 2013. A copy of the final rule is available here.

**OIG Accepts Online Submissions of its Self-Disclosure Protocol**

The U.S. Department of Health & Human Services, Office of Inspector General (OIG) launched a new online submission process for the Self-Disclosure Protocol (SDP). As of July 8, 2013, the OIG now accepts online submissions of its SDP, which previously was only accepted via paper submission. This new online portal comes just a few months after the OIG issued an updated SDP on April 17, 2013, and offers another method for providers to voluntarily disclose evidence of potential fraud to OIG.

The SDP, as we previously discussed in our blog on April 26th (available here), allows health care providers to voluntarily identify, disclose and resolve instances of potential fraud involving federal health care programs, including Medicare and Medicaid. Providers who utilize the SDP have the opportunity to resolve possible liability arising from the potential violation of federal criminal, civil or administrative laws, and thereby reduce the penalties and damages associated with such violations.

While the process of self-disclosing to the OIG is becoming easier and more streamlined for providers, providers should still seek health care counsel when contemplating making a self-disclosure to ensure that the matter is one that should be disclosed through the SDP process.

The OIG’s online SDP submission portal is available here.

**OIG Issues Negative Advisory Opinion on Proposed Agreement To Offer GPO Members an Equity Interest in GPO Parent Corporation**

On July 23rd, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) posted Advisory Opinion 13-09, an unfavorable opinion in which the OIG concluded that a proposal to offer members of a group purchasing organization (GPO) an equity interest in the GPO’s parent organization could potentially generate prohibited remuneration under the anti-kickback statute (AKS) and be grounds for the imposition of sanctions under the OIG’s exclusion authority and the civil monetary penalty provisions.

Our analysis of the Opinion is available here. The full text of Advisory Opinion 13-09 can be found here.

**FDA Issues Several Guidance Documents**

- On May 8, 2013, the Food and Drug Administration (FDA) released two draft guidance documents addressing the FDA’s implementation of regulations related to access to investigational drugs. The first draft guidance, entitled “Charging for Investigational Drugs Under an IND – Qs & As,” seeks to provide information for industry, researchers, and physicians about the implementation of the FDA’s regulation on charging for investigational drugs under an Investigational New Drug Application (IND). The draft guidance is available here. The second draft guidance, entitled “Expanded Access to Investigational Drugs for Treatment Use – Qs & As,” seeks to provide information about the implementation of the FDA’s regulations on expanded access to investigational drugs for treatment use under an investigational new drug application. The draft guidance is available here.

- On June 25, 2013, the FDA released draft guidance entitled “Expedited Programs for Serious Conditions — Drugs and Biologics.” This guidance provides a single resource for information on FDA’s policies and procedures for the following FDA programs that facilitate and expedite development and review of new drugs.
to address unmet medical need in the treatment of a serious or life-threatening condition: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. The guidance is available here.

- On August 6, 2013, the FDA released final guidance entitled “Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring.” The guidance is intended to assist sponsors of clinical investigations in developing risk-based monitoring strategies and plans for investigational studies of medical products, including human drug and biological products, medical devices, and combinations thereof. The guidance makes clear that sponsors can use a variety of approaches to fulfill their responsibilities for monitoring clinical investigator (CI) conduct and performance in investigational new drug (IND) studies conducted or investigational device exemption (IDE) studies. The guidance is available here.

- On September 9, 2013, the FDA released final guidance entitled “Guidance for Clinical Investigators, Sponsors, and IRBs, Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND.” This guidance describes when an IND is required, specific situations in which an IND is not required, and a range of issues that, in FDA’s experience, have been the source of confusion or misperceptions about the application of the IND regulations. The guidance is available here.

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The Firm specializes in addressing the complex legal, regulatory, business and financial needs of its clients; it helps clients negotiate favorable reimbursement rates from insurers and government; gain regulatory approval for facilities expansion or new services; merge, acquire or network with other organizations; and purchase or lease new technology and equipment. GW also assists numerous health care providers and others to comply with complicated, costly, and often onerous state and federal regulations.

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